TABLE OF CONTENTS

Section I

General Information

A. Licensure and Accreditation …….

B. Standards of Service ……..

C. Holiday Coverage ……

D. Medical Staff ……

E. Billing Information ……..

Section II

Test Codes and Specifications

A. Specimen Requirements ……

B. Serology Studies …….

C. Biopsy Test Specifications ……..

D. Biopsy Site Selection ……

I. GENERAL INFORMATION

Immco Diagnostics incorporates pioneering research, the development and manufacture of innovative diagnostics, and clinical laboratory expertise into a comprehensive solution for laboratories.

INTRODUCTION

Since the beginning in 1971, autoimmunity has been our focus. Supported by our extensive research and a proven track record, Immco Diagnostics has developed from a specialized reference laboratory to an international organization offering high quality autoimmune diagnostic products worldwide. We have expanded our laboratory services to include oral pathology, immunogenetics and transplant immunology. We continue to grow and offer opportunities to partner with the labs we serve.

Immco Diagnostics' immunology laboratory provides testing for an extensive list of prevalent and esoteric autoimmune diseases using cutting edge diagnostics. We use multiple technologies including direct immunofluorescence (DIF) and indirect immunofluorescence (IFA), enzyme linked immunosorbent assays (ELISA), and Western blot detection methods to support healthcare practitioners across a wide clinical spectrum. We provide serology for autoimmune diseases such as celiac disease, lupus, rheumatoid arthritis, systemic sclerosis, as well as autoimmune diabetes, Wegener granulomatosis and polymyositis.

As a distinguished leader in the field of oral pathology, Immco Diagnostics has been serving the needs of oral and maxillofacial surgeons, periodontists, endodontists, and dentists for over 40 years. Immco has established an excellent reputation with specialists who rely on our expertise and prompt turnaround for their patients. We provide accuracy in diagnosing odontogenic cysts and tumors, oral soft tissue tumors and malignancies and other autoimmune mediated blistering diseases. We provide state of the art services for standard tissue processing and staining, immunofluorescence and immunocytochemistry.

Immco Diagnostics' transplant immunology provides immunologic and genetic testing of the highest quality to ensure the most favorable outcome in organ and cellular transplantation. We utilize state of the art technology for delivery of the most sensitive and reliable assays in human leukocyte antigen (HLA) testing. HLA typing is performed using molecular based DNA analysis through the polymerase chain reaction. The detection and identification of HLA antibodies is achieved through the Luminex platform. Lymphocyte cross match testing is performed by flow cytometry.

Immco Diagnostics' immunogenetics provides HLA tissue typing for select alleles to determine differential diagnosis and treatment of specific ailments. Celiac disease is associated with HLA- DQ2 and DQ8 antigen. Nacrolepsy demonstrates a strong relationship with HLA alleles DR15 and DQ6. Ankylosing spondylitis is associated with HLA-B27. HLA analysis also provides a means of assessing familial risk associated with these disorders.

Allergy
Cardiology
Dermatopathology
Endocrinology
Gastroenterology
Hepatology
Immunogenetics
Immunoglobulin-Complement
Immunohematology
Infertility
Nephrology
Neuroimmunology
Ocular Pathology
Oral Pathology
Otology
Rheumatology
Transplant Immunology
Vasculitis
Vesiculo-Bullous diseases

A. LICENSURE AND ACCREDITATION

Immco Diagnostics is CLIA accredited and licensed by the New York State Department of Health and by the states of Florida, Maryland, Pennsylvania, and Rhode Island. Our company is ISO 13485:2003 certified.

B. STANDARDS OF SERVICE

Immco Diagnostics is known for high quality and accurate reports, keen consultations and impeccable customer service. Biological specimens are collected by complimentary courier or express mail service. Reports can be viewed at Immco online, a convenient HIPAA compliant lab information system. Our lab also offers flexible billing options to suit your needs. Healthcare professionals have come to know the expert capabilities of our specialized lab, along with our outstanding and personal service.

C. HOLIDAY COVERAGE

Immco Diagnostics observes the following holidays: New Year's Day, Good Friday, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Day After Thanksgiving, Christmas Eve and Christmas Day. Please be aware that we are not staffed on these holidays. Should you have any questions or concerns please contact Customer Care between the hours of 8:00 am and 5:00 pm prior to the holiday. Commercial courier services may also be delayed or closed on these major holidays, so please check with these couriers before shipping samples.

D. MEDICAL TEAM

The Immco Diagnostics' Medical team draws upon exclusive clinical and research experience, frequently contributing to the scientific literature in the field of immunology. Members of our staff include PhD's, DDS's and MD's, and are certified by the American Board of Oral Pathologists, American Board of Medical Microbiology, the American Board of Medical Laboratory Immunology and the National Registry of Clinical Chemistry. Clients have ready access to pathologists with expertise in immunopathology, dermatopathology and oral pathology for consultations.

BIOGRAPHIES

Thomas C. Shanahan PhD, MS, ABMLI
Director of the Lab & Senior Vice President of Laboratory Services



Dr. Shanahan received his doctorate from the Temple University School of Medicine in Philadelphia, PA and subsequently trained as a postdoctoral fellow in Clinical Immunology at the Royal Victoria Hospital, McGill University in Montreal, Quebec. He is a diplomat of the American Board of Medical Laboratory Immunology and past accreditation commissioner and co-chair for the American Society for Histocompatibility and Immunogenetics. Dr. Shanahan currently serves on the New York State Transplant Council for the New York State Department of Health. Previous appointments include Director of Histocompatibility and Immunogenetics at the Erie County Medical Center, Buffalo General Hospital, and Strong Memorial Hospital, and faculty appointments in the Department of Microbiology and Immunology at the SUNY Buffalo School of Medicine and Department of Pathology at the University of Rochester Medical Center.

Dr. Jill M. Kramer
Assistant Director of Diagnostic Immunopathology



Jill M. Kramer received her PhD and DDS degrees from the University at Buffalo. She completed her specialty training in Oral and Maxillofacial Pathology at Long Island Jewish Medical Center and her post-doctoral studies at the Feinstein Institute for Medical Research. She is a fellow in the American Academy of Oral and Maxillofacial Pathologists and a diplomate in the American Board of Oral and Maxillofacial Pathology. Dr. Kramer is currently an assistant professor in the Department of Oral Biology and she holds adjunct appointments within the Departments of Oral Diagnostic Sciences and Microbiology and Immunology at the University at Buffalo.
Dr. Kramer conducts NIH-funded research in the area of immune dysfunction in Sjögren's syndrome and she has authored numerous manuscripts detailing the role of immune cells in this disease. She serves as a reviewer for many scientific journals and is an active member of several scientific societies, including the American Association for Dental Research, the American Association of Immunologists and the Society for Leukocyte Biology. Dr. Kramer has worked as a diagnostic immunologist and oral pathologist at Immco since 2014.

Dr. Hemlata S. Bhakoo PhD, HCLD/ELD
Assistant Director of Andrology



Dr. Bhakoo received her doctorate from the University of Illinois at Urbana-Champaign. Following that, she trained as a post-doctoral fellow at Roswell Park Memorial Institute in Buffalo, New York. Dr. Bhakoo established an In Vitro Fertilization (IVF) Laboratory at Children's Hospital, Department of Obstetrics & Gynecology, in conjunction with University of Buffalo in 1987. Subsequently, she established another IVF laboratory for a private Infertility clinic in 1999 where she continues to serve as a director of the Andrology laboratory & Tissue Bank licensed by New York State Department of Health. She is a member of the American Society for Reproductive Medicine (ASRM) and American Board of Bioanalysis (ABB). Dr. Bhakoo is a Faculty member (volunteer) in the Department of Biotechnical & Clinical Laboratory Sciences.

Alfredo Aguirre DDS, MS
Consultant- Oral & Maxillofacial Pathology



Dr. Aguirre is a Professor and Director of the Advanced Oral and Maxillofacial Pathology training program in the Department of Oral Diagnostic Sciences at the State University of New York at Buffalo. He is a Diplomate of the American Board of Oral and Maxillofacial Pathology and a Fellow of the American Academy of Oral and Maxillofacial Pathology. Dr. Aguirre has published more than 70 peer reviewed scientific articles in prestigious international journals. He has also written chapters on Oral Pathology for two different contemporary textbooks in periodontics.

E. BILLING INFORMATION

Immco Diagnostics will bill hospitals, reference laboratories, clinics or medical groups. Alternatively, Immco Diagnostics will bill patients' insurance directly, provided all the necessary billing information is supplied at the time services are rendered (See requirements listed below).

1 Immco Diagnostics does not have capitation contract agreements with any HMO's. Due to Knox-Keene regulations, if a third party payer is initially billed and is denied as an HMO member, these charges will be billed back to the patients.
2 Immco Diagnostics does not write off third party insurance balances. If a Doctor mistakenly sends a specimen to Immco Diagnostics and the claim is partially paid as "not contracted providers", the balance will be billed to the patient.
3 Immco Diagnostics will bill Medicare for tests performed at Immco Diagnostics. If a claim is denied as "not eligible for the specified date(s) of service", the charges will be billed to the patient.
4 Changes to Billing instructions must be supplied within 30 days from the date of the invoice. Immco Diagnostics will not process any billing instruction change requests received after the 30-day period. The charges will remain the patient's responsibility.

If local or state requirements preclude providing the patient's name to ensure confidentiality, Immco Diagnostics will be unable to bill patients' insurance directly; the charges will be billed to the client. All billing discrepancies should be reported to our Billing Department immediately. Our Billing Department is available from 8:00am to 4:30pm EST by calling 800- 537-8378, extension 314 for Billing and Collections. Our Billing Specialists are available to answer questions and resolve any problems. All bills are due and payable upon receipt.

Immco Diagnostics Federal I.D. number is: 16-1012347

Professional Courtesy
"Professional Courtesy" testing is strictly prohibited as stated in the Anti-Kick Back Statute U.S.C. 1320a – 7b; therefore, Immco Diagnostics cannot honor request for this service.

Patient Billing
Immco Diagnostics can bill the patient's insurance directly if complete billing information is provided on the Test Requisition Form at the time the specimen is submitted. Immco Diagnostics Patient Statements are issued immediately following response from insurance. The patient is solely responsible for the charges. Patient bills are due upon receipt.

Third Party Billing
Immco Diagnostics will bill the patient's insurance company directly for tests performed by Immco Diagnostics if the information listed below is provided. Immco Diagnostics will not bill third party payers for referral testing submitted to Immco Diagnostics for performance by a send out laboratory.

Billing Information Requirements (to be entered on Immco Diagnostics Test Requisition form):

Patient Name
Patient Date of Birth
Patient Sex
Patient Address, including City, State, Zip
Patient Phone Number with Area Code
Patient Relationship to Subscriber
Insurance Carrier Name

Insurance Carrier Address, including City, State, Zip
Subscriber Name and Date of Birth
Policy Number or Members ID
Group Number
Requesting Physician Name
Requesting Physician UPIN, Provider # or License #
Diagnosis (ICD-9-CM Code) applicable to the patient's condition at time of service

Patients are responsible for the yearly deductibles, co-payments and any balance not covered by the insurance company. If insurance payment is not received within 60 days, the patient is billed directly.

Medicare Billing
Immco Diagnostics is a Medicare Provider. If your patient has Medicare coverage, please send us complete information. Immco Diagnostics will bill Medicare and accept 80% assignment. Complete information must be entered on the Test Requisition Form at the time the specimen is submitted. *Please note: Due to HIPAA Transaction Code Standards effective October 16, 2003, a valid diagnosis code is mandatory for billing Medicare. Medicare billing information is not complete and will not be accepted without a valid diagnosis code.*

Billing Information Requirements (to be entered on Immco Diagnostics Test Requisition Form):
Patient Full Name (as it appears on the card)
Patient Address, including City, State, Zip
Patient Phone Number with Area Code
Patient Sex
Patient Date of Birth
Medicare HIC# (9 numerics + 1 alpha suffix)
Diagnosis (ICD-9-CM code) applicable to the patient's condition at time of service.
Referring Physician's Name (First, MI, Last)
Referring Physician UPIN 5 digits + alpha prefix)
Physician's or qualified non-physician practitioner's signature (as per CMS requirements).

This information must be included on Immco Diagnostics Test Requisition Forms at time of service.

LMRP and NCD Requirements Medicare tests listed on the National Coverage Determinants (NCD) & Local Medical Review Policies (LMRP) will not be reimbursed by Medicare without a covered diagnosis code applicable to the patient at time of service. If a diagnosis code cannot be provided that matches the NCD or LMRP requirement, an Advance Beneficiary Notice (ABN) should be obtained from the patient and forwarded with the requisition.

Referrals from Hospitals Under Medicare rules, Immco Diagnostics can only bill Medicare for a hospital-referred test when the specimen was not collected as part of an inpatient or outpatient encounter, i.e., the specimen was not drawn in a hospital facility or by hospital personnel. All other testing for hospital patients must be billed directly to the hospital.

CPT Codes CPT codes listed in this Directory are provided only as guidance to assist you in billing. CPT codes listed reflect our interpretation of CPT coding requirements and are subject to change at any time. It is the client's responsibility to verify the accuracy of the codes. A copy of the changes to CPT coding recommendations for 2005 precedes the test listing section. If you have any questions, please refer to the Current Procedural Terminology (CPT) manual published by the American Medical Association. To verify

reimbursement, or if you have any questions regarding usage of a CPT code, please contact your local Medicare carrier.

Medical Necessity/Diagnosis Codes Every third party bill must have a valid diagnosis code. Please be sure to put the ICD-10 Code(s) applicable to the patient's condition for the specified date of service on the requisition in the box marked "Diagnostic Codes ICD-10". Medicare diagnosis codes must be coded to the highest level of specificity. Please refer to the International Classification of Diseases (ICD-10) manual, as well as the Medical Regulations and Manuals issued or authorized by the Center for Medicare and Medicaid Services (CMS) for diagnosis coding rules and regulations. If the claim is denied due to lack of medical necessity, Immco Diagnostics will send a request for an additional ICD-10 code or other evidence of medical necessity directly to the ordering Doctor.

Medicaid Billing Immco Diagnostics is a non-covered provider with Medicaid **Failure to provide pertinent billing information may delay results **

II. TEST CODES AND SPECIFICATIONS

*** Please note that test codes in this manual are categorized by disease association and are not necessarily in numerical order.**

A. Specimen Requirements:

Specimen Collection Kits are available free of charge from Immco Diagnostics. Call 800.537.8378 ext. 321 for an immediate shipment of collection kits**..**

a. Serum Studies

Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place 2-3ml serum into white capped tube provided. If separation facilities are not available, the blood can be sent in the tube used for collection.

b. Genetic Studies

Send 2 tubes uncoagulated whole blood in one lavender top and one tiger top tube. Do not refrigerate or freeze.

c. Biopsy Studies

When submitting specimens for **immunofluorescence only**, place one biopsy specimen from the edge of the lesion in the **red capped** tube provided with the kit and place one biopsy specimen from the normal site in the **purple capped** tube. These tubes contain a holding solution for immunofluorescence specimens.

When submitting specimens for **routine histological studies (H&E) only,** place one incisional or excisional biopsy specimen in the **green** jar provided with the collection kit or in a tube containing 10% formalin.

When submitting specimens for **immunofluorescence and H&E studies**, take one biopsy specimen from the edge of the lesion and divide it in half. Place one half in **green** jar provided with the collection kit or in a tube containing 10% formalin for H&E, and place the other half in the **red capped** tube provided with the collection kit. Take a second biopsy from a normal site and place it in the **purple capped** tube provided with the test kit.

For additional information, please consult the Collection & Handling.

The red capped and purple capped tubes provided with Immco collection kits contain a holding solution for immunofluorescence specimens.

B. SEROLOGY STUDIES

RHEUMATOLOGY

Systemic Lupus Erythematosus (SLE)

ANA Titer and Pattern on HEp-2 & Mouse Kidney

Immco Test Code: #001
Methodology: Indirect Immunofluorescence
Substrate: HEp-2 and Mouse Kidney
Reference Range: Negative: < 1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to 5120 at an additional charge.
CPT Code: 86038
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Collect 2-3 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: This test is for detection of antibodies to nuclear antigens. The homogeneous pattern is primarily associated with systemic lupus erythematosus (SLE). Antibodies to centromere antigens are highly specific for calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia, commonly referred to as CREST syndrome, a limited form of systemic sclerosis (SSc). Centromere antibodies can also occasionally be found in low titers in some other autoimmune variants. Antinuclear antibodies with a speckled pattern are commonly associated with SLE, although they do occur in some cases of Sjögren's syndrome and mixed connective tissue disorders. ANA antibodies with a nucleolar pattern are commonly associated with SSc, although they do occur in some cases of SLE and overlap syndromes. Overlap syndromes include dermatomyositis/polymyositis.

ANA Titer and Pattern on HEp-2 only

Immco Test Code: #002
Methodology: Indirect Immunofluorescence
Substrate: HEp-2 alone
Reference Range: Negative: <1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to 5120 at an additional charge.
CPT Code: 86038
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: This test is for detection of antibodies to nuclear antigens. The homogeneous pattern is primarily associated with systemic lupus erythematosus (SLE). Antibodies to centromere antigens are

highly specific for calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia, commonly referred to as CREST syndrome, a limited form of systemic sclerosis (SSc). Centromere antibodies can also occasionally be found in low titers in some other autoimmune variants. Antinuclear antibodies with a speckled pattern are commonly associated with SLE, although they do occur in some cases of Sjögren's syndrome and mixed connective tissue disorders. ANA antibodies with a nucleolar pattern are commonly associated with SSc, although they do occur in some cases of SLE and overlap syndromes. Overlap syndromes include dermatomyositis/polymyositis.

dsDNA (nDNA) Antibody Titer

Immco Test Code: #004
Methodology: Indirect Immunofluorescence
Substrate: Crithidia luciliae Double Stranded DNA Antibody (nDNA) IgG
Reference Range: Negative: < 1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: nDNA are highly specific for systemic lupus erythematosus. The frequency and titer of nDNA antibodies fluctuate with disease activity and tend to disappear with immunosuppressive treatment and during remission.

