Laboratory Services



# Diagnostic Immunology Laboratory

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's immunology laboratory provides testing for an extensive list of prevalent and esoteric autoimmune diseases with 200 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, and thyroiditis, as well as autoimmune diabetes, Wegener granulomatosis and polymyositis.

As a distinguished leader in the field of oral pathlogy, Immco has been serving the needs of oral and maxillofacial surgeons, periodontists, endodontists, and dentists for 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's 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 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. Narcolepsy 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.

Immco's immunohematology refers to the detection and identification of antibodies to peripheral blood cells, in particular those reactive to blood platelets. Antibodies to foreign platelets ("alloantibodies") may result from exposures through transfusions or pregnancies. Self-destructive platelet antibodies ("autoantibodies") occur as a consequence of autoimmune disease. The antigenic targets of the alloantibodies are within both the HLA and human platelet antigen (HPA) families. Platelet autoantibodies tend to recognize biochemical variants of the HPA system. Immco Diagnostics offers comprehensive detection and identification of both.

## **Diagnostic Immunology Overview**

#### Experience

The Immco team draws upon exclusive clinical and research experience, frequently contributing to the scientific literature in the field of immunology. Members of our staff incude PhD's, DDS's and MD's, and are certified by the American Board of Oral and Maxillofacial Pathology, American Board of Dermatopathologists, 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 consultation.

#### Accreditation

Our lab 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.

#### Service

We are known for high quality and accurate reports, keen consultations and excellent customer service. Biological specimens are collected by complimentary courier or express mail service. Reports are issued with 48 hour turnaround time 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.

#### Gastroenterology • Hepatology • Allergy

Immco Diagnostics is a leader in providing precise immunoassays for the detection of autoantibodies in patients with autoimmune gastric diseases, particularly celiac disease (CD) and inflammatory bowel disease (IBD). Researchers at Immco were the first to describe the testing for endomysial antibody, a specific marker for the CD. Immco also performs human tissue transglutaminase (tTG) antibody ELISAs for the detection of IgA and IgG antibodies in the serum of patients with CD. The latest addition to the array of tests is deamidated gliadin (Celiac G+) which aids in diagnosis of IgA deficient CD patients.

Serology studies are an important adjunct in diagnosis of IBD. The combination of ANCA, ASCA and ExPA provides good discrimination between the two types of IBD, Crohn's disease and ulcerative colitis. Compared to other markers available, Immco markers are more precise, specific and cost effective. Additionally, Immco offers testing for markers of autoimmune mediated hepatic diseases, and allergy related testing is performed to complement autoimmune disease diagnosis.

- Celiac Disease Inflammatory Bowel Disease
- Autoimmune Hepatitis Pernicious Anemia Allergy

#### Neuroimmunology

Immco offers a comprehensive panel of neurology tests to aid in diagnosis of various autoimmune mediated neuropathies, paraneoplastic syndromes, psychiatric lupus and myasthenia gravis.

Gangliosides are important carbohydrate determinants for autoimmune activity.

Several studies have suggested that serum antibodies against gangliosides are responsible for some forms of acute and chronic neuropathy syndromes.



Immco is the only company in the US that has developed immunoassays to detect gangliosides. These tests are also offered by our diagnostic lab.

Paraneoplastic neurological disorders are rare debilitating neurological illnesses associated with remote effects of a malignant neoplasm (e.g., small cell lung cancer, breast and gynaecological tumors). Very often the symptoms precede the detection of the paraneoplastic tumors.

Immco offers complete screening of all the paraneoplastic neuronal antibodies with confirmation for the most common markers.

- Neuropathies Neuropsychiatric lupus
- Paraneoplastic syndromes Myasthenia gravis

#### Rheumatology

Collagen vascular disorders (CVDs) are a heterogeneous group of autoimmune diseases of unknown etiology. CVDs include systemic lupus erythematosus, rheumatoid arthritis, systemic sclerosis, dermatomyositis, polymyositis, ankylosing spondylitis, Sjögren syndrome, and mixed connective tissue disease.

Proper treatment of these conditions requires prompt and accurate diagnosis. Laboratory studies for various antibodies detected in the serum of patients with CVDs help in determining the diagnosis and the prognosis. Both serology and biopsy studies are often required for diagnosis. Immco offers both serology and biopsy studies and has a comprehensive, constantly updated expanded menu for detection of the antibodies to aid in the diagnosis of CVDs. A recent new addition is the latest generation cyclic citrullinated peptide for diagnosis of rheumatoid arthritis.

- Systemic lupus erythematosus Antibodies to
- Extractable Nuclear (ENA) & Cytoplasmic Antigens
- Systemic sclerosis Dermato/Polymyositis
- Sjögren syndrome Relapsing polychondritis
- Rheumatoid arthritis

#### Otology

Sensorineural hearing loss (SNHL) is a medical emergency for which definitive diagnosis and treatment is largely unknown. One in every 10,000 to 15,000 people will suffer from this condition. There are many potential causes of SNHL yet only 10-15% of the cases are linked to a specific cause. Autoimmune hearing loss is a subset of sudden SNHL, in which there is a sudden onset, rapidly progressing or fluctuating hearing loss that can be unilateral and that often progresses to become bilateral. Autoimmune SNHL is one of the few causes of hearing loss in which prompt detection of autoantibodies and early intervention may prevent progression of hearing loss.

