

Screening ANA by IFA

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In keeping with the American College of Rheumatology's recommendation that the antinuclear antibody immunofluorescence assay (ANA IFA) is the gold standard for ANA testing, Danbury Hospital is now performing all ANA screens by ANA IFA.

ANA IFA is the preferred screening method because the HEp-2 cells used as the substrate in the ANA IFA assay have approximately 100 to 150 possible antigens (to which the human body may initiate an autoimmune response) whereas the solid phase immunoassays and Elisa assays can only detect specific autoantibodies directed against the limited number of autoantigens in the test system (typically 8-10).

Danbury Hospital uses the ImmunoConcepts HEp-2000 ANA IFA assay. In addition to detecting all of the patterns associated with the HEp-2 substrate, the ImmunoConcepts ANA IFA is unique in that the HEp-2 cells have been transfected with multiple copies of the specific DNA sequences that carry the information for the SSA/Ro autoantigen. Approximately 10 – 20% of the transfected cells over-express this antigen, so detection of auto antibodies to SSA/Ro is more consistent than it is on HEp-2 cells that have not been transfected. Autoantibodies to SSA/Ro may show a distinctive staining pattern on the transfected cells. Titers are not reported with the SSA/Ro pattern, however when this pattern is present, it is considered to be confirmatory evidence that anti-SSA/Ro antibodies are present. Absence of this distinctive pattern does not rule out the possible presence of anti-SSA/Ro antibodies.

ANA may be ordered as:

- 1) ANA IFA Screen: only the ANA IFA will be performed.
- 2) ANA IFA Reflex: an ANA IFA will be performed; if positive, ANA autoantibodies will be ordered and performed.

Questions regarding this testing can be directed to Nancy Critelli at 203-739-7424 or Dr. Leonel Edwards at 203-739-7527.

References:

American College of Rheumatology Position Statement. 01/2009.

HEp-2000 IgG Fluorescent ANA-Ro Test System package insert. Immuno Concepts, N.A Ltd., Sacramento, CA. Rev. 1.0 2007.

Coming soon: Allergy testing to be performed at Danbury Hospital Laboratory

Allergy testing using the Siemens 3gAllergy detection system on the Immulite analyzer will be performed Monday through Friday in the Core area of the laboratory. The system will utilize a 3rd generation allergen specific IgE which is validated according to the NCCLS/LA20-A guidelines. The IgE has a 0.1kU/L detection limit, 3.5 times lower than other allergen-specific IgE assays, and a functional sensitivity of 0.2kU/L. Reference ranges will be printed on reports in both Standard and Extended ranges. Comparable in sensitivity to skin testing (in vivo), this method is much easier for patients (a simple venipuncture) and will improve turnaround time for testing currently forwarded by the laboratory to a reference site.

Allergens may be ordered individually or in panels. Total IgE is performed with each allergen or panel. The *Childhood Allergy Panel* contains milk, wheat, peanut, soybean, fish-cod, egg white, cat dander, house dust mite, cockroach, dog dander and mold. The *Food Allergy Profile* contains milk, wheat, peanut, soybean, fish-cod, clam, maize (corn), scallop, shrimp, walnut, egg white. The *Upper and Lower Respiratory Panel* for the northeast part of the country includes cat dander, cockroach, common ragweed, common silver birch, dog dander, molds, elm, house dust mites, lamb's quarters, maple, oak, orchard grass, white ash. The *Nut Panel* includes almond, brazil nut, cashew, hazel nut, peanut, pecan, pine nut, pistachio and walnut and the *Venom/Insect* panel tests for honey bee, paper wasp, white faced hornet, yellow hornet, yellow jacket and cockroach. Additional allergens are available and may be ordered individually.

Questions regarding allergy testing may be directed to Dr. Leonel Edwards at 203-739-7527.

New Medicare Requirement: Physician signature required on all paper requisitions

CMS (Centers for Medicare and Medicaid) announced in December of 2010 that it would delay the final ruling scheduled to take effect on January 1, 2011, that stated a doctor's signature would be required for any *written* patient order where Medicare was to be billed. Stamped names are not acceptable. No physician signature would be required for electronic orders or for inpatients where the order is part of the patient's chart. Recently, due to confusion about what orders would require a signature, CMS delayed the implementation of this regulation, but implementation *will* occur sometime this year-possibly within the next 90 days. Please be aware that a doctor's signature will be required for any written patient order. Avoid delays in the processing of patient samples by ensuring that any written requisition that accompanies patient samples is signed by the ordering physician. Questions regarding implementation of the new rule may be directed to Client Service Representative, Sandra Smith, at 203-739-7800.

Change in hours of operation noted:

Effective February 1, 2011, the adjusted hours of operation for the Brookfield Specimen Collection Center located at the Greenknoll Professional Building, 60 Old New Milford Rd will be Monday through Friday from 7:30 AM to 4PM and Saturday, 9AM to 1PM. The satellite may be reached by calling 203-740-3838 or faxing to 203-740-3840.