Double Stranded DNA Antibody IgG

Immco Test Code: #004C
Methodology: ELISA
Reference Range:
Negative: <50 **Units:** IU/ml
Borderline: 50-60
Positive: >60
CPT Code: 83520
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: nDNA are highly specific for systemic lupus erythematosus. The frequency and titer of nDNA antibodies fluctuate with disease activity and tend to disappear with immunosuppressive treatment and during remission.

Phospholipid Antibody IgG, IgA & IgM

Immco Test Code: #008
Methodology: ELISA
Reference Range:

IgG	Negative: <23	**Units:** GPL
	Positive: >23	
IgA	Negative: <22	**Units:** APL
	Positive: >22	
IgM	Negative: <11	**Units:** MPL
	Positive: >11	

CPT Code: 86147 (x3)
Schedule/Turnaround Time: Assay performed every two weeks. Report availability is within three weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of anticardiolipin antibodies helps to identify patients at risk for venous and/or arterial thrombosis often accompanied by thrombocytopenia, a syndrome referred to as antiphospholipid syndrome. This syndrome most commonly occurs in patients with systemic lupus erythematosus (SLE) or lupus-like diseases where the criteria for SLE are not fulfilled. High levels of anticardiolipin antibodies also occur in fetal loss. Low levels of these antibodies are of limited significance.

Rheumatoid Factor (RF) IgG, IgA & IgM

Immco Test Code: #011
Methodology: ELISA
Reference Range:

IgG	Negative: <20	**Units:** EU/ml
	Borderline: 20-25	
	Positive: >25	
IgA	Negative: <20	**Units:** EU/ml
	Borderline: 20-25	
	Positive: >25	
IgM	Negative: <7	**Units:** IU/ml
	Borderline: 7-9	
	Positive: >9	

CPT Code: 86431 (x3)
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The measurement of RF is important in the diagnosis and prognosis of rheumatoid arthritis. High levels of RF occur in sera of patients who tend to develop extra- articular complications.

RNA Antibody

Immco Test Code: #013
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 83522
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: RNA antibodies occur in systemic lupus erythematosus and the frequency may vary from 17-80%. A correlation between RNA antibodies and disease activity has been reported. In some patients, ribosomal P and RNA antibodies may coexist. RNA antibodies are difficult to recognize by indirect immunofluorescence. The ELISA method represents a significant technological advance and offers a sensitive and specific serological method to assess patients.

Circulating Immune Complexes (CIC) IgG

Immco Test Code: #014
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86332
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Immune complexes are present in patients with various autoimmune and other viral or infectious diseases.

Antibodies to Extractable Nuclear Antigens (ENA) & Cytoplasmic Antigens

RNP, Sm, SS-A (Ro), SS-B (La)
Immco Test Code: #040
Methodology: ELISA
Reference Range:

RNP	Negative:	<20	**Units:** EU/ml
	Borderline:	20-25	
	Positive:	>25	
Sm	Negative:	<50	**Units:** EU/ml
	Positive	≥50	
Ro	Negative:	<20	**Units:** EU/ml
	Borderline:	20-25	
	Positive:	>25	
La	Negative:	<50	**Units:** EU/ml
	Positive:	≥50	

CPT Code: 86235 (x4)
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Autoantibodies directed against ENA are useful in the diagnosis and monitoring of various systemic connective tissue diseases.

RNP
Immco Test Code: #042
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to RNP occur in 35-45% of systemic lupus erythematosus patients and in over 95% of patients with mixed connective tissue disease.

Sm

Immco Test Code: #043
Methodology: ELISA
Reference Range:
Negative: <50 **Units:** EU/ml
Positive: ≥50
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to Sm occur in approximately 30-40% of systemic lupus erythematosus (SLE) patients. They are rare in other systemic connective tissue diseases and if present, indicate either overlap of disease or patients that have not yet fulfilled the American Rheumatology Association criteria for SLE.

SS-A (Ro)

Immco Test Code: #045
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to SS-A (Ro) occur in approximately 30-40% of systemic lupus erythematosus (SLE) patients. They also occur in 60% of patients with subacute cutaneous lupus erythematosus (LE), in almost all cases of neonatal LE, in almost all SLE patients with C2 deficiency and an about one half of patients with Sjögrens syndrome.

SS-B (La)

Immco Test Code: #046
Methodology: ELISA
Reference Range:
Negative: <50 **Units:** EU/ml
Positive: ≥50
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from

the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: SS-B (La) antibodies occur in approximately 10-15% of systemic lupus erythematosus patients and 40-60% of patients with Sjögren's syndrome. Antibodies to SS-B (La) occur frequently in association with SS-A (Ro)

Ku

Immco Test Code: #050
Methodology: Western Blot
Reference Range: Qualitative
CPT Code: 84282
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Ku antibodies have been found in 10% of patients with polymyositis/scleroderma overlap syndrome and in 10% of systemic lupus erythematosus patients. Patients with polymyositis/scleroderma overlap who are positive for Ku antibodies usually have a mild disease with a good prognosis.

Proliferating Cell Nuclear Antigen (PCNA)

Immco Test Code: #051
Methodology: Indirect Immunofluorescence
Substrate: HEp-2
Reference Range: Negative: <1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86039
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to PCNA are found in approximately 2-10% of systemic lupus erythematosus patients, most of whom have diffuse proliferative glomerulonephritis. They do not occur in patients with other connective tissue diseases. Antibodies to PCNA are not detectable after immunosuppressive therapy.

PM/Scl

Immco Test Code: #052
Methodology: ELISA
Reference Range: Semi-Quantitative
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: These antibodies are associated with a high frequency of myositis- scleroderma overlap.

CT Profile

Immco Test Code: #070
Includes Immco Test Codes: #001 (ANA on Hep-2 & mouse kidney); #004 [dsDNA (nDNA)]; #011 (RF); #040 [RNP, Sm, SS-A (Ro), SS-B (La)]; #047 (Scl-70); #048 (Jo-1); #050 (Ku); #051 (PCNA); #052 (PM/Scl).
Methodology: Indirect Immunofluorescence, ELISA, Western Blot
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86256, 83520, 86431, 86235 (x6), 84182
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Drug Induced LE Profile

Immco Test Code: #071
Includes Immco Test Codes: #001 (ANA on Hep-2 and mouse kidney); #004 [dsDNA (nDNA)].
Methodology: Indirect Immunofluorescence
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86255, 83520
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

SLE Profile I

Immco Test Code: #077
Includes Immco Test Codes: #001 (ANA on HEp-2 and Mouse Kidney); #004 [dsDNA (nDNA)].
Methodology: Indirect Immunofluorescence
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86255
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

SLE Profile II

Immco Test Code: #078
Includes Immco Test Codes: #001 (ANA on HEp-2 and mouse kidney); #004 [dsDNA (nDNA)]; #040 [RNP, Sm, SS-A (Ro), SS-B (La)].
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86255, 86235 (x4)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time**.**
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

SLE Profile III

Immco Test Code: #079

Includes Immco Test Codes: #001 (ANA on Hep-2 and Mouse Kidney); #004 [dsDNA (nDNA)]; #011 (RF); #040 [RNP, Sm, SS-A (Ro), SS-B (La)]; #050 (Ku).
Methodology: Indirect Immunofluorescence, ELISA, Western Blot
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86255, 86235(x6), 83520, 84182
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Scleroderma

Antinuclear Antibody (ANA)

Immco Test Code: #001
Methodology: Indirect Immunofluorescence
Substrate: HEp-2 and Mouse Kidney
Reference Range: Negative: < 1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to 5120 at an additional charge.
CPT Code: 86038
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 2-3 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: This test is for detection of antibodies to nuclear antigens. The homogeneous pattern is primarily associated with systemic lupus erythematosus (SLE). Antibodies to centromere antigens are highly specific for calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia, commonly referred to as CREST syndrome, a limited form of systemic sclerosis (SSc). Centromere antibodies can also occasionally be found in low titers in some other autoimmune variants. Antinuclear antibodies with a speckled pattern are commonly associated with SLE, although they do occur in some cases of Sjögren's syndrome and mixed connective tissue disorders. ANA antibodies with a nucleolar pattern are commonly associated with SSc, although they do occur in some cases of SLE and overlap syndromes. Overlap syndromes include dermatomyositis/polymyositis.

RNP Antibody

Immco Test Code: #042
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to RNP occur in 35-45% of systemic lupus erythematosus patients and in over 95% of patients with mixed connective tissue disease.

RNA Polymerase III

Immco Test Code: # 063
Methodology: ELISA
Reference Range:
Negative <20 **Units:** Units/ml
Weak Positive 20-39
Moderate Positive 40-80
Strong Positive >80
CPT Code: 83520
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Significance: Autoantibodies to RNA Polymerase III antigen are found in 11% to 23% of patients with systemic sclerosis. Patients who are positive for RNA Polymerase III antibodies do not have any of the other antibodies typically found in systemic sclerosis patients such as centromere, Scl-70, or Pm/Scl antibodies. Thus, they are a separate serologic group. Numerous studies have shown that these patients have an increased risk of the diffuse cutaneous form of scleroderma, with high likelihood of skin involvement and hypertensive renal disease.
Antibodies to several different types of RNA Polymerases are found in patients with systemic sclerosis. The recombinant immunodominant epitope of RNA Polymerase III can be used in ELISA with high specificity to detect RNA Polymerase III antibodies in patients with the diffuse cutaneous form of systemic sclerosis.

Scleroderma Profile

Immco Test Code: #075
Includes Immco Test Codes: #001 (ANA on Hep-2 and Mouse Kidney); #042 (RNP); #052 PM/Scl), #063 (RNA Polymerase III).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86039, 86235(x4), 83520
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Sjogren's Syndrome

ANA Titer and Pattern

Immco Test Code: #001
Methodology: Indirect Immunofluorescence

Substrate: HEp-2 and mouse kidney
Reference Range: Negative: < 1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to 5120 at an additional charge.
CPT Code: 86038
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 2-3 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: This test is for detection of antibodies to nuclear antigens. The homogeneous pattern is primarily associated with systemic lupus erythematosus (SLE). Antibodies to centromere antigens are highly specific for calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia, commonly referred to as CREST syndrome, a limited form of systemic sclerosis. Centromere antibodies can also occasionally be found in low titers in some other autoimmune variants. Antinuclear antibodies with a speckled pattern are commonly associated with SLE, although they do occur in some cases of Sjögren's syndrome and mixed connective tissue disorders. ANA antibodies with a nucleolar pattern are commonly associated with systemic sclerosis (SSc), although they do occur in some cases of SLE and overlap syndromes. Overlap syndromes include dermatomyositis/polymyositis.

Rheumatoid Factor (RF) IgG, IgA, IgM

Immco Test Code: #011
Methodology: ELISA
Reference Range:

IgG	Negative: <20 Borderline: 20-25 Positive: >25	**Units:** EU/ml
IgA	Negative: <20 Borderline: 20-25 Positive: >25	**Units:** EU/ml
IgM	Negative: <7 Borderline: 7-9 Positive: >9	**Units:** IU/ml

CPT Code: 86431 (x3)
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The measurement of RF is important in the diagnosis and prognosis of rheumatoid arthritis. High levels of RF occur in sera of patients who tend to develop extra- articular complications.

RNP, Sm, SS-A (Ro), SS-B (La)

Immco Test Code: #040
Methodology: ELISA
Reference Range:

RNP	Negative: <20	**Units:** EU/ml
	Borderline: 20-25	
	Positive: >25	
Sm	Negative: <50	**Units:** EU/ml
	Positive: ≥50	
Ro	Negative: <20	**Units:** EU/ml
	Borderline: 20-25	
	Positive: >25	
La	Negative: <50	**Units:** EU/ml
	Positive: ≥50	

CPT Code: 86235 (x4)
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Autoantibodies directed against ENA are useful in the diagnosis and monitoring of various systemic connective tissue diseases.

SS-A (Ro)

Immco Test Code: #045
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to SS-A (Ro) occur in approximately 30-40% of systemic lupus erythematosus patients. They also occur in 60% of patients with subacute cutaneous LE, in almost all cases of neonatal LE, in almost all SLE patients with C2 deficiency and an about one half of patients with Sjögrens syndrome.

SS-B (La)

Immco Test Code: #046
Methodology: ELISA
Reference Range:
Negative: <50 **Units:** EU/ml
Positive: ≥50
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: SS-B (La) antibodies occur in approximately 10-15% of systemic lupus erythematosus patients and 40-60% of patients with Sjögren's syndrome. Antibodies to SS-B (La) occur frequently in association with SS-A (Ro) antibodies.

Salivary Protein 1 (SP- 1) Antibodies, IgG, IgA, IgM (Test not available separate - only available in panels 076, 093, 097)

IMMCO Test Code: 094
Methodology: ELISA
CPT Code: 83520 (x3)
Reference range: Quantitative, EU/ml
<20 EU/ml Negative
20-25 EU/ml Borderline
>25 EU/ml Positive
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 4-10 ml of blood in a red top or serum separator tube. If separation facilities are not available, the blood can be sent in the tube used for collection.
Requested Sample Volume: 2 mL
Minimum Sample Volume: 0.5mL
Sample Stability: Sample is stable at ambient temperature during shipment for 5 days. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Cause for rejection: Specimens other than serum or CSF. Grossly hemolyzed, lipemic or icteric samples.
Clinical Relevance: Antibodies to SP-1 may be useful markers for identifying patients with SS at early stages of the disease or those that lack antibodies to either Ro or La. Recently novel antibodies identified to salivary gland protein 1 (SP-1), carbonic anhydrase 6 (CA6) and parotid secretory protein (PSP). These autoantibodies were present in two animal models for SS and occurred earlier in the course of the disease than antibodies to Ro or La. Patients with SS also produced antibodies to SP-1, CA6 and PSP. These antibodies were found in 45% of patients meeting the criteria for SS who lacked antibodies to Ro or La. Furthermore, in patients with idiopathic xerostomia and xerophthalmia for less than 2 years, 76% had antibodies to SP-1 and/or CA6 while only 31% had antibodies to Ro or La.
Selected References:
Shen, L. et al., (2010). A role of lymphotxin in primary sjogren's syndrome. J Immunol; 185: 6355–6363.
Shen, L. et al., (2012). Novel autoantibodies in Sjogren's syndrome. Clinical Immunology;145, 251–255.

Carbonic Anhydrase VI (CA VI) Antibodies, IgG, IgA, IgM (Test not available separate - only available in panels 076, 093, 097)

IMMCO Test Code: 095
Methodology: ELISA
CPT Code: 83520 (x3)
Reference range: Quantitative, EU/ml
<20 EU/ml Negative
20-25 EU/ml Borderline
>25 EU/ml Positive
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 4-10 ml of blood in a red top or serum separator tube. If separation facilities are not available, the blood can be sent in the tube used for collection.
Requested Sample Volume: 2 mL
Minimum Sample Volume: 0.5mL
Sample Stability: Sample is stable at ambient temperature during shipment for 5 days. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Cause for rejection: Specimens other than serum or CSF. Grossly hemolyzed, lipemic or icteric samples.
Clinical Relevance: Antibodies to CA VI may be useful markers for identifying patients with SS at early stages of the disease or those that lack antibodies to either Ro or La. Recently novel antibodies identified to salivary gland protein 1 (SP-1), carbonic anhydrase 6 (CA6) and parotid secretory protein (PSP). These autoantibodies were present in two animal models for SS and occurred earlier in the course of the disease than antibodies to Ro or La. Patients with SS also produced antibodies to SP-1, CA6 and PSP. These antibodies were found in 45% of patients meeting the criteria for SS who lacked antibodies to Ro or La. Furthermore, in patients with idiopathic xerostomia and xerophthalmia for less than 2 years, 76% had antibodies to SP-1 and/or CA6 while only 31% had antibodies to Ro or La.
Selected References:
Shen, L. et al., (2010). A role of lymphotxin in primary sjogren's syndrome. J Immunol; 185: 6355–6363.
Shen, L. et al., (2012). Novel autoantibodies in Sjogren's syndrome. Clinical Immunology;145, 251–255.

Parotid Specific Protein (PSP) Antibodies, IgG, IgA, IgM (Test not available separate - only available in panels 076, 093, 097)

IMMCO Test Code: **096**
Methodology: ELISA
CPT Code: 83520 (x3)
Reference range: Quantitative, EU/ml
<20 EU/ml Negative
20-25 EU/ml Borderline
>25 EU/ml Positive
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 4-10 ml of blood in a red top or serum separator tube. If separation facilities are not available, the blood can be sent in the tube used for collection.
Requested Sample Volume: 2 mL
Minimum Sample Volume: 0.5mL
Sample Stability: Sample is stable at ambient temperature during shipment for 5 days. If sample is stored

prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Cause for rejection: Specimens other than serum or CSF. Grossly hemolyzed, lipemic or icteric samples.
Clinical Relevance: Antibodies to PSP may be useful markers for identifying patients with SS at early stages of the disease or those that lack antibodies to either Ro or La. Novel antibodies identified to salivary gland protein 1 (SP-1), carbonic anhydrase 6 (CA6) and parotid secretory protein (PSP) were present in two animal models for SS and occurred earlier in the course of the disease than antibodies to Ro or La. Patients with SS also produced antibodies to SP-1, CA6 and PSP. These antibodies were found in 45% of patients meeting the criteria for SS who lacked antibodies to Ro or La. Furthermore, in patients with idiopathic xerostomia and xerophthalmia for less than 2 years, 76% had antibodies to SP-1 and/or CA6 while only 31% had antibodies to Ro or La.
Selected References:
Shen, L. et al., (2010). A role of lymphotxin in primary sjogren's syndrome. J Immunol; 185: 6355–6363.
Shen, L. et al., (2012). Novel autoantibodies in Sjogren's syndrome. Clinical Immunology;145, 251–255.

