Test Definition: ANA2

Antinuclear Ab, S

Overview

Useful For

Evaluating patients suspected of having a systemic rheumatic disease

Testing Algorithm

See Connective Tissue Disease Cascade (CTDC) in Special Instructions.

Special Instructions

- Connective Tissue Disease Cascade (CTDC)

Method Name

Enzyme-LinkedImmunosorbentAssay(ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

If suspicious of connective tissue disorder, see CTDC / Connective Tissue Disease Cascade, Serum.

If suspicious of autoimmune liver disease, see ALDG / Autoimmune Liver Disease Panel, Serum.

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume:0.5 mL

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-General Request (T239)

-Gastroenterology and Hepatology Client Test Request (T728)

-Renal Diagnostics Test Request (T830)

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	21 days	
	Frozen	21 days	

Clinical and Interpretive

Clinical Information

Measurement of antinuclear antibodies (ANA) in serum is the most commonly performed screening test for patients suspected of having a systemic rheumatic disease, also referred to as connective tissue disease.(1) ANA occur in patients with a variety of autoimmune diseases, both systemic and organ-specific. They are particularly common in the systemic rheumatic diseases, which include lupus erythematosus (LE), discoid LE, drug-induced LE, mixed connective tissue disease, Sjogren syndrome, scleroderma (systemic sclerosis), CREST (calcinosis, Raynaud phenomenon, esophageal dysmotility, sclerodactyly, telangiectasia) syndrome, polymyositis/dermatomyositis, and rheumatoid arthritis.(1)

The diagnosis of a systemic rheumatic disease is based primarily on the presence of compatible clinical signs and symptoms. The results of tests for autoantibodies including ANA and specific autoantibodies are ancillary. Additional diagnostic criteria include consistent histopathology or specific radiographic findings. Although individual systemic rheumatic diseases are relatively uncommon, a great many patients present with clinical findings that are compatible with a systemic rheumatic disease and large numbers of tests for ANA are ordered to eliminate the possibility of a systemic rheumatic disease.

See Connective Tissue Disease Cascade (CTDC) in Special Instructions.

Reference Values

< or =1.0 U (negative)

1.1-2.9 U (weakly positive)

3.0-5.9 U (positive)

> or =6.0 U (strongly positive)

Reference values apply to all ages.

Interpretation

A large number of healthy individuals have weakly-positive antinuclear antibody (ANA) results, many of which are likely to be clinical false-positives; therefore, second-order testing of all positive ANA yields a very low percentage of positive results to the specific nuclear antigens.

A positive ANA result at any level is consistent with the diagnosis of systemic rheumatic disease, but a result greater than or equal to 3.0 U is more strongly associated with systemic rheumatic disease than a weakly-positive result.

Positive ANA results greater than 3.0 U are associated with the presence of detectable autoantibodies to specific nuclear antigens. The nuclear antigens are associated with specific diseases (eg, anti-Scl 70 is associated with scleroderma) and can be detected with second-order testing.

Cautions

Some patients without clinical evidence of an autoimmune disease or a systemic rheumatic disease may have a detectable level of antinuclear antibody (ANA). This finding is more common in women than men, and the frequency of a detectable ANA in healthy women over 40 years old may approach 15% to 20%. ANA may also be detectable following viral illnesses, in chronic infections, or in patients treated with many different medications.

Supportive Data

In a study performed in the Mayo Clinic immunology antibody laboratory, more than 75% of patients with a systemic rheumatic disease had antinuclear antibody (ANA) results greater than 3.0 U and the positive predictive value of these results for a systemic rheumatic disease was greater than 85%. Weakly positive ANA results were not a strong indicator of systemic rheumatic disease. The likelihood of finding an autoantibody to a specific nuclear antigen on a second-order testing increased directly with the level of ANA: 92% of sera that had detectable autoantibodies on second-order testing had an ANA level greater than 3.0 U.(2)

An ANA result of greater than or =3.0 U is the cutoff for CTDC / Connective Tissue Disease Cascade, Serum, a test algorithm designed to evaluate patients with signs and symptoms consistent with connective tissue diseases and the preferred initial test for these patients.

Results of tests for ANA performed by ELISA in the immunology antibody laboratory show that ELISA and traditional indirect immunofluorescence methods for ANA are substantially equivalent.

Clinical Reference

1. Kavanaugh A, Tomar R, Reveille J, et al: Guidelines for use of the antinuclear antibody test and tests for specific autoantibodies to nuclear antigens. Pathol Lab Med 2000;124:71-81

2. Homburger HA, Cahen YD, Griffiths J, Jacob GL: Detection of antinuclear antibodies: comparative evaluation of enzyme immunoassay and indirect immunofluorescence methods. Arch Pathol Lab Med 1998;122:993-999

Performance

Method Description

The method used to detect antinuclear antibody (ANA) is enzyme-linked immunosorbent assay (ELISA). A HEp-2 lysate supplemented with various purified antigens (double-stranded deoxyribonucleic acid [dsDNA], histone, SS-A [Ro], SS-B [La] Smith, RNP, Scl-70, Jo-1, plus centromere antigen) are coated onto microtiter plate wells. A dilution of patient serum is added to the well and incubated. After washing to remove unbound serum protein, an enzyme-conjugated antihuman-IgG antibody is added to detect human IgG bound to the microtiter plate well. After incubation and washing to remove unbound conjugate, a substrate to the enzyme is added to the well. After incubation, the enzyme substrate reaction is stopped. The complete assay is measured on a spectrophotometer plate reader. The optical density measured is proportional to the antibody present in the patient serum. Testing is performed on the Agility instrument by Dynex.(Package insert: ELISA kits, Bio-Rad Laboratories, Hercules CA 07/14)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 day

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86038

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
ANA2	Antinuclear Ab, S	94875-2

Result ID	Test Result Name	Result LOINC Value
ANA2	Antinuclear Ab, S	94875-2