Several studies have shown that anti-hsp70 (68kD) is a suitable test for diagnosis of autoimmune SNHL. The levels of anti-hsp70 antibody fluctuate with disease activity and hence the test is also useful for monitoring patient response to treatment. Immco in collaboration with the University of California, San Diego has standardized the assay for the detection of autoimmune hearing loss (Patent No. US005422282). Recent studies have shown that Immco OTOblot<sup>™</sup> is currently the best serology test available for the detection for SNHL. Other autoimmune SNHL markers include PO, phospholipids, circulating immune complexes and antinuclear antibodies.

#### • Autoimmune/Sensorineural • Hearing Loss

#### **Endocrinology** • Infertility

Autoimmune endocrine diseases, including those involving the thyroid (Graves disease, Hashimoto thyroiditis), Type I diabetes, infertility and Addison disease are among the most common endocrine disorders. These disorders often strike young people, resulting in considerable loss of productivity and long term increases in health care costs. Prompt and accurate diagnosis of these conditions is essential. Immco offers comprehensive laboratory tests to support diagnosis.



- Type I diabetes Thyroid
- Adrenal Parathyroid
- Pernicious anemia Infertility

#### Cardiology

Oxidized LDL (oxLDL) plays an important role in atherogenesis by binding to scavenger receptors, leading to unregulated accumulation of cholesterol in macrophages and formation of foam cells. Numerous studies have shown that autoantibody reactive with oxLDL is present in circulation and is a marker for coronary artery disease (CAD). There is mounting evidence linking oxLDL to accelerated atherosclerosis and CAD. This has resulted in an increased awareness among cardiologists to assess oxLDL as a useful diagnostic indicator for better therapeutic management of patients with CAD. Immco is the only company in the US that has developed the assay for detection of oxLDL. Other adjunct markers include phospholipids and heart antibodies.

• Coronary artery disease • Autoimmune carditis

#### Vesiculo Bullous Diseases

Immco has been the forerunner in developing and offering the latest -markers in the diagnosis of autoimmune diseases affecting the skin. We offer direct and indirect immunofluorescence studies in combination with the latest ELISA assays in detection of antiskin antibodies to aid in the diagnosis and prognosis of chronic vesiculo bullous skin diseases. We also utilize specialized salt-split techniques that aid in diagnosis of more challenging cases.

- Pemphigus/Pemphigoid/Epidermolysis bullosa acquisita
- Herpes gestationis
- Dermatitis herpetiformis Chronic ulcerative stomatitis
- Lichen planus/Lichenoid Reactions

#### Vasculitis • Nephrology

Antineutrophil cytoplasmic antibodies (ANCA) are serological indicators that aid in the diagnosis of various necrotizing systemic vasculitides. cANCA is primarily associated with Wegener granulomatosis and the antigen specificity of cANCA is PR3. pANCA occurs in patients with polyarteritis nodosa and Churg-Strauss syndrome. The antigen specificity of the pANCA in small vessel vasculitis is MPO. In some patients with pANCA, especially patients with IBD, the specificity of the antigen is bacterial permeability increasing factor (BPI). ANCA are detected by immunofluorescence and by ELISA. The presence of antiphospholipid (aPL) antibodies and its cofactor b2-glycoprotein I help to identify patients at risk for antiphospholipid syndrome (APS). APS may involve venous and/or arterial thrombosis, thrombocytopenia and recurrent fetal loss.

Antibodies to glomerular basement membrane (GBM) in the kidney occur in glomerulonephritis and Goodpasture disease. The GBM antibody test provides excellent sensitivity for the detection of GBM autoantibodies.

- Wegener granulomatosis Polyarteritis nodosa
- Churg-Strauss syndrome Antiphospholipid syndrome

#### **Oral Pathology Overview**

Immco has been providing specialized oral and maxillofacial pathology biopsy service for nearly 40 years. We have established an excellent reputation with medical

and dental specialists who rely on our expertise and high quality diagnostic services.

Immco specializes in diagnosis of blistering diseases affecting the mouth. Our distinguished team of oral and maxillofacial pathologists have extensive experience and are certified by the American Board of Oral and Maxillofacial Pathology. In addition, Immco offers a complete compendium of tests for oral



pathology diagnostics, including direct immunofluorescence, essential for prompt and timely diagnosis of autoimmune mediated diseases affecting the oral cavity.

We provide state of the art services including standard tissue processing and staining, special stains, immunofluorescence and immunocytochemistry. We also provide consultations and second opinions upon request. Our services are tailored to the needs of the specialist's clinical practice.



## Easy as 1, 2, 3

## **Getting started with Immco Diagnostics**

Immco is committed to exceed every client expectation with premium diagnostic services, simple test referral, prompt turnaround time, and impeccable customer care.

Immco is pleased to partner with you to meet your autoimmune and oral pathology testing needs.

### Step 1

Contact your Immco sales or customer care representative (1.800.537.8378) to request free collection kits and customized preprinted test request forms. You can also request these materials online by visiting www.Immco.com. An Immco customer care representative will work with you to set up your account. Select from a number of reporting options including HIPAA compliant and secure online reporting, fax, USPS Express, or standard US mail.

### Step 2

Forward your test specimens to us free of charge via FedEx with preprinted Immco shipping labels or by courier service.

### Step 3

Receive your report within 48 hours of sample receipt.



# For details about our products and services, please contact techsupport@immco.com.

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