Sjogren's Syndrome Profile (includes tests 094 - salivary protein 1 antibodies - IgG, IgA & IgM, 095 – Carbonic anhydrase VI antibodies - IgG, IgA & IgM & 096 Parotid specific/Secretory protein antibodies - IgG, IgA & IgM, 001 Antinuclear antibodies by HEp- 2 and Mouse Kidney, 011-Rheumatoid factor IgG, IgA & IgM, 045-Ro & 046-La)
IMMCO Test Code: **076**
Methodology: Indirect Immunofluorescence and ELISA
CPT Code: 83520 (x9), 86038, 86431 (x3), 86235 (x2)
Reference range: See reference ranges for individual tests
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 4-10 ml of blood in a red top or serum separator tube. If separation facilities are not available, the blood can be sent in the tube used for collection.
Requested Sample Volume: 2 mL
Minimum Sample Volume: 0.5mL
Sample Stability: Sample is stable at ambient temperature during shipment for 5 days. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Cause for rejection: Specimens other than serum or CSF. Grossly hemolyzed, lipemic or icteric samples.
Clinical Relevance: Sjogren's syndrome (SS) is a systemic autoimmune disease in which loss of salivary gland and lachrymal gland function is associated with hypergammaglobulinemia, autoantibody production, mild kidney and lung disease and eventually lymphoma. SS involves dry eyes and dry mouth without systemic features that may be either primary or secondary to another autoimmune disease, such as SLE in patients with SS diagnosed at a late stage in their disease, after the salivary glands and lachrymal glands are already destroyed. Only symptomatic treatment can be offered for abnormal lachrymal and salivary gland function. The diagnosis for SS is currently at a crossroad with the American College of Rheumatology providing which requires characteristic autoantibodies (SS-A/SS-B) or minor salivary gland biopsy. Since lip biopsies are not frequently performed in clinical practice, there is increased emphasis placed on autoantibodies in diagnosis.
Recently novel antibodies identified to salivary gland protein 1 (SP-1), carbonic anhydrase 6 (CA6) and parotid secretory protein (PSP) using western blot methodology. Further studies have shown that the isotype differentiation of the markers adds to the sensitivity of diagnosis of SS. These autoantibodies occurred earlier in the course of the disease than antibodies to Ro or La. In addition antibodies to SP-1, CA-6 and PSP were found in patients meeting the criteria for SS who lacked antibodies to Ro or La. Furthermore, in patients with idiopathic xerostomia and xerophthalmia for less than 2 years, 76% had antibodies to SP-1 and/or CA6 while only 31% had antibodies to Ro or La.
Antibodies to different isotypes (IgG, IgM & IgA) of SP-1, CA6 and PSP are useful markers for identifying

patients with SS at early stages of the disease or those that lack antibodies to either Ro or La.

Selected References:

Fox, R (2005). Sjogren's syndrome. Lancet; 366: 321–331.
Shen, L. et al., (2012). Novel autoantibodies in Sjogren's syndrome. Clinical Immunology;145, 251–255.
Shen, L. et al., (2013). Different stages of primary sjogren's syndrome involving lyphotoxin and Type I interferon. J Immunol; 191(2): 608-13.

Early Sjogren's Syndrome Profile (includes tests 094 - salivary protein 1 antibodies - IgG, IgA & IgM, 095 – Carbonic anhydrase VI antibodies - IgG, IgA & IgM, & 096 Parotid specific/secretory protein antibodies - IgG, IgA & IgM)

IMMCO Test Code: **093**
Methodology: ELISA
CPT Code: 83520 (x9)
Reference range: Quantitative, EU/ml
<20 EU/ml Negative
20-25 EU/ml Borderline
>25 EU/ml Positive
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 4-10 ml of blood in a red top or serum separator tube. If separation facilities are not available, the blood can be sent in the tube used for collection.
Requested Sample Volume: 2 mL
Minimum Sample Volume: 0.5mL
Sample Stability: Sample is stable at ambient temperature during shipment for 5 days. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Cause for rejection: Specimens other than serum or CSF. Grossly hemolyzed, lipemic or icteric samples.
Clinical Relevance: Sjogren's syndrome (SS) is a systemic autoimmune disease in which loss of salivary gland and lachrymal gland function is associated with hypergammaglobulinemia, autoantibody production, mild kidney and lung disease and eventually lymphoma. SS involves dry eyes and dry mouth without systemic features that may be either primary or secondary to another autoimmune disease, such as SLE in patients with SS diagnosed at a late stage in their disease, after the salivary glands and lachrymal glands are already destroyed. Only symptomatic treatment can be offered for abnormal lachrymal and salivary gland function. The diagnosis for SS is currently at a crossroad with the American College of Rheumatology providing which requires characteristic autoantibodies (SS-A/SS-B) or minor salivary gland biopsy. Since lip biopsies are not frequently performed in clinical practice, there is increased emphasis placed on autoantibodies in diagnosis.
Recently novel antibodies identified to salivary gland protein 1 (SP-1), carbonic anhydrase 6 (CA6) and parotid secretory protein (PSP) using western blot methodology. Further studies have shown that the isotype differentiation of the markers adds to the sensitivity of diagnosis of SS. These autoantibodies occurred earlier in the course of the disease than antibodies to Ro or La. In addition antibodies to SP-1, CA-6 and PSP were found in patients meeting the criteria for SS who lacked antibodies to Ro or La. Furthermore, in patients with idiopathic xerostomia and xerophthalmia for less than 2 years, 76% had antibodies to SP-1 and/or CA6 while only 31% had antibodies to Ro or La.
Antibodies to different isotypes (IgG, IgM & IgA) of SP-1, CA6 and PSP are useful markers for identifying patients with SS at early stages of the disease or those that lack antibodies to either Ro or La.

Selected References:

Fox, R (2005). Sjogren's syndrome. Lancet; 366: 321–331.

Shen, L. et al., (2012). Novel autoantibodies in Sjogren's syndrome. Clinical Immunology;145, 251–255.
Shen, L. et al., (2013). Different stages of primary sjogren's syndrome involving lyphotoxin and Type I interferon. J Immunol; 191(2): 608-13.

Comprehensive Sjogren's Syndrome Profile (includes tests 094 - salivary protein 1 antibodies IgG, IgA & IgM, 095 – Carbonic anhydrase VI antibodies IgG, IgA & IgM & 096 Parotid specific/secretory protein antibodies, IgG, IgA & IgM, 001 Antinuclear antibodies by HEp-2 and Mouse Kidney, 011 - Rheumatoid factor IgG, IgA & IgM, 045-Ro & 046 -La, 511- H & E studies of minor gland biopsies for focus scores)

IMMCO Test Code: **097**

Methodology: Indirect Immunofluorescence, ELISA, and H & E studies.

CPT Code: 83520 (x9), 86038, 86431 (x3), 86235 (x2), 88305 (x1)

Reference range: Quantitative: EU/ml, Titer, Report

<20 EU/ml Negative

20-25 EU/ml Borderline

>25 EU/ml Positive

Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.

Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 4-10 ml of blood in a red top or serum separator tube. If separation facilities are not available, the blood can be sent in the tube used for collection.

Sample Stability: Sample is stable at ambient temperature during shipment for 5 days. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.

Cause for rejection: Specimens other than serum or CSF. Grossly hemolyzed, lipemic or icteric samples.

Clinical Relevance: Sjogren's syndrome (SS) is a systemic autoimmune disease in which loss of salivary gland and lachrymal gland function is associated with hypergammaglobulinemia, autoantibody production, mild kidney and lung disease and eventually lymphoma. SS involves dry eyes and dry mouth without systemic features that may be either primary or secondary to another autoimmune disease, such as SLE in patients with SS diagnosed at a late stage in their disease, after the salivary glands and lachrymal glands are already destroyed. Only symptomatic treatment can be offered for abnormal lachrymal and salivary gland function. The diagnosis for SS is currently at a crossroad with the American College of Rheumatology providing which requires characteristic autoantibodies (SS-A/SS-B) or minor salivary gland biopsy. Since lip biopsies are not frequently performed in clinical practice, there is increased emphasis placed on autoantibodies in diagnosis.

Recently novel antibodies identified to salivary gland protein 1 (SP-1), carbonic anhydrase 6 (CA6) and parotid secretory protein (PSP) using western blot methodology. Further studies have shown that the isotype differentiation of the markers adds to the sensitivity of diagnosis of SS. These autoantibodies occurred earlier in the course of the disease than antibodies to Ro or La. In addition antibodies to SP-1, CA-6 and PSP were found in patients meeting the criteria for SS who lacked antibodies to Ro or La. Furthermore, in patients with idiopathic xerostomia and xerophthalmia for less than 2 years, 76% had antibodies to SP-1 and/or CA6 while only 31% had antibodies to Ro or La.

Antibodies to different isotypes (IgG, IgM & IgA) of SP-1, CA6 and PSP are useful markers for identifying patients with SS at early stages of the disease or those that lack antibodies to either Ro or La.

Selected References:

Fox, R (2005). Sjogren's syndrome. Lancet; 366: 321–331.
Shen, L. et al., (2012). Novel autoantibodies in Sjogren's syndrome. Clinical Immunology; 145, 251–255.
Shen, L. et al., (2013). Different stages of primary sjogren's syndrome involving lyphotoxin and Type I interferon. J Immunol; 191(2): 608-13.

Dermatomyositis/Polymyositis

ANA Titer and Pattern on HEp-2 and Mouse Kidney

Immco Test Code: #001
Methodology: Indirect Immunofluorescence
Substrate: HEp-2 and Mouse Kidney
Reference Range: Negative: < 1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to 5120 at an additional charge.
CPT Code: 86038
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 2-3 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: For detection of antibodies to nuclear antigens. The homogeneous pattern is primarily associated with systemic lupus erythematosus (SLE). Antibodies to centromere antigens are highly specific for calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia, commonly referred to as CREST syndrome, a limited form of systemic sclerosis. Centromere antibodies can also occasionally be found in low titers in some other autoimmune variants. Antinuclear antibodies with a speckled pattern are commonly associated with SLE, although they do occur in some cases of Sjögren's syndrome and mixed connective tissue disorders. ANA antibodies with a nucleolar pattern are commonly associated with systemic sclerosis (SSc), although they do occur in some cases of SLE and overlap syndromes. Overlap syndromes include dermatomyositis/polymyositis.

SS-A (Ro) Antibody

Immco Test Code: #045
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to SS-A (Ro) occur in approximately 30-40% of systemic lupus erythematosus (SLE) patients. They also occur in 60% of patients with subacute cutaneous lupus erythematosus (LE), in almost all cases of neonatal LE, in almost all SLE patients with C2 deficiency and an about one half of patients with Sjögrens syndrome.

Mi-2 Antibody for Dermatomyositis

Immco Test Code: #049
Methodology: Line Immunoassay
Reference Range: Qualitative
CPT Code: 86235, 84181
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to Mi-2 occur in 15-20% of patients with adult dermatomyositis.

Ku Antibody for Polymyositis/Scleroderma Overlap

Immco Test Code: #050
Methodology: Line Immunoassay
Reference Range: Qualitative
CPT Code: 84181
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Ku antibodies have been found in 10% of patients with polymyositis/scleroderma overlap syndrome and in 10% of systemic lupus erythematosus patients. Patients with polymyositis/scleroderma overlap who are positive for Ku antibodies usually have a mild disease with a good prognosis.

PM/Scl for Myositis

Immco Test Code: #052
Methodology: ELISA
Reference Range: Semi-Quantitative
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.

Clinical Relevance: These antibodies are associated with a high frequency of myositis-scleroderma overlap.

Signal Recognition Particle (SRP)

Immco Test Code: #053
Methodology: Line Immunoassay
Reference Range: Qualitative
CPT Code: 84182
Schedule/Turnaround Time: Assay performed once per week. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of SRP antibodies is predominantly associated with polymyositis. The prevalence of SRP antibodies in idiopathic inflammatory myopathy is 4-5%.

Jo-1 IgG

Immco Test Code: #088
Methodology: Line Immunoassay
Reference Range: Qualitative
CPT Code: 83516
Schedule/Turnaround Time: Assay performed once per week. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of Jo-1 antibodies is predominantly associated with idiopathic form of myositis. Antibody titer may fluctuate with disease activity.

Complete Myositis Profile

Immco Test Code: #072

Includes Immco Test Codes: #001 (ANA on Hep-2 & mouse kidney); #049 (Mi-2); #050 (Ku); #053 (SRP); 081* (PL7); #082* (PL12); #083* (EJ); #084* (OJ); #085* (Ro-052); #086* (PM/Scl75); #087* (PM/Scl 100); #088* (Jo-1 LIA)
Methodology: Indirect Immunofluorescence, ELISA, Line Immunoassay
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 84182 (x2), 86516 (x9)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to

shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.
*****These tests are only offered in complete Myositis Profile and not listed individually.

Myositis Interstitial Lung Disease Panel

Immco Test Code: #198
Includes Immco Test Codes: #050 (Ku); #053 (SRP); 081 (PL7); #082 (PL12); #083 (EJ); #084 (OJ); #085 (Ro-052/SS-A -52); #086 (PM/Scl 75); #087 (PM/Scl 100); #088 (Jo-1), #192 (MDA5/CADM 140); #196 (KS)
Methodology: Line Immunoassay
Reference Range: Qualitative
CPT Code: 83516 (x12)
Schedule/Turnaround Time: Assay performed once per week. Report availability is three - four weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Interstitial Lung Disease (ILD) co-occurs with autoimmune inflammatory myopathy (IM) patients in between 10-20% of the cases. Depending on the autoantibody present the occurrence of ILD can be seen in 2/3 of the IM patients.
The prevalence of ILD in anti-synthetase (Jo-1, PL 7, PL 12, EJ, OJ, KS) positive inflammatory myopathy patients was found to be as high as 73%.
Anti-Ku antibodies are detected in multiple autoimmune diseases and has high co relation to these patients developing ILD.
In SRP positive myositis patients, the prevalence of ILD has been documented at 23%.
Anti-SSA 52 kD antibodies commonly co-occur with other myositis related antibodies. They are found in 1/3rd of CADM140 kD positive patients, and are also associated with anti-synthetase antibodies.
Antibodies to PM/Scl are found in 40-50% of Scleroderma-polymyositis overlap syndrome patients and correlate with a benign course of ILD.
Autoantibodies to clinically amyopathic dermatomyositis C-ADM 140/MDA5 are specifically detected in Japanese patients with dermatomyositis and are known to have a strong association with rapidly progressive interstitial lung disease (RP-ILD). Japanese studies have shown that anti-MDA5 is seen in between 38%-50 of juvenile dermatomyositis (JDM patients), all of whom had ILD. A small subsets of with very high titers of antiMDA5 had RP-ILD. The reported rates of ILD in USA patients with JDM are far lower than in adult DM. The risk of P140 kD antibody positive DM patients developing ILD reached close to 100%.
References
Gunawardena, H., Betteridge, Z. E., & McHugh, N. J. (2009). Myositis-specific autoantibodies: their clinical and pathogenic significance in disease expression. *Rheumatology*, *48*(6), 607-612. Casciola-Rosena L, Mammena AL. Myositis autoantibodies. Curr Opin Rheumatol.
2012;24:602-608
*****These tests are only offered in complete Myositis Profile and not listed individually.

Myositis Malignancy Panel I

Immco Test Code: #199
Includes Immco Test Codes: #038 (U-1sn RNP); #039 (U-2 sn RNP); #049 (Mi-2); #050 (Ku); #053 (SRP); 081 (PL7); #082 (PL12); #083 (EJ); #084 (OJ); #085 (Ro-052/SS-A-52); #086 (PM/Scl75); #087(PM/Scl 100); #088 (Jo-1); #191 (TIF 1 Gamma); #192 (MDA5/CADM 140); #193 (MORC3, p140/NXP2); #194 (SAE-1); #195 (CN1A); #196 (KS); #197 (U3RNP/Fibrillarin)
Methodology: Line Immunoassay

Reference Range: Qualitative
CPT Code: 83516 (x20)
Schedule/Turnaround Time: Assay performed once per week. Report availability is three - four weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Anti-U1snRNP antibodies typically appear in both SLE and Mixed Connective Tissue Disease (MCTD). In MCTD, the presence of U1 snRNP is required for diagnosis. MCTD is typified by the high-titer RNP antibody activity in isolation; anti-RNP antibody activity in SLE commonly accompanies anti-Sm antibodies. U2 snRNP autoantibodies are myositis-associated autoantibodies and are found frequently, but not exclusively, in patients with myositis. Other myositis-associated autoantibodies include autoantibodies to U1-RNP, U2-RNP, PM/SCL and Ku. Antibodies to Mi-2 occur in 15-20% of patients with adult dermatomyositis. Ku antibodies have been found in 10% of patients with polymyositis/scleroderma overlap syndrome and in 10% of systemic lupus erythematosus patients. Patients with polymyositis/scleroderma overlap who are positive for Ku antibodies usually have a mild disease with a good prognosis.
The presence of SRP antibodies is predominantly associated with polymyositis. The prevalence of SRP antibodies in idiopathic inflammatory myopathy is 4-5%.
Antibodies against PL-7 and PL-12 have a prevalence of approximately 3% to up to 6% in myositis patients, partly overlapping with SLE, SSc or interstitial lung fibrosis. The prevalence of antibodies against EJ and OJ in myositis patients is up to 3%.
Ro-52 is observed in approximately 30% of patients with myositis.
PM-Scl antibodies are associated with a high frequency of myositis-scleroderma overlap. Anti-155/140 antibodies are directed against the transcription intermediate family-1 (TIF-1) members TIF-1α, and TIF-1γ. –TIF-1α/γ antibodies are frequently detected is juvenile dermatomyositis (DM) and may present a more severe clinical course. The frequency of anti–TIF-1α/γ antibodies in juvenile DM is 23–29%. These antibodies are frequently detected in patients with cancer-associated DM. The incidence of cancer in anti–TIF-1α/γ–positive patients with adult DM is 42–75%.
Autoantibodies to clinically amyopathic dermatomyositis C-ADM 140/MDA5 are specifically detected in Japanese patients with dermatomyositis and are known to have a strong association with rapidly progressive interstitial lung disease (RP-ILD). Japanese studies have shown that anti-MDA5 is seen in between 38%-50 of juvenile dermatomyositis (JDM patients), all of whom had ILD. A small subsets of with very high titers of antiMDA5 had RP-ILD. The reported rates of ILD in USA patients with JDM are far lower than in adult DM.
Anti-NXP-2/MJ antibodies associated with young onset DM, calcinosis, no internal organ involvement and good response of myopathy to therapy. Anti-NXP-2/MJ reported in juvenile DM is also found in adult PM/DM, and could be a new useful biomarker. Studies show that anti- NXP-2 and anti-TIF-1γ antibodies are frequent DM specificities (found in 55% of patients) and are present in most patients with cancer-associated DM.
Anti-SAE may occur in patients who present with clinically amyopathic dermatomyositis first and then progress to develop myositis with a high frequency of systemic features including dysphagia but a low frequency of interstitial pneumonia. Anti-SAE positive patients had mainly skin and muscle manifestations while dysphagia, interstitial lung disease, arthritis and constitutional symptoms were absent.
Sporadic inclusion body myositis (sIBM) is an inflammatory myopathy characterized by both degenerative and autoimmune features. Circulating autoantibody against a 43 kDa muscle autoantigen has been demonstrated in sIBM. Anti-cN1A autoantibodies were shown to be over 70% sensitive and over 95% specific for sIBM.

