Antinuclear Antibody (ANA) by IFA
The immunofluorescence ANA assay (Antibodies, Inc) utilizes the method considered the gold standard for ANA testing by the American College of Rheumatology; circulating autoantibodies reactive with nuclear antigens of HEp-2 cells are detected. Unlike multiplex or ELISA assays, the HEp-2 cell substrate provides 100-150 possible autoantigens to detect ANAs with greater sensitivity than the solid phase assays. The pattern and semiquantitative titer provide useful information for both the diagnosis and the monitoring of therapy for patients with systemic lupus erythematosus (SLE) and other connective tissue diseases such as rheumatoid arthritis (RA), scleroderma, and Sjögren’s Disease.

Selected References

Anti Neutrophil Cytoplasmic Antibody (ANCA) by direct immunofluorescence
The ANCA assay (INOVA) detects the presence of IgG antibodies that bind to human neutrophil antigens using direct immunofluorescence.¹² Screening all samples with ethanol fixed slides allows ANCA reactivity to be separated into two diagnostically useful categories. The pattern and semiquantitative titer are reported. Current research indicates that two patterns may be clinically useful:

A granular cytoplasmic pattern (cANCA) is a serologic marker in up to 96% of Wegener’s granulomatosis patients. This severe systemic vascular disease that causes irreversible injury to the kidneys and lungs presents with initial symptoms and biopsy findings that are frequently non-specific. Early diagnosis and treatment can greatly improve renal outcome. The degree of reactivity of cANCA has been found to follow the disease course so repeat testing can be important in disease management. The antigenic specificity of this pattern is primarily serine protease 3 (PR3).

A classic perinuclear pattern (pANCA) is primarily due to antibodies to myeloperoxidase (MPO) but may also be caused by others including elastase and lactoferrin. This pattern has been associated with more organ-limited vasculitis, in particular rapidly progressive glomerulonephritis. All pANCA reactions on ETOH-fixed slides are confirmed by testing on formalin slides.

ANCA antibodies have been associated with ulcerative colitis² and primary sclerosing cholangitis but the specific antigen is unknown at this time. Reactivity to other cytoplasmic and nuclear antigens may be observed. Concurrent antinuclear antibody (ANA) screening with Hep-2 cells may aid in determining the specificity of the antibodies.

Selected References

Cardiolipin Antibody
The Cardiolipin antibody (IgG) test (GenBio) is an ELISA for the quantitative detection of autoimmune antibodies to cardiolipin (aCL), a subset of antiphospholipid antibodies. This assay includes standardized cofactor beta 2 glycoprotein (b2-GP1) and phosphotydyl serine to assure measurement of both anti-cardiolipin and anti-b2-GP1 activity. Elevated levels of anti-cardiolipin have been associated with thrombosis in patients with “anti-phospholipid syndrome” and systemic lupus erythematosus (SLE).
Results are reported as GPL units.

**Double-stranded DNA (dsDNA) ELISA**
The double-stranded DNA (dsDNA) antibody test (INOVA) is an ELISA for the semi-quantitative detection of auto-antibodies to double-stranded DNA. Presence of these antibodies may be helpful in the diagnosis and monitoring of therapy for patients with systemic lupus erythematosus (SLE). Results are reported in International Units/milliliter (IU/ml). This assay has been calibrated against the Wo/80 dsDNA standard from the World Health Organization.

*Helicobacter pylori* IgG ELISA; *Helicobacter pylori* IgA ELISA
The presence of antibodies to *Helicobacter pylori* is assayed by means of a qualitative ELISA (INOVA). This assay serves as an alternative to more invasive procedures and is intended to aid in the diagnosis of *H. pylori* infections in patients with clinical signs and symptoms of gastrointestinal disease.

*Helicobacter pylori* Western blot (For Research Use Only)
Antibodies to *Helicobacter pylori*, a bacterium that colonizes the gastric mucosa and is associated with gastritis and peptic ulcers, are demonstrated qualitatively with this Western blot assay. This method provides a characterization of the immune response by detecting specific reactivity to discrete bacterial antigens. If the samples contain antibodies to *H. pylori* in sufficient quantities then specific bands will be detected. Additional studies will hopefully elucidate the diagnostic implications of the proteins.¹ Reactivity is determined by comparison to controls.

**Selected Reference**

**Lyme Disease Testing (Lyme Panel)**

*Borrelia burgdorferi* (Lyme) ELISA
Antibodies to *Borrelia burgdorferi* are detected with a semi-quantitative enzyme immunoassay (ELISA) technique. Our validated in-house assay has been in use for over 20 years and adheres to strict quality control criteria for lot-to-lot reactivity. Patient serum is diluted in an adsorbent solution that reduces the incidence of false positives.² Serum giving a positive reaction is assigned a titer based on the standard curve and assayed by Lyme Western Blot for confirmation.

*Borrelia burgdorferi* (Lyme) Western Blot
The Lyme Western Blot assay qualitatively detects antibodies to *Borrelia burgdorferi*, the etiologic agent of Lyme disease. This method provides a detailed characterization of the immune response by detecting specific reactivity to discrete borrelial antigens. Presence of IgG and IgM antibodies are detected. If the samples contained *B. burgdorferi* antibodies in sufficient quantities, then specific bands will be present. Reactivity is determined by comparison to controls.³,⁴ and ⁵.

**Selected References**
Rheumatoid factor (RF)

Rheumatoid factor is an immunoglobulin with antigenic specificity for the Fc fragment of human IgG. Detection and quantitation of RF is clinically useful due to their presence in many rheumatic and chronic inflammatory diseases. Rheumatoid arthritis usually produces the highest titers but systemic lupus erythematosus, polyarthritis and other chronic inflammatory diseases also produce significant RF. The majority of patients with juvenile rheumatoid arthritis (JRA) are RF negative. However, a positive RF may provide prognostic information in a JRA patient with polyarticular disease, as these children are more likely to develop severe chronic arthritis.

Our laboratory uses latex agglutination, one of the most widely used methods to detect RF. Serum containing RF will cause agglutination of latex particles that have been coated with human gamma globulins. Titration of positives provides semi quantitative results. Positive samples are reported as the highest titer exhibiting RF activity.

Test Orders, Sample Requirements, and Turn-around-time

Physician orders only.

Testing is performed in batch twice per week, Monday through Friday, and results are available no later than 5 days from date of sample receipt.

Contact our Immunology laboratory for specific test requirements, forms and shipping information prior to obtaining the patient blood specimen (Monday through Friday, 8:00 AM to 4:30 PM) at 302-651-6776.