Overview

Useful For
Evaluating patients with signs and symptoms consistent with systemic lupus erythematosus (SLE)
Monitoring patients with documented SLE for flares in disease activity

Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
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 a General Request (T239) with the specimen.

Specimen Minimum Volume
0.35 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
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<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Icterus</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Other</td>
<td>NA</td>
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</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>21 days</td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>21 days</td>
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Clinical and Interpretive

Clinical Information

Double-stranded (ds, native) DNA (dsDNA) antibodies of the IgG class are an accepted criterion (American College of Rheumatology) for the diagnosis of systemic lupus erythematosus (SLE).(1-3) dsDNA antibodies are detectable in approximately 85% of patients with untreated SLE, and are rarely detectable in other connective tissue diseases. Weakly positive results caused by low-avidity antibodies to dsDNA are not specific for SLE and can occur in a variety of diseases.

Testing for IgG antibodies to dsDNA is indicated in patients who have a positive test for antinuclear antibodies (ANA) along with signs and symptoms that are compatible with the diagnosis of SLE. If the ANA test is negative, there is no reason to test for antibodies to dsDNA.(2)

The levels of IgG antibodies to dsDNA in serum are known to fluctuate with disease activity in lupus erythematosus, often increasing prior to an increase in inflammation and decreasing in response to therapy.(1,2)

Reference Values

<30.0 IU/mL (negative)

30.0-75.0 IU/mL (borderline)

>75.0 IU/mL (positive)

Negative is considered normal.

Reference values apply to all ages.

Interpretation

A positive test result for double-stranded DNA (dsDNA) antibodies is consistent with the diagnosis of systemic lupus erythematosus.

A reference range study conducted at the Mayo Clinic demonstrated that, within a cohort of healthy adults (n=120), no individuals between the ages of 18 and 60 (n=78) had detectable anti-dsDNA antibodies. Above the age of 60 (n=42), 11.9% of individuals (n=5) had a borderline result for dsDNA antibodies and 4.8% of individuals (n=2) had a positive result.

Cautions

Measurements of IgG antibodies to dsDNA are semiquantitative. Slight changes in the levels of these antibodies should not be relied upon to predict changes in the clinical course of patients with systemic lupus erythematosus (SLE). Clinical flares of disease in patients with SLE may not be accompanied by changes in the levels of dsDNA antibodies.

A positive result may occur in patients with diseases other than SLE. A negative result does not exclude a diagnosis of SLE.

Clinical Reference

Performance

Method Description
Microwells are precoated with calf thymus double-stranded DNA (dsDNA) antigen. The calibrators, controls, and diluted patient samples are added to the wells and autoantibodies recognizing the dsDNA antigen bind during the first incubation. After washing the wells to remove all unbound proteins, purified peroxidase-labeled goat-antihuman IgG conjugate is added. The conjugate binds to the captured human autoantibody and the excess unbound conjugate is removed by a further wash step. The bound conjugate is visualized with 3,3',5,5' tetramethylbenzidine (TMB) substrate, which gives a blue reaction product, the intensity of which is proportional to a concentration of autoantibody in the sample. Sulfuric acid is added to each well to stop the reaction. This produces a yellow end-point color, which is read at 450 nm. (Package insert: QUANTA Lite dsDNA SC ELISA, INOVA Diagnostics Inc, San Diego, CA 04/2010)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday; 4 p.m.

Analytic Time
1 day

Maximum Laboratory Time
3 days

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 or approved by the U.S. 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
# Test Definition: ADNA

DNA Double-Stranded Ab, IgG, S

## LOINC® Information

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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>ADNA</td>
<td>DNA Double-Stranded Ab, IgG, S</td>
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<table>
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