Autoantibodies to five of the aminoacyl-transfer RNA (tRNA) synthetases have been described, and each is associated with a syndrome of inflammatory myopathy with interstitial lung disease (ILD) and arthritis. Anti-KS was more closely associated with ILD than with myositis.
The presence of anti–U3 RNP autoantibodies in systemic sclerosis (SSc) identifies a well-defined clinical subset of the disease. This antibody should be considered in African American and/or male SSc patients who have positive ANA with pure nucleolar staining. SSc patients with anti– U3 RNP are younger and have more rapid progression of disease. Patients with anti–U3 RNP have a significantly greater frequency of internal organ involvement, skeletal muscle involvement and pulmonary hypertension.

References

Gunawardena, H., Betteridge, Z. E., & McHugh, N. J. (2009). Myositis-specific autoantibodies: their clinical and pathogenic significance in disease expression. *Rheumatology*, *48*(6), 607-612. Casciola-Rosena L, Mammena AL. Myositis autoantibodies. Curr Opin Rheumatol.
2012;24:602-608

*****These tests are only offered in complete Myositis Profile and not listed individually.

Relapsing Polychondritis

Collagen Type II Antibody

Immco Test Code: #015
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 83520
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Collagen II antibodies occur in 22% of patients with sensory neural hearing loss, 30% of patients with sudden deafness and 67% of patients with Meniere's disease. Collagen II antibodies also occur in patients with relapsing polychondritis and in patients with rheumatoid arthritis.

Rheumatoid Arthritis

ANA Titer and Pattern on HEp-2 & Mouse Kidney

Immco Test Code: #001
Methodology: Indirect Immunofluorescence
Substrate: HEp-2 and Mouse Kidney
Reference Range: Negative: < 1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to 5120 at an additional charge.
CPT Code: 86038
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.

Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 2-3 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: For detection of antibodies to nuclear antigens. The homogeneous pattern is primarily associated with systemic lupus erythematosus (SLE). Antibodies to centromere antigens are highly specific for calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia, commonly referred to as CREST syndrome, a limited form of systemic sclerosis (SSc). Centromere antibodies can also occasionally be found in low titers in some other autoimmune variants. Antinuclear antibodies with a speckled pattern are commonly associated with SLE, although they do occur in some cases of Sjögren's syndrome and mixed connective tissue disorders. ANA antibodies with a nucleolar pattern are commonly associated with (SSc), although they do occur in some cases of SLE and overlap syndromes. Overlap syndromes include dermatomyositis/polymyositis.

Keratin (AKA) Antibody Titer

Immco Test Code: #009
Methodology: Indirect Immunofluorescence
Substrate: Rodent Esophagus
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Keratin antibodies have a high degree of specificity for rheumatoid arthritis and can be used adjunct to rheumatoid factor (RF) and cyclic citrullinated peptides (CCP) antibodies in the diagnosis of rheumatoid arthritis.

Rheumatoid Factor (RF) IgG, IgA & IgM

Immco Test Code: #011
Methodology: ELISA
Reference Range:

IgG	Negative: <20 Borderline: 20-25 Positive: >25	**Units:** EU/ml
IgA	Negative: <20 Borderline: 20-25 Positive: >25	**Units:** EU/ml
IgM	Negative: <7 Borderline: 7-9 Positive: >9	**Units:** IU/ml

CPT Code: 86431(x3)
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The measurement of RF is important in the diagnosis and prognosis of rheumatoid arthritis. High levels of RF occur in sera of patients who tend to develop extra- articular complications.

Cyclic Citrullinated Peptides (CCP) IgG Antibody

Immco Test Code: #017
Methodology: ELISA
Reference Range:
Negative: <25
Units: units/ml Positive: ≥25
CPT Code: 86235
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Cyclic citrullinated peptides are specifically recognized by autoantibodies in serum of patients with Rheumatoid Arthritis. A diagnostic and prognostic value for the measurement of CCP antibodies has been found in relation to joint involvement and radiological damage in early RA.

HLA DR4 (Erosive Rheumatoid Arthritis)

Immco Test Code: #147
Methodology: Polymerase chain reaction (PCR) with Sequence Specific Primers
Reference Range: Reported positive with subtype or negative
CPT Code: 83891, (DNA extraction and isolation); 83898(x23), (Amplification), DR; 83894, Gel separation; 83912, (Interpretation and reporting).
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Clinical Relevance: There is a strong association of HLA DR4 subtypes with erosive rheumatoid arthritis. For example, DR4 subtypes *04:01 and *04:04 are associated with disease. A strong association between the DR4 heterozygotes *04:01/*04:04 and juvenile rheumatoid arthritis suggests that this genetic combination predisposes an early onset of disease.
Although DR4 does not predict disease, it is a useful indicator of disease progression and prognosis when other clinical factors are taken into account. For example, the presence of the DR4 marker in a patient with

pre-erosive arthritis indicates the likelihood of rapid progression to erosive disease. Furthermore, patients with two DR4 susceptibility genes are at high risk for extra-articular manifestations such as vasculitis and Felty's syndrome. Therefore testing for DR4 susceptibility genes, in conjunction with other diagnostic tools, assists in making therapeutic decisions early after the initial diagnosis.

HLA- B27 Genotyping

Immco Test Code: #149
Methodology: Sequence Specific Primers
Reference Range: No established reference ranges. Reported positive or negative
CPT Code: 83891, 83894, 83912, 83898 (x19)
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Clinical Relevance: The HLA-B27 genetic marker, in particular the *27:02, *27:04, and *27:05 subtypes, are strongly associated with conditions collectively referred to as seronegative arthropathies. At the forefront of these syndromes is the disease ankylosing spondylitis (AK).
AK, a rheumatic condition primarily affecting the spine and axial skeleton, may also involve multiple organ systems. Generally, 95% of patients with AK express a B27 susceptibility marker as compared to 3-5% of the non-afflicted population.
Other diseases with similar features are also strongly associated with HLA-B27. Among patients experiencing reactive arthritis, an autoimmune response to gastrointestinal infections, 60-70% exhibit the HLA-B27 marker. Spinal and peripheral joint inflammation occurring in conjunction with psoriasis and inflammatory bowel disease, and anterior uveitis, show similar associations with HLA-B27.

RA Profile I

Immco Test Code: #073
Includes Immco Test Codes: #001 (ANA on HEp-2 & Mouse Kidney); #011 (RF); #017 (CCP).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86431 (x3), 86235
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

RA Profile II

Immco Test Code: #074
Includes Immco Test Codes: #001 (ANA on HEp-2 & Mouse Kidney); #009 (AKA); #011 (RF); #017 (CCP).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86431 (x3), 86255, 86235

Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements for Antibody Testing: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

RA Profile III

Immco Test Code: #069
Includes Immco Test Codes: #001 (ANA on HEp-2 & Mouse Kidney); #009 (AKA); #011 (RF); #017 (CCP), #147 (HLA DR4), #149 (HLA-B27).
Methodology: Indirect Immunofluorescence, ELISA, Sequence Specific Primers
Reference Range: See reference ranges for individual tests
CPT Codes: 86038, 86431 (x3), 86255, 86235, 83891, 83894, 83912, 83898 (x19)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements for Antibody Testing: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Specimen Requirements for HLA DR4 & HLA B27: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
Sample Stability Sample is stable at ambient temperature and should be analyzed within 76 hours.
Clinical Relevance: See individual tests.

Vasculitis/Thrombosis

ANCA (Antineutrophil Cytoplasmic Antibodies) Titer

Immco Test Code: #003
Methodology: Indirect Immunofluorescence
Substrate: Ethanol and Formalin Fixed Human Polymorphonuclear Leukocytes
Reference Range: Negative: <1:20
Units: Titer & ANCA pattern reported on all positives.
Note: Positive samples at a 1:20 screening dilution are titered to an endpoint at an additional charge. Positive samples are confirmed by PR3 or MPO ELISA.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The cytoplasmic ANCA (cANCA) pattern is suggestive of Wegener's granulomatosis and other systemic small vessel vasculitides such as microscopic polyarteritis/polyangitis, idiopathic crescentic and necrotizing glomerulonephritis. The perinuclear ANCA (pANCA) reaction patterns are observed in patients with systemic small vessel vasculitis but have also been described in other non-vasculitic autoimmune diseases including ulcerative colitis, Crohn's disease and chronic hepatitis.

MPO (pANCA) Antibody

Immco Test Code: #056
Methodology: ELISA
Reference Range:
Negative: <10 **Units:** IU/ml
Borderline: 10-12.5
Positive: >12.5
CPT Code: 83520
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: pANCA occur in vasculitis, glomerulonephritis, Churg-Strauss syndrome, polyarteritis nodosa, systemic lupus erythematosus, and rheumatoid arthritis. A major antigen of pANCA is myeloperoxidase (MPO), which constitutes a potent microbicidal system within the neutrophil granulocytes. Additional target antigens such as human leukocyte elastase, and lactoferrin have also been associated with the pANCA fluorescence pattern. Antibodies to MPO can also be induced by drugs such as hydralazine, clozapine, and L tryptophan. Occupational exposure to environmental factors such as silica dust may provoke an anti-MPO positive progressive glomerulonephritis. Measurement of MPO specific ANCA is an important aid in the evaluation of clinical subtypes within systemic vasculitides.

PR3 (cANCA) Antibody

Immco Test Code: #057
Methodology: ELISA
Reference Range:
Negative: <10 **Units:** IU/ml
Borderline: 10-12.5
Positive: >12.5
CPT Code: 83520
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) for up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: cANCA are directed against several proteins such as Cathepsin G, Elastase and Proteinase 3 (PR3). PR3, the major antigen in this group, is a neutral serine proteinase localized in the azurophilic granules of the neutrophils. Antibodies against the PR3 antigen serve as a marker for Wegener's granulomatosis (WG), a systemic necrotising vasculitides which exists in two forms, extended and limited. Extended WG is characterized by granulomatous inflammation of the respiratory tract with cANCA reactivity occurring in 90% of patients.
Limited WG is characterized without renal involvement, and cANCA reactivity is detected in 67% of patients. Disease onset can occur at any age. Men are twice as frequently affected as women. Several studies

have established a direct correlation between PR3 antibody levels and the active phase of WG. The concentration of serum anti-PR3 rises dramatically during disease exacerbations (90% frequency), and relapses are usually accompanied by significant titer increases.

Phospholipid Antibody IgG, IgA, IgM

Immco Test Code: #008
Methodology: ELISA
Reference Range:

IgG	Negative: <23	**Units:** GPL
	Positive: ≥23	
IgA	Negative: <22	**Units:** APL
	Positive: ≥22	
IgM	Negative: <11	**Units:** MPL
	Positive: ≥11	

CPT Code: 86147(x3)
Schedule/Turnaround Time: Assay performed every two weeks. Report availability is within three weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of cardiolipin antibodies helps to identify patients at risk for venous and/or arterial thrombosis often accompanied by thrombocytopenia, a syndrome referred to as antiphospholipid syndrome. This syndrome most commonly occurs in patients with systemic lupus erythematosus (SLE) or lupus-like diseases where the criteria for SLE are not fulfilled. High levels of cardiolipin antibodies also occur in fetal loss. Low levels of these antibodies are of limited significance.

Circulating Immune Complexes (CIC)

Immco Test Code: #014
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86332
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Immune complexes are present in patients with various autoimmune and other viral or infectious diseases.

GBM (Glomerular Basement Membrane) Antibody Titer IgG & IgA

Test Code: #270
Methodology: Indirect Immunofluorescence
Substrate: Primate Kidney
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255 (x2)/Titer 86256 (x1 or x2)
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to GBM occur in glomerulonephritis and Goodpasture syndrome. Rapidly progressive glomerulonephritis (RPGN) is characterized by crescentic glomerulonephritis. RPGN may be classified into 3 types: 1) Immune complex mediated disease characterized by the presence of DNA antibodies or streptococcal antibodies 2) Glomerular basement membrane (GBM) mediated glomerulonephritis and Goodpasture syndrome 3) antineutrophil cytoplasmic antibody (ANCA) associated glomerulonephritis.

Vasculitis Profile

Immco Test Code: #080
Includes Immco Test Codes: #003 (ANCA); #008 (Phospholipid); #014 (CIC); #270 (GBM).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests.
CPT Codes: 86255, 86147 (x3), 86332, 86255 (x2)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

VESICULO-BULLOUS DISEASES

Pemphigus/Pemphigoid/Epidermolysis Bullosa Acquisita (EBA)

Intercellular (IC) and Basement Membrane Zone (BMZ) Antibodies (Dual Substrate)

Immco Test Code: #105
Methodology: Indirect Immunofluorescence
Substrate: Primate Esophagus and Guinea Pig Esophagus
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255

Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The detection of anti-skin (IC and BMZ) antibodies aids in the diagnosis, and sometimes prognosis, of chronic vesicular-bullous diseases including pemphigus, pemphigoid, cicatricial pemphigoid, and epidermolysis bullosa acquisita (EBA). Epithelial intercellular antibodies are diagnostic for pemphigus and occur in over 90% of patients with active forms. Because of the species specificity of intercellular antibodies, the use of the dual substrates further distinguishes the intercellular antibodies of pemphigus vulgaris and vegetans from the antibodies of pemphigus foliaceus and erythematosus. Antibodies to basement membrane antigens of stratified squamous epithelium occur in about 70% of active bullous pemphigoid, 50% of vesicular pemphigoid and EBA and 10% of cicatricial pemphigoid patients.

IC Paraneoplastic Pemphigus Antibody Titer

Immco Test Code: #104
Methodology: Indirect Immunofluorescence
Substrate: Rodent bladder, Primate esophagus and Guinea Pig esophagus
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Paraneoplastic pemphigus is a form of pemphigus associated with malignancy. Positive paraneoplastic pemphigus sera give immunofluorescence reactions not only of pemphigus antibodies, but also react with other epithelia. Thus serum tests for this suspected condition are performed on an additional substrate.

Differentiation of Bullous Pemphigoid from Epidermolysis Bullosa Acquisita (EBA) on "Split Skin"

Immco Test Code: #106
Methodology: Indirect Immunofluorescence
Substrate: Split Primate Skin
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red

top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Epidermolysis bullosa acquisita (EBA) can mimic bullous pemphigoid (BP) clinically, histologically and immunologically. In this indirect immunofluorescence assay, EBA and BP antibodies can be distinguished by their localization in skin that is split at the lamina lucida.

Pemphigoid IgG4 Antibody

Immco Test Code: #109
Methodology: Indirect Immunofluorescence
Substrate: Primate Esophagus and Split Primate Skin
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of circulating basement membrane zone (BMZ) antibodies is characteristic of patients with bullous pemphigoid (BP) and is routinely employed in making the diagnosis. The positive tests, however, occur in 50-70% of patients with BP, thus necessitating consideration of other tests especially in patients who are seronegative. Studies have shown that BMZ antibodies primarily are of IgG4 subclass and are present in all BMZ antibody positive BP cases. Of BP patients negative for BMZ antibodies, 72% were found positive when tested for IgG4 subclass antibodies. Testing for IgG4 subclass BMZ antibodies enhances the sensitivity of serum tests from 68.5% to 91%.

Desmoglein 1 (DSG1) Antibody

Immco Test Code: #112
Methodology: ELISA
Reference Range Values:
Negative <14.0 **Units:** U/ml
Indeterminate 14.0-20.0
Positive >20.0
CPT Code: 83516 (x1)
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is table refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.

Clinical Relevance: Pemphigus includes a group of often fatal, autoimmune blistering diseases characterized by intraepithelial lesions. Pemphigus vulgaris and its variants may present with oral or other mucosal lesions alone or with mucosal plus skin lesions. Pemphigus foliaceus and its variants present with skin lesions alone. Indirect Immunofluorescence studies reveal that both forms of pemphigus are caused by autoantibodies to cell surface antigens of stratified epithelia of mucous membranes and skin. These antibodies bind to calcium dependent adhesion molecules in cell surface desmosomes, notably desmoglein 1(DSG-1) in pemphigus foliaceus and desmoglein 3 (DSG-3) in pemphigus vulgaris. Pemphigus vulgaris patients with both mucosal and skin lesions have antibodies to both DSG-3 and DSG-1. The diagnosis of pemphigus depends on biopsy and serum studies that characterize lesions and detect the autoantibodies that cause them. Serum studies afford highly sensitive diagnostic aids. Originally they were performed by indirect immunofluorescence using monkey esophagus and other tissues sections. The identification of the reactive antigens as DSG-1 and DSG-3 has made it possible to develop highly specific and sensitive ELISA methods.

Desmoglein 3 (DSG3) Antibody

Immco Test Code: #113

Methodology: ELISA

Reference Range Values:
Negative <9.0 **Units:** U/ml
Indeterminate 9.0-20.0
Positive >20.0
CPT Code: 83516 (x1)
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is table refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: Pemphigus includes a group of often fatal autoimmune blistering diseases characterized by intraepithelial lesions. Pemphigus vulgaris and its variants may present with oral or other mucosal lesions alone or with mucosal plus skin lesions. Pemphigus foliaceus and its variants present with skin lesions alone. Indirect Immunofluorescence studies reveal that both forms of pemphigus are caused by autoantibodies to cell surface antigens of stratified epithelia of mucous membranes and skin. These antibodies bind to calcium dependent adhesion molecules in cell surface desmosomes, notably desmoglein 1(DSG-1) in pemphigus foliaceus and desmoglein 3 (DSG-3) in pemphigus vulgaris. Pemphigus vulgaris patients with both mucosal and skin lesions have antibodies to both DSG-3 and DSG-1. The diagnosis of pemphigus depends on biopsy and serum studies that characterize lesions and detect the autoantibodies that cause them. Serum studies afford highly sensitive diagnostic aids. Originally they were performed by indirect immunofluorescence using monkey esophagus and other tissues sections. The identification of the reactive antigens as DSG-1 and DSG-3 has made it possible to develop highly specific and sensitive ELISA methods.

Bullous Pemphigoid 180 (BP180) Antibody

Immco Test Code: #114
Methodology: ELISA
Reference Range Values:

Negative: < 9 **Units:** U/ml
Positive: ≥ 9
CPT Code: 83516 (x1)
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is table refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: Bullous pemphigoid (BP) is an autoimmune mediated immunobullous skin disorder found mainly in the elderly population and is characterized by frequent occurring of tense blisters and erythema. Antibodies are directed to the basement membrane zone and are found in the serum of patients as linear IgG or C3 sediments. Target antigens of the autoantibodies in BP patient serum are BP230 and BP180, also called BPAG1 and BPAG2.
Molecular weight of these antigens is 230 kD and 180 kD respectively. BP180 is thought to be the direct target of the autoantibody because of its location, and the autoantibodies against BP230 are thought to be secondarily produced. The antibodies against BP180 are thought to be pathogenic, because the rabbit antibody against mouse in the NC16a region of BP180 forms blisters similar to BP when injected into neonatal mice. The main epitope of BP180 is located in the region close to cell membrane called NC16a and most patient serum reacts with the recombinant NC16a protein. Serum levels of BP180 co-relate with the disease activity.

Bullous Pemphigoid 230 (BP230) Antibody

Immco Test Code: #115
Methodology: ELISA
Reference Range Values:
Negative: < 9 **Units:** U/ml
Positive: ≥ 9
CPT Code: 83516 (x1)
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is table refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: Bullous pemphigoid (BP) is an autoimmune mediated immunobullous skin disorder found mainly in the elderly population and is characterized by frequent occurring of tense blisters and erythema. Antibodies are directed to the basement membrane zone and are found in the serum of patients as linear IgG or C3 sediments. Target antigens of the autoantibodies in BP patient serum are BP230 and BP180, also called BPAG1 and BPAG2.
Molecular weight of these antigens is 230 kD and 180 kD respectively. BP180 is thought to be the pathogenic autoantibody, however, not all BP patients have BP180 antibody in their serum. BP230 antibody is considered to be a useful serologic marker of the disease and co-relates well with the disease activity.

Pemphigus/Pemphigoid Profile I

Immco Test Code: #122
Includes Immco Test Codes: #105 (IC and BMZ); #106 (Differentiation of BP from EBA).
Methodology: Indirect Immunofluorescence
Reference Range: See reference ranges for individual tests.
CPT Codes: 86255 (x2)
Schedule/Turnaround Time: Assays performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Pemphigus Profile

Immco Test Code: #127
Includes Immco Test Codes: #105 (IC and BMZ); #112 (DSG 1); #113 (DSG 3).
Methodology: Indirect Immunofluorescence**,** ELISA
Reference Range Values: See reference ranges for individual tests.
CPT Code: 86255 (x1), 83516 (x2)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is table refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: See individual tests.

Pemphigoid Profile **Immco Test Code:** #128

Includes Immco Test Codes: #105 (IC and BMZ); #106 (Differentiation of BP from EBA);
#114 (BP 180); #115 (BP 230).
Methodology: Indirect Immunofluorescence**,** ELISA
Reference Range Values: See reference ranges for individual tests.
CPT Code: 86255 (x2), 83516 (x2)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is table refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: See individual tests.

Pemphigus/Pemphigoid Profile II

Immco Test Code: #129
Includes Immco Test Codes: #105 (IC and BMZ); #106 (Differentiation of BP from EBA);

#112 (DSG 1); #113 (DSG 3); #114 (BP 180); #115 (BP 230).
Methodology: Indirect Immunofluorescence**,** ELISA
Reference Range Values: See reference ranges for individual tests.
CPT Code: 86255 (x2) 83516 (x4)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is table refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: See individual tests.

Dermatitis Herpetiformis (DH)

Endomysial (EMA) Antibody IgA Antibody Titer

Immco Test Code: #100
Methodology: Indirect Immunofluorescence
Substrate: Primate Smooth Muscle
Reference Range: Negative: <1:2.5
Units: Titer
Note: Positive samples at a 1:2.5 screening are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The detection of endomysial antibodies aids in the diagnosis of gluten sensitive enteropathy, i.e. celiac disease (CD) and dermatitis herpetiformis (DH). Patients with CD and DH are reported to have antibodies to endomysium, reticulin and gliadin. Of the various antibody markers of CD and DH, EMA of the IgA class seem to be the most sensitive and specific marker.

Reticulin (ARA) IgA Antibody Titer

Immco Test Code: #101
Methodology: Indirect Immunofluorescence
Substrate: Rodent Kidney
Reference Range: Negative: <1:2.5
Units: Titer
Note: Positive samples at a 1:2.5 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the

tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Reticulin antibodies aid in the diagnosis of Celiac Disease (CD). The primary antigen of interest is R1.

Deamidated Gliadin (Celiac G +) Antibody IgA, IgG

Immco Test Code: #102
Methodology: ELISA
Reference Range:
Negative: <20.0 **Units:** EU/ml
Borderline: 20.0-25.0
Positive: >25.0
CPT Code: 83516 (x2)
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: Serological methods of diagnosis are commonly used to screen and support diagnosis of celiac disease (CD) and dermatitis herpetiformis (DH). The revised European Society of Pediatric Gastroenterology and Nutrition (ESPGAN) criteria for diagnosis of CD include only a single biopsy with clear cut remission of clinical symptoms on a gluten-free diet. Positive serology at the time of diagnosis and disappearance with gluten-free diet contributes to the diagnosis. Gliadin antibodies (AGA) in combination with other serological assays are commonly used in the diagnosis of CD. Both IgA and IgG gliadin antibodies are detected in the sera of patients with CD. IgG gliadin antibody tests are important towards the diagnosis of CD in patients who are IgA deficient. Studies show that 1-2% of the general population is IgA deficient and that the incidence of CD in IgA deficient subjects is significant hence the need for specific tests.

DH Profile II

Immco Test Code: #124
Includes Immco Test Codes: #100 (EMA); #101 (ARA); #102 (Celiac G+ Deamidated Gliadin).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests
CPT Codes: 86255(x2), 83520(x3)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

DH Profile III
Immco Test Code: #125
Includes Immco Test Codes: #100 (EMA); #102 (Celiac G+ Deamidated Gliadin).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests
CPT Codes: 86255, 83520(x3)
Schedule/Turnaround Time See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Chronic Ulcerative Stomatitis

SES-ANA Stratified Epithelium Specific Antinuclear Antibody
Immco Test Code: #107
Methodology: Indirect Immunofluorescence
Substrate: HEp-2, Primate Esophagus, Guinea Pig Esophagus
Reference Range: Based upon selective reactions on substrates used in the differential assay.
Units: Titer
Note: Positive samples at 1:10 screening are titered to an end point at an additional charge.
CPT Code: 86038, 86255 (x2)
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The detection of stratified epithelium specific antinuclear antibodies assists in the diagnosis of connective tissue disease, and/or chronic ulcerative stomatitis.

NEUROIMMUNOLOGY

Neuropathies

Myelin-Associated Glycoprotein (MAG) Antibody IgM
Immco Test Code: #456
Methodology: Indirect Immunofluorescence
Substrate: Primate Peripheral Nerve/Bovine Optic Nerve
Reference Range: Negative: <1:10
Units: Titer
Note: Positive IFA samples are confirmed by Western Blot at an additional charge.

CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Neuropathies associated with anti-MAG are often slowly progressive with evidence of demyelination and a variable degree of axonal loss associated with gait ataxia. 50% of all peripheral neuropathy cases with IgM paraproteinemia possess anti-MAG antibodies.
Detection of anti-MAG autoantibodies is useful, as it suggests active demyelination in a peripheral neuropathy.

Sulfated Glucuronyl Paragloboside (SGPG) Antibody IgM

Immco Test Code: #464
Methodology: ELISA
Reference Ranges: >1 Positive and <1 is Negative
CPT Codes: 83516
Schedule/Turnaround time: Assay performed every three weeks. Report availability is within three weeks from the time of specimen receipt.
Specimen requirements: Specimen need not be refrigerated or frozen. Collect 5-10ml of blood in a red top or serum separator tube (minimum: 0.5 mL). If possible, separate serum from the clot and place into orange tube provided with the Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable at refrigerated (2-8°C) up to five days and frozen (-20°C) up to a year.
Clinical relevance: Autoantibodies against MAG or SGPG in peripheral neuropathies with monoclonal IgM gammopathies occur in about 50% of patients. The presence of the reactive epitope on MAG led to the discovery of peripheral nerve acidic glycolipid SGPG.
The detection of MAG IgM antibodies is useful as it suggests the presence of active demyelination in peripheral neuropathy. Neuropathies associated with anti-MAG are often slowly progressive with evidence of demyelination and a variable degree of axonal loss associated with gait ataxia. 50% of all peripheral neuropathy cases with IgM paraproteinemia possess MAG antibodies. Majority of the MAG-positive patients will also be positive for SGPG because of the sharing of the common epitope between them. SGPG positive cases in the absence of MAG IgM antibodies suggest a multi-focal motor neuropathy with conduction blocked.

Paraneoplastic Syndromes

Hu Antibody/Antinuclear Neuronal Antibody I (ANNA-1)

Immco Test Code: #500
Methodology: Indirect Immunofluorescence
Substrate: Primate Cerebellum; Rodent Intestine/Liver
Reference Range: Negative: <1:10
Units: Titer
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48

hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to Hu antigen are present in patients with paraneoplastic neurologic syndrome such as encephalomyelitis and are frequently associated with small cell lung cancer and neuroblastoma. Hu antibodies are rarely associated with non-small cell lung cancer, prostate cancer or seminoma.

Yo Antibody/Purkinje Cell Antibody (PCA1)

Immco Test Code: #501
Methodology: Indirect Immunofluorescence
Substrate: Primate Cerebellum; Rodent Intestine/Liver
Reference Range: Negative: <1:10
Units: Titer
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kit. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to Yo are associated with paraneoplastic disorders (cerebellar degeneration) as well as with small cell lung cancer, gynecologic and breast cancer.

Ri Antibody

Immco Test Code: #502
Methodology: Indirect Immunofluorescence
Substrate: Primate Cerebellum; Rodent Intestine/Liver
Reference Range: Negative: <1:10
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to Ri are associated with paraneoplastic syndromes. The paraneoplastic syndrome associated with the presence of antibodies to Ri includes symptoms such as opsoclonus, ataxia, nystagmus, dizziness and dysarthria.

Tr Antibody/Purkinje Cell Antibody (PCA II)

Immco Test Code: # 506

Methodology: Indirect Immunofluorescence
Substrate: Primate Cerebellum-Rodent Intestine/Liver
Reference Range: Negative: <1:10
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Anti-Tr reactivity is usually associated with paraneoplastic cerebellar degeneration and Hodgkin's disease. It is usually seen in men with a mean onset of around 60 years. No confirmatory test is currently available.

Paraneoplastic Neuronal Profile I

Immco Test Code: #503
Includes Immco Test Codes: #500 (Hu); #501 (Yo); #502 (Ri).
Methodology: Indirect Immunofluorescence
Reference Range: See reference ranges for individual tests
CPT Codes: 86255 (x3)
Schedule/Turnaround Time: Assays performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Motor & Sensory Neuropathy Profile I

Immco Test Code: #505
Includes Immco Test Codes: #456 (MAG); #500 (Hu); #502 (Ri)
Methodology: Indirect Immunofluorescence, ELISA, Western Blot confirmation if appropriate
Reference Range: See reference ranges for individual tests.
CPT Code: 83520 (x8), 86255 (x3).
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Paraneoplastic Neuronal Profile II

Immco Test Code: #507

Includes Immco Test Codes: #500 (Hu); #501 (Yo); #502 (Ri), #506 (Tr)
Methodology: Indirect Immunofluorescence
Reference Range: See reference ranges for individual tests.
CPT Codes: 86255 (x4)
Schedule/Turnaround Time: Assays performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Motor and Sensory Neuropathy Profile II

Immco Test Code: #508
Includes Immco Test Codes: #456 (MAG), #464 (SGPG); #500 (Hu); #501 (Yo); #502 (Ri), #506 (Tr).
Methodology: ELISA, Indirect Immunofluorescence, Western Blot confirmation if appropriate
Reference Range: See reference range for individual tests.
CPT Codes: 83516 (x1-SGPG) 86255 (Hu,Yo, Ri, Tr, MAG with 84181)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 4-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Requested Sample Volume: 5 mL
Minimum Sample Volume: 2 mL
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Cause for rejection: Specimens other than serum. Grossly hemolyzed, lipemic or icteric samples.
Clinical Relevance:
Sulfate-3-Glucuronyl Paragloboside (SGPG) Antibody, IgM
Autoantibodies against MAG or SGPG in peripheral neuropathies with monoclonal IgM gammopathies occur in about 50% of patients. The presence of the reactive epitope on MAG led to the discovery of peripheral nerve acidic glycolipid SGPG. The detection of MAG IgM antibodies is useful as it suggests the presence of active demyelination in peripheral neuropathy. Neuropathies associated with MAG are often slowly progressive with evidence of demyelination and a variable degree of axonal loss associated with gait ataxia. 50% of all peripheral neuropathy cases with IgM paraproteinemia possess MAG antibodies. Majority of the MAG-positive patients will also be positive for SGPG because of the sharing of the common epitope between them. SGPG positive cases in the absence of MAG IgM antibodies suggest a multi-focal motor neuropathy with conduction block.
MAG IgM:
Neuropathies associated with MAG are often slowly progressive with evidence of demyelination and a variable degree of axonal loss associated with gait ataxia. 50% of all peripheral neuropathy cases with IgM paraproteinemia possess MAG antibodies. Detection of MAG autoantibodies is useful, as it suggests active demyelination in a peripheral neuropathy.
Hu
Antibodies to Hu antigens also called antineuronal nuclear antibody (ANNA-1) are present in patients with paraneoplastic neuronal syndrome such as encephalomyelitis and are frequently associated with small cell

lung cancer and neuroblastoma and rarely in non-small cell lung cancer, prostate cancer or seminoma.

Yo

Antibodies to Yo are associated with paraneoplastic disorders (cerebellar degeneration) occurring in patients with small cell lung cancer, ovarian or breast cancer.

Ri

Antibodies to Ri, referred to as antineuronal nuclear antibody Type 2 (ANNA-2) is associated with paraneoplastic syndromes including opsoclonus, ataxia, nystagmus, dizziness and dysarthria.

Tr

There is a strong link between the presence of the Tr antibodies and paraneoplastic cerebellar degeneration in patients with Hodgkin's disease (80 %). The Tr antibody titers tend to drop after treatment of Hodgkin's disease. The cerebellar degeneration is usually irreversible, although one study showed remission of the cerebellar degeneration in 14 % of the patients; this was most striking in younger patients.

Sensory Neuropathy Antibody Panel

Immco Test Code: #509

Includes Immco Test Codes: #456 (MAG); #464 (SGPG); #500 (Hu); #501 (Yo); #502 (Ri), #506 (Tr)

Methodology: Indirect Immunofluorescence, ELISA, Western Blot confirmation if appropriate

CPT codes: for the tests below is 83516(x1-SGPG) 86255(x5) -Hu,Yo, Ri, Tr, MAG with 84181

Reference Ranges: See reference ranges for individual tests.

Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.

Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 4-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.

Requested Sample Volume: 5 mL

Minimum Sample Volume: 2 mL

Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.

Cause for rejection:

Specimens other than serum. Grossly hemolyzed, lipemic or icteric samples.

Clinical Relevance:

Sulfate-3-Glucuronyl Paragloboside (SGPG) Antibody, IgM

Autoantibodies against MAG or SGPG in peripheral neuropathies with monoclonal IgM gammopathies occur in about 50% of patients. The presence of the reactive epitope on MAG led to the discovery of peripheral nerve acidic glycolipid SGPG. The detection of MAG IgM antibodies is useful as it suggests the presence of active demyelination in peripheral neuropathy. Neuropathies associated with MAG are often slowly progressive with evidence of demyelination and a variable degree of axonal loss associated with gait ataxia. 50% of all peripheral neuropathy cases with IgM paraproteinemia possess MAG antibodies. Majority of the MAG-positive patients will also be positive for SGPG because of the sharing of the common epitope between them. SGPG positive cases in the absence of MAG, IgM antibodies suggest a multi-focal motor neuropathy with conduction block.

MAG IgM:

Neuropathies associated with MAG are often slowly progressive with evidence of demyelination and a variable degree of axonal loss associated with gait ataxia. 50% of all peripheral neuropathy cases with IgM paraproteinemia possess antibodies. Detection of autoantibodies is useful, as it suggests active demyelination in a peripheral neuropathy.

Hu

Antibodies to Hu antigens also called antineuronal nuclear antibody (ANNA-1) are present in patients with

paraneoplastic neuronal syndrome such as encephalomyelitis and are frequently associated with small cell lung cancer and neuroblastoma and rarely in non-small cell lung cancer, prostate cancer or seminoma.

Yo

Antibodies to Yo are associated with paraneoplastic disorders (cerebellar degeneration) occurring in patients with small cell lung cancer, ovarian or breast cancer.

Ri

Antibodies to Ri, referred to as antineuronal nuclear antibody Type 2 (ANNA-2) is associated with paraneoplastic syndromes including opsoclonus, ataxia, nystagmus, dizziness and dysarthria.

Tr

There is a strong link between the presence of the Tr antibodies and paraneoplastic cerebellar degeneration in patients with Hodgkin's disease (80 %). The Tr antibody titers tend to drop after treatment of Hodgkin's disease. The cerebellar degeneration is usually irreversible, although one study showed remission of the cerebellar degeneration in 14 % of the patients; this was most striking in younger patients.

GASTROENTEROLOGY · HEPATOLOGY

Celiac Disease

Endomysial (EMA) Antibody Titer IgA

Immco Test Code: #100
Methodology: Indirect Immunofluorescence
Substrate: Primate Smooth Muscle
Reference Range: Negative: <1:2.5
Units: Titer
Note: Positive samples at a 1:2.5 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The detection of endomysial antibodies aids in the diagnosis of gluten sensitive enteropathy, i.e. celiac disease (CD) and dermatitis herpetiformis (DH). Patients with CD and DH are reported to have antibodies to endomysium, reticulin and gliadin. Of the various antibody markers of CD and DH, EMA of the IgA class is the most sensitive and specific marker.

Endomysial (EMA) IgG Antibody Titer

Immco Test Code: #110
Methodology: Indirect Immunofluorescence
Substrate: Primate Smooth Muscle
Reference Range: Negative: <1:2.5
Units: Titer
Note: Positive samples at a 1:2.5 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.

Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.

Clinical Relevance: Endomysial IgG antibodies in human serum aid in the diagnosis of celiac disease in patients with IgA deficiency.

Reticulin (ARA) IgA Antibody Titer

Immco Test Code: #101
Methodology: Indirect Immunofluorescence
Substrate: Rodent Kidney
Reference Range: Negative: <1:2.5
Units: Titer
Note: Positive samples at a 1:2.5 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Reticulin antibodies aid in the diagnosis of celiac disease. The primary antigen of interest is R1.

Deamidated Gliadin (Celiac G+) Antibody IgA, IgG

Immco Test Code: #102
Methodology: ELISA
Reference Range:
Negative: <20.0 **Units:** EU/ml
Borderline: 20.0-25.0
Positive: >25.0
CPT Code: 83516 (x2)
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: Deamidated gliadin antibodies in combination with other serological assays are commonly used in the diagnosis of celiac disease (CD). Both IgA and IgG gliadin antibodies are detected in the sera of patients with CD. IgG gliadin antibody tests are important towards the diagnosis of CD in patients who are IgA deficient. Studies show that 1-2% of the general population is IgA deficient and that the incidence of CD in IgA deficient subjects is significant, hence the need for specific tests.

HLA DQ α1*0501, β1*0201

Immco Test Code: #150
Methodology: Polymerase chain reaction (PCR) with sequence specific primers, PCR with sequence specific probe hybridization
Reference Range: Qualitative
CPT Code: 83891, 83900 (x2), 83898 (x52), 83912.
Turnaround Time: Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen should remain at ambient temperature without refrigeration. Collect 5 ml of uncoagulated whole blood in EDTA (purple top tubes) or in ACD (yellow top tubes).
Clinical Relevance: Most frequently the genetic markers associated with celiac disease are HLA-DQα1*05:01 in conjunction with HLA-DQβ1*02:01. Less frequently associated genes are HLA-DQα1*03:01 in conjunction with HLA-DQβ1*03:02. Generally, the HLA-DQα1 marker should be found in conjunction with its corresponding HLA-DQβ1 marker to be considered clinically significant. The presence of these markers does not provide a definitive diagnosis for celiac disease however their absence strongly suggests a diagnosis other than celiac disease.

CD Profile II

Immco Test Code: #121
Includes Immco Test Codes: #100 (EMA); #101 (ARA); #102 (Deamidated Gliadin).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests
CPT Codes: 86255 (x2), 83520 (x3)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

CD Profile III

Immco Test Code: #180
Includes Immco Test Codes: #100 (EMA); #102 (Deamidated Gliadin).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests
CPT Codes: 86255, 83520 (x3)
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Complete CD Profile

Immco Test Code: #130

Includes Immco Test Codes: #100 (EMA); #102 (Celiac G+); #150 (HLA)
Methodology: Indirect Immunofluorescence, ELISA, Luminex
Reference Range: See reference ranges for individual tests.
CPT Codes: 86255 IFA, 83520 (x3) ELISA, 83891, DNA extraction and isolation; 83900 (x2), Amplification, DQA and DQB; 83896 (x52); Hybridization with nucleic acid probes; 83912, Interpretation and reporting
Schedule/Turnaround Time See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen.
For antibody testing: Collect 2-5 mL of blood in a red top or serum separator tube.
For genetic testing: Collect 5-10mL of uncoagulated whole blood in EDTA (purple top tubes) or in ACD (yellow top tubes).
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The detection of endomysial antibodiesaids in the diagnosis of gluten sensitive enteropathy, i.e. CD and dermatitis herpetiformis (DH). Patients with CD and DH are reported to have antibodies to endomysium, tissue transglutaminase and gliadin. Several studies have shown that endomysial antibodies have 100% specificity and sensitivity in diagnosing CD. Tissue transglutaminase antibody levels are also useful in monitoring gluten compliance of the patients. Measurement of IgG levels with deamidated gliadin is helpful for establishing diagnosis of CD in IgA deficient patients. Absence of susceptibility genes suggests the absence of disease risk with approximately 95% certainty.

Inflammatory Bowel Disease (IBD)

ANCA (Antineutrophil Cytoplasmic Antibody) Titer

Immco Test Code: #003
Methodology: Indirect Immunofluorescence
Substrate: Ethanol and Formalin Fixed Human Polymorphonuclear Leukocytes
Reference Range: Negative: <1:20
Units: Titer & ANCA pattern reported on all positives.
Note: Positive samples at a 1:20 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The cytoplasmic ANCA (cANCA) pattern is suggestive of Wegener's granulomatosis and other systemic small vessel vasculitides such as microscopic polyarteritis/polyangitis, idiopathic crescentic and necrotizing glomerulonephritis. The perinuclear ANCA (pANCA) reaction patterns are observed in patients with systemic small vessel vasculitis but have also been described in other non-vasculitic autoimmune diseases including ulcerative colitis, Crohn's disease and chronic hepatitis.

Gastric Parietal Cell Antibody (AGPA) Titer

Immco Test Code: #214
Methodology: Indirect Immunofluorescence

Substrate: Mouse Kidney/Stomach
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: AGPA are commonly associated with pernicious anemia and chronic atrophic gastritis where they occur in about 90% and 50% of cases, respectively. Although healthy individuals may have gastric parietal cell antibodies, this finding may reflect asymptomatic atrophic gastritis. Negative findings for gastric parietal cell antibodies provide strong evidence for excluding pernicious anemia.

Autoimmune Pancreatitis (AIP) Panel

Immco Test Code: #188
Includes Immco Test Codes: #001 (ANA on HEp-2 & Mouse Kidney); #011 (RF); #400 (IgG); # 407 IgG4.
Methodology: Indirect Immunofluorescence, ELISA and Nephelometry
Reference Ranges: See individual tests.
CPT Codes: 86038, 86431 (x3), 82784 (x1) 82778 (x1)
Schedule/Turnaround time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10ml of blood in a red top or serum separator tube (minimum: 0.5 mL). If possible, separate serum from the clot and place into orange tube provided with the Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If ample is stored prior to shipment, it is stable at refrigerated (2-8 degree centigrade) up to five days and frozen (- 20 degree centigrade) up to a year.
Clinical Relevance: The elevated serum IgG4 level is nearly diagnostic of AIP. IgG4 shows specificity of 98% and sensitivity of 80-92% when cutoff values of 135mg/dl are used. IgG levels are also elevated and shows specificity of 73% and sensitivity of 75%. Antinuclear antibodies (ANA) and rheumatoid factor (RF) levels are also increased and show a lower sensitivity rate. However a combination of IgG4, IgG, ANA and RF can increase the sensitivity rate up to 97%.

Analyte	Sensitivity (%)	Specificity (%)
IgG4	80-92	98
IgG	72-73	75
Antinuclear Antibodies (ANA)	63-66	-
Rheumatoid Factor (RF)	20-28	-
IgG4, IgG, ANA and RF	97	98

Autoimmune Liver Diseases

ANA (Antinuclear Antibody) Titer and Pattern on HEp-2 & Mouse Kidney

Immco Test Code: #001
Methodology: Indirect Immunofluorescence
Substrate: HEp-2 and Mouse Kidney
Reference Range: Negative: < 1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to 5120 at an additional charge.
CPT Code: 86038
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 2-3 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: This test is for detection of antibodies to nuclear antigens. The homogeneous pattern is primarily associated with systemic lupus erythematosus (SLE). Antibodies to centromere antigens are highly specific for calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia, commonly referred to as CREST syndrome, a limited form of systemic sclerosis. Centromere antibodies can also occasionally be found in low titers in some other autoimmune variants. Anti-nuclear antibodies with a speckled pattern are commonly associated with SLE, although they do occur in some cases of Sjögren's syndrome and mixed connective tissue disorders. ANA antibodies with a nucleolar pattern are commonly associated with systemic sclerosis (SSc), although they do occur in some cases of SLE and overlap syndromes. Overlap syndromes include dermatomyositis/polymyositis.

AMA (Mitochondrial) Antibody Titer

Immco Test Code: #152
Methodology: Indirect Immunofluorescence
Substrate: Mouse Kidney/Stomach
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: AMA occur in over 90% of primary biliary cirrhosis (PBC) cases and 3- 11% of active chronic hepatitis patients. AMA are absent in patients with extra hepatic biliary obstruction and other liver diseases. The universal presence of AMA in PBC and their virtual absence in extra hepatic jaundice makes their detection of considerable value in differential diagnosis. ASMA in high titer ($\geq$160) occur in the majority of cases of chronic hepatitis and in intermediate titers (40-80) in acute viral hepatitis. Occasionally they may occur in cases of PBC where they are also found in intermediate titers.

ASMA (Anti-Smooth Muscle Antibody) Titer

Immco Test Code: #153
Methodology: Indirect Immunofluorescence
Substrate: Mouse Kidney/Stomach
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: ASMA in high titer (≥160) occur in the majority of cases of chronic active hepatitis and in intermediate titers (40-80) in acute viral hepatitis. Occasionally they may occur in cases of primary biliary cirrhosis where they are also found in intermediate titers.

AMA (Mitochondrial) & ASMA (Anti-Smooth Muscle Antibody) Titer

Immco Test Code: #154
Methodology: Indirect Immunofluorescence
AMA Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
ASMA Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255 (x2)
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: AMA occur in over 90% of primary biliary cirrhosis (PBC) cases and 3- 11% of active chronic hepatitis patients. AMA are absent in patients with extra hepatic biliary obstruction and other liver diseases. The universal presence of AMA in PBC and their virtual absence in extra hepatic jaundice makes their detection of considerable value in differential diagnosis. ASMA in high titer (≥160) occur in the majority of cases of chronic active hepatitis and in intermediate titers (40-80) in acute viral hepatitis. Occasionally they may occur in cases of primary biliary cirrhosis where they are also found in intermediate titers.

LKM (Liver Kidney Microsomal) Antibody Titer

Immco Test Code: #156
Methodology: Indirect Immunofluorescence

Substrate: Mouse Kidney/Stomach/Liver
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Autoimmune hepatitis (AIH) is a distinct chronic inflammatory liver disease characterized by the attack of the immune system directed against "self" antigens, especially those expressed in the liver. Liver kidney microsomal antibodies can be induced not only by autoimmune mechanisms, but also by drugs such as tienic acid, dihydralazine, halothane, phenytoin, phenobarbital, carbamazepine, and by Hepatitis C and D infections. AIH consists of two separate disease groups: Type 1 and Type 2. Their distinction is based on the presence of marker autoantibodies in serum of affected patients. AIH Type 1 is characterized by antinuclear antibodies (ANA) and anti-smooth muscle antibodies (ASMA). Type 1 is the more common type of AIH, accounting for 60-70% of patients with AIH. Type 2 is a somewhat rarer disease characterized by the presence of autoantibodies against microsomal antigens of liver and kidney and the absence of ANA and ASMA.

SP100 IgG ELISA

Immco Test Code: #166
Methodology: ELISA
Reference Range:

Negative	0.0 - 20.0 Units
Equivocal	20.1 - 24.9 Units
Positive	> 25 Units

CPT Code: 83516
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: SP100 antibodies have been found in approximately 25% of primary biliary cirrhosis (PBC) patients and are highly specific for PBC. In addition, SP100 antibodies are found in some patients who test negative for conventional markers of PBC such as mitochondrial antibody (AMA) and mitochondrial M2 antibody (M2). The presence of SP100 antibodies can add to the strength of diagnosis of PBC in cases where the clinical presentation and/or serological picture may be unclear.

GP (Gastric Parietal) Antibody 210 IgG ELISA

Immco Test Code: #167
Methodology: ELISA

Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-24.9
Positive: >25
CPT Code: 83516
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Serological assays are important aids to the recognition and diagnosis of PBC since many antibodies associated with PBC are present before symptoms become evident. Anti-mitochondrial antibodies (AMA), detected by indirect immunofluorescence assay (IFA), are the classic serological markers of PBC. AMA are found in up to 90-95% of PBC patients. At least 5-10% of PBC patients test negative for AMA by both IFA and ELISA assays. The failure to find AMA or other markers of PBC can contribute to the delay in the diagnosis of PBC and the possibility of additional liver damage. About 50% of sera from PBC patients contain antinuclear antibodies (ANA). One ANA specifically associated with PBC is a nuclear rim/ membranous staining, characteristic of the nuclear membrane protein gp210. This protein is part of a complex of proteins that form pores on the nuclear membrane. Anti-gp210 antibodies can be detected in approximately 25% of all PBC patients and 10-50% of AMA- negative PBC patients. Although gp210 antibodies have a relatively low sensitivity for PBC, their specificity appears to be greater than 99%. In addition, gp210 antibodies may identify a subgroup of patients with a more severe disease course. The presence of gp210 antibodies can strengthen the diagnosis of PBC in cases where the clinical presentation may be unclear.

LC-1

Immco Test Code: #169
Methodology: Indirect Immunofluorescence
Substrate: Mouse kidney/liver/stomach
Reference Range:
Negative <1:10 Units
Positive >1:10 Units
CPT Code: 86376
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Anti-liver cytosol type 1 autoantibodies have been reported in association with anti-LKM-1 autoantibodies in 30% of individuals with LKM-1 positive AIH. In 10% of cases, anti-LC-1 antibodies are the only liver-related circulating autoantibodies.

Actin IgA (F-Actin) ELISA

Immco Test Code: #172
Methodology: ELISA
Reference Range:
Negative 0.0 - 20.0 Units
Equivocal 20.1 - 24.9 Units
Positive ≥ 25 Units
CPT Codes: 86325
Schedule/Turnaround Time: Assay performed once every two weeks. Report availability is two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of IgA antibodies against F-Actin in patients having positive serologic markers for celiac disease, such as anti-endomysial, anti-transglutaminase, and/or anti- gliadin peptide IgA, correlated with more severe intestinal injury. Anti-F-Actin IgA antibodies decrease following institution of a gluten-free diet and suggest measurement of these antibodies may have a role in monitoring with gluten-free diet compliance. Positive results should be confirmed with biopsy.

PBC Profile

Immco Test Code: #185
Includes Immco Test Codes: #001 (ANA); #152 (AMA); #166 (SP 100), #167 (GP 210).
Methodology: Indirect Immunofluorescence, ELISA
Reference Range: See reference ranges for individual tests.
CPT Codes: 86038, 86255, 83516 (x2).
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

Pernicious Anemia

Gastric Parietal Cell Antibody (AGPA) Titer

Immco Test Code: #214
Methodology: Indirect Immunofluorescence
Substrate: Mouse Kidney/Stomach
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red

top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: AGPA are commonly associated with pernicious anemia and chronic atrophic gastritis where they occur in about 90% and 50% of cases, respectively. Although healthy individuals may have gastric parietal cell antibodies, this finding may reflect asymptomatic atrophic gastritis. Negative findings for gastric parietal cell antibodies provide strong evidence for excluding pernicious anemia.

ENDOCRINOLOGY AND INFERTILITY

Type 1 Diabetes

Islet Cell Antibody Titer
Immco Test Code: #215
Methodology: Indirect Immunofluorescence
Substrate: Primate Pancreas
Reference Range: Negative: <1:5
Units: Titer
Note: Positive samples at a 1:5 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86341
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Most cases of diabetes fall into two clinical categories: insulin dependent diabetes mellitus (IDDM or Type I diabetes) and non-insulin dependent diabetes mellitus (NIDDM or Type II diabetes). Prognosis, treatment and disease management are different for each type. It is well accepted that Type I diabetes is an autoimmune disease targeting ß-cells of the islets of Langerhans in the pancreas. The autoimmune response to islet cell antigens elicits antibody responses to antigens such as glutamic acid decarboxylase (GAD), ICA-512 and insulin. They have been found to be highly predictive markers, particularly if present in high titer. Detection of these ICAbs by indirect immunofluorescence on pancreas substrate is considered the gold standard for diagnosis of Type I diabetes. These cytoplasmic ICAbs are currently used for the prediction of Type I diabetes. ICAbs are detected in up to 90% of newly diagnosed diabetic patients. The level of ICAbs appears to be highest prior to the onset of Type I diabetes and diminishes progressively thereafter.

Diabetes Profile
Immco Test Code: #223
Include Immco Test Code: #143 (HLA DQ2); #144 (HLA DQ6); #145 (HLA DQ8); #215 (Islet Cell).
Methodology: Indirect immunofluorescence, ELISA, Sequence Specific Primers
Reference Range: See individual tests.
CPT Codes: See individual tests.

Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen.
For Antibody Testing: Collect 2-5 mL of blood in a red top or serum separator tube.
For Genetic Testing: Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
Sample Stability: Sample is stable at ambient temperature during shipment. Sample is stable at ambient temperature and should be analyzed within 76 hours.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection. Collect 5-10mL of uncoagulated whole blood in EDTA (purple top tubes) or in ACD (yellow top tubes).
Clinical Relevance: see individual tests.

Adrenal

Adrenal Antibody Titer

Immco Test Code: #213
Methodology: Indirect Immunofluorescence
Substrate: Primate Adrenal Gland
Reference Range: Negative: ≤1:4 and undiluted
Units: Titer
Note: Positive samples screened undiluted are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed once per week. Report availability is one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Most cases of Addison's disease are caused by the destruction of the adrenal cortex. About 70% of cases of Addison's disease are autoimmune mediated, while tuberculosis accounts for 20%. 10% are due to less common causes such as chronic infections, amyloidosis, metastatic neoplasia, and surgical removal of the adrenal gland. Major clinical manifestations of Addison's disease (anorexia, abdominal pain, wasting, apathy, weakness, fasting hypoglycemia, diminished ability to conserve sodium and excrete free water, hyponatremia, increased production of ACTH, and ß2 lipoprotein) are attributable to deficiencies of cortisol and aldosterone. The diagnosis of Addison's disease is first made by biochemical methods to detect insufficient levels of cortisol followed by testing to establish the cause. Of such testing (which includes the ACTH stimulation test, insulin induced hypoglycemia test and x-ray exams) the autoantibody test for the presence of antibodies to adrenal cortex is of prime significance as over 70% of patients with Addison's disease exhibit autoimmune etiology.
Indirect immunofluorescence on human or primate adrenal cortex provides a simple, precise, and reliable method of detecting autoantibodies in Addison's disease. Adrenal cortex antibodies (AAcAb) are present in greater than 90% of patients with recent onset autoimmune Addison's disease. AAcAb are also markers of potential Addison's disease.

Infertility

Phospholipid (Cardiolipin) Antibody IgG, IgA, IgM

Immco Test Code: #008
Methodology: ELISA
Reference Range:

IgG	Negative: <23 Positive: >23	**Units:** GPL
IgA	Negative: <22 Positive: >22	**Units:** APL
IgM	Negative: <11 Positive: >11	**Units:** MPL

CPT Code: 86147 (x3)
Schedule/Turnaround Time: Assay performed every two weeks. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of anticardiolipin antibodies helps to identify patients at risk for venous and/or arterial thrombosis often accompanied by thrombocytopenia, a syndrome referred to as antiphospholipid syndrome. This syndrome most commonly occurs in patients with systemic lupus erythematosus (SLE) or lupus-like diseases where the criteria for SLE are not fulfilled. High levels of cardiolipin antibodies also occur in fetal loss. Low levels of these antibodies are of limited significance.

Ovary Antibody Titer

Immco Test Code: #490
Methodology: Indirect Immunofluorescence
Substrate: Primate Ovary
Reference Range: Negative: <1:10
Units: Titer
CPT Code: 86255
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to steroid cell antigens have been identified in association with premature menopause, infertility and in patients with in vitro fertilization (IVF). The appearance of these antibodies often precedes onset of ovarian failure. Patients with these disorders may have autoantibodies to testicular Leydig cells, ovarian granulosa cells and placental syncytiotrophoblasts.

Spermatozoa Antibody Titer

Immco Test Code: #492

Methodology: ELISA
Reference Ranges:
Negative <60 **Units:** U/ml
Positive >60
CPT Codes: 89325
Schedule/Turnaround time: Assay performed once weekly. Report availability is within two weeks from the time of specimen receipt.
Specimen requirements: Specimen need not be refrigerated or frozen. Collect 5-10ml of blood in a red top or serum separator tube (minimum 0.5 mL). If possible, separate serum from the clot and place into orange tube provided with the Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable at refrigerated (2-8 degree centigrade) up to five days and frozen (- 20 degree centigrade) up to a year.
Clinical relevance: Antibodies directed against spermatozoa antigens may cause infertility in women or men. The application of the Spermatozoa Antibody ELISA is recommended for the study of immunologically caused disorders of fertility.
Infertility is a growing problem with which up to 20% of all couples of reproductive age are confronted temporarily or long term. In 20% of these cases the presence of spermatozoa antibodies in the male or the female patient is subject. The main cause of an immunological fertility disorder is the formation of antibodies directed against spermatozoa antigens.
Spermatozoa antibodies exert heterogeneous effects on the ability of spermatozoa to fertilize. Spermatozoa antibodies affect the motility, agglutinating processes, penetration of the spermatozoa into the cervical mucus and interaction with oocytes. The rate of pregnancies in couples with spermatozoa antibodies on the part of the man or the woman are 38% lower compared to control groups. Furthermore an influence on the implantation and on the early embryological development could be confirmed. Men having more than 50% of their spermatozoa coated with spermatozoa antibodies show a significant conspicuously reduced rate of fertility.

CARDIOLOGY

Phospholipid Antibody IgG, IgA, IgM

Immco Test Code: #008
Methodology: ELISA
Reference Range:

IgG	Negative: <23 Positive: >23	**Units:** GPL
IgA	Negative <22 Positive >22	**Units:** APL
IgM	Negative <11 Positive >11	**Units:** MPL

CPT Code: 86147 (x3)
Schedule/Turnaround Time: Assay performed every two weeks. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to

shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of cardiolipin antibodies helps to identify patients at risk for venous and/or arterial thrombosis often accompanied by thrombocytopenia, a syndrome referred to as antiphospholipid syndrome. This syndrome most commonly occurs in patients with systemic lupus erythematosus (SLE) or lupus-like diseases where the criteria for SLE are not fulfilled. High levels of cardiolipin antibodies also occur in fetal loss. Low levels of these antibodies are of limited significance.

TRANSPLANT IMMUNOLOGY

Organ Transplant Candidate
Immco Test Code: #131
Includes Immco Test Codes:
HLA antibody Screen & Typing: A, B, Bw, DR, DQ, DRw-low resolution/ABO/Pre-transplant thrombotic risk assessment.
Methodology: Sequence Specific Primers, Gel Agglutination, Luminex, ELISA
Reference Range: Varies by test.
CPT Code: 83891; 83898 (x95); 83894; 83912 (x2); 86021 (x2); 86900; 86901.
Schedule Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 2 10ml yellow top (ACD) tubes and 1 10ml red top (no anticoagulant).
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 72 hours.

Deceased Donor Evaluation
Immco Test Code: #132
Includes Immco Test Codes:
HLA Typing: A, B, Bw, Cw, DR, DQ, DRw-Low resolution/ABO/Lymphocyte crossmatch.
Methodology: Sequence Specific Primers, Gel Agglutination, Flow Cytometry
Reference Range: Varies by test.
CPT Code: 83891; 83898 (x95); 83894; 83912 (x2); 86900; 88184; 88185 (x2); 88187.
Schedule Turnaround Time: Contact laboratory before submission.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 6 10 ml yellow (ACD) tubes and 1 10ml red top (no anticoagulant).
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 24 hours.

Living Donor for Organ Transplant
Immco Test Code: #133
Includes Immco Test Codes:
HLA antibody Screen & Typing: A, B, Bw, DR, DQ, DRw-low resolution/ABO/Lymphocyte crossmatch.
Methodology: Sequence Specific Primers, Gel Agglutination, Flow Cytometry
Reference Range: Not applicable.
CPT Code: 83891; 83898 (x95); 83894; 83912 (x2); 86900; 88184; 88185 (x2); 88187.
Schedule Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Donor: 2 10ml yellow (ACD) tubes and 1 10ml red top (no anticoagulant). Recipient: 1 10ml red top tube (no anticoagulant).
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 72 hours.

Bone Marrow Transplant Candidate/Donor
Immco Test Code: #134
Includes Immco Test Codes:
HLA Typing: A, B, Bw, Cw, DR, DQ, DRw-high resolution
Methodology: Sequence Specific Primers
Reference Range: Not applicable
CPT Code: 83891; 83898 (x460); 83894 (x6); 83912 (x6).
Schedule Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 3-6 10ml lavender (EDTA) tubes.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
New York State Clients: Sample is stable at ambient temperature and should be analyzed within 76 hours.

Donor Specific Antibodies
Immco Test Code: #135
Method: Luminex
Reference Range: Donor specific antibodies present or absent.
CPT Code: 86021 (x2); 83912.
Schedule Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: 1 10ml red top tube (no anticoagulant).
Sample Stability: Sample is stable at ambient temperature.

IMMUNOGENETICS

Disease Associations

HLA DQ 2 (Diabetes)
Immco Test Code: #143
Methodology: Sequence Specific Primers
Reference Range: Reported positive or negative.
CPT Codes: 83891; 83898 (x31); 83894; 83912.
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
Clinical Relevance: Type I diabetes has a high association with DQ2 and there appears to be a link between celiac disease and early onset of male Type 1 diabetes. Recent studies indicate a combination of DQ2 and DQ8 (both acid peptide presenters) greatly increase the risk of adult onset Type 1 diabetes and ambiguous type I/II diabetes. HLA DR3 plays a prominent role in autoimmune diabetes. However, DQ2 presence with DR3 decreases the age of onset and the severity of the autoimmune disorder. DQ2 represents the second highest risk factor for celiac disease; the highest risk is a close family member with the disease. Due to its link to celiac disease, DQ2 has the highest association of any HLA serotype with autoimmune disease. Close to 95% of all celiacs have DQ2, and of this group, 30% have 2 copies of DQ2. Of the DQ2 homozygotes who eat wheat, lifelong risk is between 20 and 40% for celiac disease.

HLA DQ 6 (Diabetes)

Immco Test Code: #144
Methodology: Polymerase chain reaction (PCR) with Sequence Specific Primers
Reference Range: Reported positive or negative.
CPT Code: 83891; 83898 (x31); 83894; 83912.
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
Clinical Relevance: Insulin dependent diabetes mellitus is positively associated with DQ8, DQ2, and DQ6 (DQB1*06:04), and negatively associated with DQ6 (DQB1*06:02), DQ6 (DQB1*06:03), and DQ7 in Swedish Caucasians. The protection conferred by DQ6 (DQB1*06:02) is stronger in younger individuals and there is decrease in the effect of protection with increasing age. Three dimensional modeling of the susceptible DQ6 (DQB1*06:04) and protective DQ6 (DQB1*06:02), which share the same DQA chain (DQA1*01:02) but differ in the DQB chain at 6 residues, identifies residue 57 and 70 to be important for protection.

HLA DQ 8 (Diabetes)

Immco Test Code: #145
Methodology: Polymerase chain reaction (PCR) with Sequence Specific Primers
Reference Range: Reported positive or negative.
CPT Code: 83891; 83898 (x31); 83894; 83912.
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
Clinical Relevance: In Europe, DQ8 is associated with juvenile diabetes and celiac disease. The highest risk factor for Type 1 diabetes is the HLA DQ8/DQ2 phenotype. In parts of eastern Scandinavia both DQ2 and DQ8 are high increases frequencies of late onset Type I and ambiguous Type I/II diabetes. In the United States, however there appears to be shift in autoimmune disease risk for immigrants from Mexico. Increased immunoreactivity of Hispanics in Houston appear to be associated with DR4-DQ8. The haplotype may incur the highest risk for rheumatoid arthritis. Many disease associated with DQ8 have dual linkage with DR4, and certain DR4 (*04:05) have independent and dependent risk association with DQ8, for example with juvenile diabetes.

HLA DR 3/DR4 (AIH, Addison's, Graves' Disease)

Immco Test Code: #146
Methodology: Sequence specific primers
Reference Range: Reported positive or negative.
CPT Code: 83891; 83898 (x23); 83894; 83912.
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.

New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
Clinical Relevance: HLA DR3 and DR4 are markers for autoimmune hepatitis (AIH) and has been included in the scoring system to aid in the diagnosis and treatment. The presence of HLA DR3 and/or DR4 may not be clinically significant and should be correlated with the presence of other AIH markers (ANA, SMA, LKM-1) to aid in the diagnosis.

HLA DR 4 (Erosive Rheumatoid Arthritis)

Immco Test Code: #147
Methodology: Sequence specific primers
Reference Range: Reported positive with subtype or negative.
CPT Code: 83891; 83898 (x31); 83894; 83912.
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
Clinical Relevance: Rheumatoid Arthritis is a heterogeneous clinical syndrome. While some patients may experience a rather benign course, others experience a rapidly progressive synovitis, leading to irreversible joint damage. The presence of the HLA DR4 genetic marker serves as a risk indicator for severe forms of the disease. Because the DR4 marker is more prevalent than the disease itself, it is not a highly specific diagnostic tool. However, taking into consideration HLA DR4 subtypes, the limitation may be resolved. For example, DR4 subtypes *04:01 and *04:04 are associated with the disease whereas the *04:02 and *04:03 members of the DR4 family are not. A strong association between the DRS heterozygotes *04:01/*04:04 and juvenile rheumatoid arthritis suggests that this genetic combination predisposes an early onset of disease. Although DR4 does not predict disease, it is a useful indicator of disease progression and prognosis when other clinical factors are taken into account. For example, the presence of the DR4 marker in a patient with pre-erosive arthritis indicates the likelihood of rapid progression to erosive disease.

HLA B27 (Ankylosing Spondylitis)

Immco Test Code: #149
Methodology: Sequence Specific Primers
Reference Range: Reported positive with subtype or negative.
CPT Codes: 83891; 83898 (x31); 83894; 83912.
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.

HLA DQ 1 *5:01*, b1, *02:01*

Immco Test Code: #150
Methodology: Sequence Specific Primers
Reference Range: Reported positive with subtype or negative.
CPT Codes: 83891; 83898 (x54); 83894; 83912.
Schedule/Turnaround Time: Assay performed daily. Report availability is within 48 hours from the time of specimen receipt.

Specimen Requirements: Specimen must be kept in ambient temperature and should not be refrigerated or frozen. Collect 5 ml of blood in a lavender top Hemogard (EDTA) tube.
Sample Stability: Sample is stable at ambient temperature and should be analyzed within 76 hours.
New York State Clients: EDTA specimens should be analyzed within 48 hours of collection.
Clinical Relevance: Most frequently the genetic markers associated with celiac disease are HLADQa1*05:01 in conjunction with HLA-DQβ1*02:01. Less frequently associated genes are HLA-DQa1*03:01 in conjunction with HLA-DQβ1*03:02. Generally, the HLA-DQa1 marker should be found in conjunction with its corresponding HLA-DQβ1 marker to be considered clinically significant. The presence of these markers does not provide a definitive diagnosis of celiac disease. However, their absence strongly suggests a diagnosis other than celiac disease.

OTOLOGY

Autoimmune Hearing Loss (Sensorineural Hearing Loss)

ANA Titer and Pattern on HEp-2 & Mouse Kidney

Immco Test Code: #001
Methodology: Indirect Immunofluorescence
Substrate: HEp-2 and Mouse Kidney
Reference Range: Negative: <1:40
Units: Titer & ANA pattern reported on all positives.
Note: Positive samples at a 1:40 screening dilution are titered to 5120 at an additional charge.
CPT Code: 86038
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 2-3 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8°C) up to five days and frozen (-20°C or lower) up to one year.
Clinical Relevance: For detection of antibodies to nuclear antigens. The homogeneous pattern is primarily associated with systemic lupus erythematosus (SLE). Antibodies to centromere antigens are highly specific for calcinosis, Raynaud's phenomenon, esophageal immotility, sclerodactyly, and telangiectasia, commonly referred to as CREST syndrome, a limited form of systemic sclerosis (SSc). Centromere antibodies can also occasionally be found in low titers in some other autoimmune variants. Antinuclear antibodies with a speckled pattern are commonly associated with SLE, although they do occur in some cases of Sjögren's syndrome and mixed connective tissue disorders. ANA antibodies with a nucleolar pattern are commonly associated with systemic sclerosis (SSc), although they do occur in some cases of SLE and overlap syndromes. Overlap syndromes include dermatomyositis/polymyositis.

ANCA (Antineutrophil Cytoplasmic Antibody) Titer

Immco Test Code: #003
Methodology: Indirect Immunofluorescence
Substrate: Ethanol and Formalin Fixed Human Polymorphonuclear Leukocytes
Reference Range: Negative: <1:20
Units: Titer & ANCA pattern reported on all positives.
Note: Positive samples at a 1:20 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255.

Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The cytoplasmic ANCA (cANCA) pattern is suggestive of Wegener's granulomatosis and other systemic small vessel vasculitides such as microscopic polyarteritis/polyangitis, idiopathic crescentic and necrotizing glomerulonephritis. The perinuclear ANCA (pANCA) reaction patterns are observed in patients with systemic small vessel vasculitis but have also been described in other non-vasculitic autoimmune diseases including ulcerative colitis, Crohn's disease and chronic hepatitis.

Phospholipid Antibody IgG, IgA, IgM

Immco Test Code: #008
Methodology: ELISA
Reference Range:

IgG	Negative: <23	Units: GPL
	Positive: >23	
IgA	Negative: <22	Units: APL
	Positive: >22	
IgM	Negative: <11	Units: MPL
	Positive: >11	

CPT Code: 86147 (x3).
Schedule/Turnaround Time: Assay performed every two weeks. Report availability is within three weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The presence of cardiolipin antibodies helps to identify patients at risk for venous and/or arterial thrombosis often accompanied by thrombocytopenia, a syndrome referred to as antiphospholipid syndrome. This syndrome most commonly occurs in patients with systemic lupus erythematosus (SLE) or lupus-like diseases where the criteria for SLE are not fulfilled. High levels of cardiolipin antibodies also occur in fetal loss. Low levels of these antibodies are of limited significance.

Rheumatoid Factor (RF); IgG, IgA & IgM

Immco Test Code: #011
Methodology: ELISA
Reference Range:

IgG	Negative: <20	**Units:** EU/ml
	Borderline: 20-25	
	Positive: >25	
IgA	Negative: <20	**Units:** EU/ml
	Borderline: 20-25	
	Positive: >25	

IgM Negative: <7 **Units:** IU/ml
Borderline: 7-9
Positive: >9
CPT Code: 86431 (x3).
Schedule/Turnaround Time: Assay performed once per week. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The measurement of RF is important in the diagnosis and prognosis of rheumatoid arthritis. High levels of RF occur in sera of patients who tend to develop extra- articular complications.

Circulating Immune Complexes (CIC)

Immco Test Code: #014
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86332
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Immune complexes are present in patients with various autoimmune and other viral or infectious diseases.

Collagen Type II Antibody

Immco Test Code: #015
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 83520.
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to

shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Collagen II antibodies occur in 22% of patients with sensory neural hearing loss, 30% of patients with sudden deafness and 67% of patients with Meniere's disease.
Collagen II antibodies also occur in patients with relapsing polychondritis and in patients with rheumatoid arthritis.

68 KD (hsp-70) Antibodies by Line Blot

Immco Test Code: #340
Methodology: Line Immunoassay
Reference Range: Qualitative
CPT Code: 84182.
Schedule/Turnaround Time: Assay performed once per week. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Sensorineural hearing loss (SNHL), commonly referred to as nerve deafness, may be caused by genetic factors, acquired factors (i.e. infections) or can be immune mediated. In the majority of cases, no cause of SNHL is apparent. Such cases are referred to as idiopathic SNHL. A subgroup of idiopathic SNHL cases is treatable with immunosuppressive therapy. The laboratory studies used to identify these cases should include serum antibody tests to 68kD (hsp-70) inner ear antigen. 22% of patients with bilateral rapidly progressive SNHL have antibodies that react with the 68kD antigen. 68kD (hsp-70) antibodies also occur in approximately 60% of patients with bilateral Meniere's disease, 35% of patients with unilateral Meniere's disease and 37% of patients with contralateral delayed endolymphatic hydrops. In situations where corticosteroids are contra-indicated, methotrexate or cytoxan treatment may be prescribed.

P0 Antibodies by Western Blot

Immco Test Code: #350
Methodology: Western Blot
Reference Range: Qualitative
CPT Code: 84182.
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Antibodies to P0 at the 30kD protein occur in 46% of patients with Meniere's disease, 40% of patients with otosclerosis, 28% of patients with idiopathic progressive sensorineural hearing loss and in 18% of patients with sudden deafness. Sensorineural hearing loss (SNHL), commonly referred to as nerve deafness, may be caused by genetic factors, acquired factors (i.e. infections) or can be immune mediated. In the majority of cases, no cause of SNHL is apparent. Such cases are referred to as idiopathic SNHL. A subgroup of idiopathic SNHL cases is treatable with immunosuppressive therapy. The laboratory studies used to identify these cases should include serum antibody tests to 68kD (hsp-70) inner ear antigen

and other auto antigens such as to P0, a 30 KD antigen. Approximately 60% of patients with progressive SNHL have antibodies to P0. A strong positive correlation between chronic progressive hearing loss and the presence of P0 antibodies has been observed.

SNHL Profile I

Immco Test Code: #370
Includes Immco Test Codes: #001 (ANA); #003 (ANCA); #008 (Phospholipid); #011 (RF); #014 (CIC); #015 (Collagen Type II); #340 (68kD); #350 (P0).
Methodology: Indirect Immunofluorescence, ELISA, Western Blot, Line Immunoassay
Reference Range: See reference ranges for individual tests.
CPT Codes: 86038; 86255; 84182 (x2); 86147 (x3); 86431 (x3); 86332; 83520.
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

SNHL Profile II

Immco Test Code: #375
Includes Immco Test Codes: #340 (68kD); #350 (P0).
Methodology: Western Blot, Line Immunoassay
Reference Range: See reference ranges for individual tests.
CPT Codes: 84182 (x2).
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

VASCULITIS · NEPHROLOGY

ANCA (Antineutrophil Cytoplasmic Antibody) Titer

Immco Test Code: #003
Methodology: Indirect Immunofluorescence
Substrate: Ethanol and Formalin Fixed Human Polymorphonuclear Leukocytes.
Reference Range: Negative: <1:20
Units: Titer & ANCA pattern reported on all positives.
Note: Positive samples at a 1:20 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255
Schedule/Turnaround Time: Assay performed daily Monday-Friday. Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with

Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: The cytoplasmic ANCA (cANCA) pattern is suggestive of Wegener's granulomatosis and other systemic small vessel vasculitides such as microscopic polyarteritis/polyangitis, idiopathic crescentic and necrotizing glomerulonephritis. The perinuclear ANCA (pANCA) reaction patterns are observed in patients with systemic small vessel vasculitis but have also been described in other non-vasculitic autoimmune diseases including ulcerative colitis, Crohn's disease and chronic hepatitis.

Circulating Immune Complexes (CIC)

Immco Test Code: #014
Methodology: ELISA
Reference Range:
Negative: <20 **Units:** EU/ml
Borderline: 20-25
Positive: >25
CPT Code: 86332.
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: Immune complexes are present in patients with various autoimmune and other viral or infectious diseases.

MPO (pANCA) Antibody

Immco Test Code: #056
Methodology: ELISA
Reference Range:
Negative: <10 **Units:** IU/ml
Borderline: 10-12.5
Positive: >12.5
CPT Code: 83520
Schedule/Turnaround Time: Assay performed every two weeks. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: pANCA occurs in vasculitis, glomerulonephritis, Churg-Strauss syndrome, polyarteritis nodosa, systemic lupus erythematosus, and rheumatoid arthritis. A major antigen of pANCA is myeloperoxidase (MPO), which constitutes a potent microbicidal system within the neutrophil granulocytes. Additional target antigens such as human leukocyte elastase, and lactoferrin have also been

associated with the pANCA fluorescence pattern. Antibodies to MPO can also be induced by drugs such as hydralazine, clozapine, and L-tryptophan. Occupational exposure to environmental factors such as silica dust may provoke an anti-MPO positive progressive glomerulonephritis. Measurement of MPO specific ANCA is an important aid in the evaluation of clinical subtypes within systemic vasculitides.

PR3 (cANCA) Antibody

Immco Test Code: #057
Methodology: ELISA
Reference Range:
Negative: <10 **Units:** IU/ml
Borderline: 10-12.5
Positive: >12.5
CPT Code: 83520
Schedule/Turnaround Time: Assay performed every two weeks. Report availability is within two weeks from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) for up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: cANCA are directed against several proteins such as Cathepsin G, Elastase and Proteinase 3 (PR3). PR3, the major antigen in this group, is a neutral serine proteinase localized in the azurophilic granules of the neutrophils. Antibodies against the PR3 antigen serve as a marker for Wegener's granulomatosis (WG), a systemic necrotising vasculitides which exists in two forms, extended and limited. Extended WG is characterized by granulomatous inflammation of the respiratory tract with cANCA reactivity occurring in 90% of patients.
Limited WG is characterized without renal involvement, and cANCA reactivity is detected in 67% of patients. Disease onset can occur at any age. Men are twice as frequently affected as women. Several studies have established a direct correlation between PR3 antibody levels and the active phase of WG. The concentration of serum anti-PR3 rises dramatically during disease exacerbations (90% frequency), and relapses are usually accompanied by significant titer increases.

GBM (Glomerular Basement Membrane) Antibody Titer IgG & IgA

Test Code: #270
Methodology: Indirect Immunofluorescence
Substrate: Primate Kidney
Reference Range: Negative: <1:10
Units: Titer
Note: Positive samples at a 1:10 screening dilution are titered to an endpoint at an additional charge.
CPT Code: 86255 (x2)/Titer 86256 (x1 or x2)
Schedule/Turnaround Time: Assay performed once weekly. Report availability is within one week from the time of specimen receipt.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.

Clinical Relevance: Antibodies to GBM occur in glomerulonephritis and Goodpasture syndrome. Rapidly progressive glomerulonephritis (RPGN) is characterized by crescentic glomerulonephritis. RPGN may be classified into 3 types: 1) Immune complex mediated disease characterized by the presence of DNA antibodies or streptococcal antibodies 2) Glomerular basement membrane (GBM) mediated glomerulonephritis and Goodpasture syndrome 3) antineutrophil cytoplasmic antibody (ANCA) associated glomerulonephritis.

Nephrology Profile

Immco Test Code: #290
Includes Immco Test Codes: #003 (ANCA); #270 (GBM).
Methodology: Indirect Immunofluorescence
Reference Range: See reference ranges for individual tests.
CPT Codes: 86255 (x3).
Schedule/Turnaround Time: See individual tests for scheduling and turnaround time.
Specimen Requirements: Specimen need not be refrigerated or frozen. Collect 5-10 ml of blood in a red top or serum separator tube. If possible, separate serum from clot and place into orange tube provided with Immco Diagnostics' collection kits. If separation facilities are not available, the blood can be sent in the tube used for collection.
Sample Stability: Sample is stable at ambient temperature during shipment. If sample is stored prior to shipment, it is stable refrigerated (2-8˚C) up to five days and frozen (-20˚C or lower) up to one year.
Clinical Relevance: See individual tests.

C. BIOPSY TEST SPECIFICATIONS

To provide the clinician with a proper interpretation of immunofluorescence and histological findings, complete information should be provided on Immco Diagnostics' Test Requisition, including:
Sex
Suspected diagnosis Site(s) of biopsy Major clinical findings Treatment
Major laboratory findings
If SLE is suspected, check the American College Rheumatology Association criteria

Red capped tube: Lesional or Perilesional skin/mucosal biopsies.

Purple capped tube: Normal skin/mucosal biopsies. Note: If these tubes are unavailable, submit specimen in Zeus/Michel's fixative. Transport at room temperature.

Sample Stability: Stable in appropriate solution at room temperature for 5 days.

Biopsy Study Site Selection and Considerations

Suspected Diagnosis	Tissue	Site	Special Considerations
Pemphigus, Pemphigoid, LABD, EBA, HG, CUS	Skin or Mucosa	▪Take the first biopsy from a Perilesional area, adjacent to active or new blister ▪Take a second biopsy from an adjacent normal area at least 3 mm from a lesion	For Ocular MMP oral rather than conjunctival biopsies are suggested, when Perilesional biopsies may not be taken
Dermatitis Herpetiformis	Skin	▪Take a biopsy from the normal skin, 3-5 mm away from the active lesion	

Connective Tissue Disorders (LE, MCTD, Dermatomyositis, Scleroderma, etc.)	Skin, Mucosa	▪Take biopsy from erythematous, active border of fresh lesion. ▪For SLE, take one biopsy from Lesional and a second biopsy from non-Lesional sun protected skin	Biopsy studies should be accompanied by serum studies to help rule out systemic LE and other diseases with systemic involvement
Lichen Planus and Lichenoid Reactions	Skin, Mucosa	▪Take a biopsy from the lesion	Normal skin biopsy specimens are of limited value in this group of cases
Vasculitis	Skin	▪Take the first biopsy from erythematous, active border of a fresh lesion (<48 hrs. old) ▪Take a second normal biopsy ~10 mm from a lesion	Since the changes detected by immunofluorescence precede histologic changes, immunofluorescence studies of older lesions are of limited value
Porphyria/ Pseudoporphyria	Skin	▪Take biopsy from Lesional areas of thickened skin	Normal skin biopsy specimens are of limited value in this group of cases

D. Biopsy Site Selection

Proper biopsy sites for various tests and conditions indicated below:

a. Direct Immunofluorescence

Vesiculo-Bullous Diseases

Pemphigus, Pemphigoid, Linear IgA Bullous Dermatosis, Epidermis Bullosa Acquisita, Herpes Gestationis

Tissue: skin, mucosa

Site: Perilesional, erythematous adjacent to active or new blister. For DH, take skin biopsy 3-5 mm away from the active lesion.

b. Connective tissue disorders

Lupus Erythematosus, Mixed Connective Tissue Disease, Dermatomyositis, Scleroderma.

Tissue: skin

Site: Erythematosus or active border of new lesion. Take biopsy for SLE from lesional and non-lesional sun protected skin (e.g. buttock).

c. Lichen Planus and Lichenoid Reactions

Tissue: skin, musosa

Site: Take biopsy from a new lesion.

d. Vasculitis

Tissue: skin

Site: Take biopsy from erythematosus, active border of a fresh lesion (<48 hrs old).

e. Porphyria/Pseudoporphyria

Tissue: skin

Site: Take from a new lesion.

f. Histopathology (H&E)

g. In all cases, take biopsy from a Lesional site

DERMATOPATHOLOGY·OCULAR PATHOLOGY

Immco Test Code: #510
Routine Panel Tests for the Presence of: IgG; IgA; IgM; Fibrin; C3, C5b-9, and IgG4)
Note: If a connective tissue disease is suspected, a test for the presence of C5b9 will be added at an additional charge. If a vesiculo-bullous disease (i.e. MMP, BP, PV, LABD, and EBA) is suspected, a test for the presence of IgG4 will be added at an additional charge.
Methodology: Direct Immunofluorescence.
Reference Range: Detailed interpretation accompanies report.
CPT Code: 88346 (x5).
Turnaround Time: Report availability is within 48 hours from the time of specimen receipt.
Biopsy Site Selection: Proper biopsy sites are dependent on the suspected diagnosis. See the preceding table.

Light Microscopy (H&E)

Immco Test Code: #511
Methodology: H&E, Special Stains may be required for diagnostic purposes. These will be ordered and charged in addition to the H&E fee if necessary.
Reference Range: Not applicable. Detailed interpretation accompanies report.
CPT Code: 88305
Turnaround Time: Report availability is within 48 hours from the time of specimen receipt.
Biopsy Site Selection: Take biopsy from a Lesional site, in an area without ulceration.
Specimen Requirements: Place the incisional or excisional biopsy specimen in the green tube provided with Immco collection kits or in a tube containing 10% neutral buffered formalin.
Transport at room temperature.
Sample Stability: Stable in appropriate solution at room temperature indefinitely.

Light Microscopy Consultation

Immco Test Code: #512
Methodology: Light Microscope Analysis and Interpretation
Reference Range: Not applicable. Detailed interpretation accompanies report.
CPT Code: 88321
Turnaround Time: Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: H&E slides of skin &/or mucosa specimens submitted in a slide folder will be accepted. If applicable, please send a copy of previous report with slides. Please note that slides cannot be returned. Transport at room temperature.
Sample Stability: Stable at room temperature indefinitely.

Hereditary Epidermolysis Bullosa Classification

Immco Test Code: #513
Routine panel tests for the presence of collagen IV, cytokeratin, collagen VII and Laminin.
Methodology: Direct Immunofluorescence
Reference Range: Not applicable. Detailed interpretation accompanies report.
CPT Code: 88346 (x4)
Turnaround Time: Report availability is within one week from the time of specimen receipt.
Biopsy Site Selection: Take biopsy from a normal or induced lesion on normal skin.
Specimen Requirements: The red and purple tubes provided with Immco collection kits contain a holding

solution for immunofluorescence specimens. A biopsy from a Lesional or Perilesional site should be placed in the red tube and a biopsy from a normal site should be placed in the purple tube. If these tubes are unavailable, submit specimen in Zeus/Michel's fixative.
Transport at room temperature.
Sample Stability: Stable in appropriate solution at room temperature for 5 days.

Special Staining
Differentiation of Bullous Pemphigoid from EBA: Indicated when biopsy is positive for basement membrane zone depots.

Antigen mapping for localization of Collagen IV & Laminin
Immco Test Code: #550
Methodology: Direct Immunofluorescence
Reference Range: Not applicable. Detailed interpretation accompanies report.
CPT Code: 88346 (x2)
Turnaround Time: Report availability is within one week from the time of specimen receipt.
Biopsy Site Selection: Take biopsy from a Lesional site.
Specimen Requirements: Place the biopsy specimen in the red tube provided with Immco collection kits or in a tube containing Zeus/Michel's fixative. Transport at room temperature.
Sample Stability: Stable in appropriate solution at room temperature for 5 days.

Localization of immune deposits by "Induced in vitro Split". Only on Normal Biopsies
Immco Test Code: #551
Methodology: Direct Immunofluorescence
Reference Range: Not applicable. Detailed interpretation accompanies report.
CPT Code: 88346 (x4)
Turnaround Time: Report availability is within one week from the time of specimen receipt.
Biopsy Site Selection: Take biopsy from a normal site.
Specimen Requirements: Place the biopsy specimen in the purple tube provided with Immco collection kits or in a tube containing Zeus/Michel's fixative. Transport at room temperature.
Sample Stability: Stable in appropriate solution at room temperature for 5 days.

Oral Pathology
Immco Test Code: #510
Routine panel tests for the presence of: IgG; IgA; IgM; Fibrin; C3.
*Note: If a connective tissue disease is suspected, a test for the presence of C5b9 will be added at an additional charge
*Note: If a vesiculo-bullous disease (i.e. MMP, BP, PV, LABD, and EBA) is suspected, a test for the presence of IgG4 will be added at an additional charge
Methodology: Direct Immunofluorescence
Reference Range: Not applicable. Detailed interpretation accompanies report.
CPT Code: 88346 (x5)
Turnaround Time: Report availability is within 48 hours from the time of specimen receipt.
Biopsy Site Selection: Proper biopsy sites are dependent on the suspected diagnosis. See the following table.

Light Microscopy (H&E)
Immco Test Code: #511

Methodology: H&E, Special Stains may be required for diagnostic purposes. These will be ordered and charged in addition to the H&E fee if necessary.
Reference Range: Not applicable. Detailed interpretation accompanies report.
CPT Code: 88305
Turnaround Time: Report availability is within 48 hours from the time of specimen receipt.
Biopsy Site Selection: Take biopsy from a Lesional site, in an area without ulceration.
Specimen Requirements: Place the incisional or excisional biopsy specimen in the green tube provided with Immco collection kits or in a tube containing 10% neutral buffered formalin.
Transport at room temperature.

Light Microscopic Consultation

Immco Test Code: #512
Methodology: Light Microscope Analysis and Interpretation
Reference Range: Not applicable. Detailed interpretation accompanies report.
CPT Code: 88321
Turnaround Time: Report availability is within 48 hours from the time of specimen receipt.
Specimen Requirements: H&E slides of skin &/or mucosa specimens submitted in a slide folder will be accepted. If applicable, please send a copy of previous report with slides. Please note that slides cannot be returned. Transport at room temperature.
Sample Stability: Stable at room temperature indefinitely.