Overview

Useful For
Evaluating patients with clinical signs and symptoms compatible with systemic sclerosis including skin involvement, Raynaud phenomenon, and arthralgias

Aiding in the diagnosis of calcinosis, Raynaud phenomenon, esophageal dysfunction, sclerodactyly, and telangiectasis (CREST) syndrome

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

Special Instructions
- Connective Tissue Disease Cascade (CTDC)

Method Name
MultiplexFlowImmunoassay

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.5 mL

Specimen Minimum Volume
0.35 mL

Reject Due To
- Gross hemolysis: Reject
- Gross lipemia: Reject
- Gross icterus: OK

Specimen Stability Information

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

Clinical Information
Centromere antibodies occur primarily in patients with the calcinosis, Raynaud phenomenon, esophageal dysfunction, sclerodactyly, and telangiectasis (CREST) syndrome variant of systemic sclerosis (scleroderma). CREST syndrome is characterized by the following clinical features: calcinosis, Raynaud phenomenon, esophageal hypomotility, sclerodactyly, and telangiectasia.(1) Centromere antibodies were originally detected by their distinctive pattern of fine-speckled nuclear staining on cell substrates used in the fluorescent antinuclear antibody test.(2) In subsequent studies, centromere antibodies were found to react with several centromere proteins of 18 kDa, 80 kDa, and 140 kDa named as CENP-A, CENP-B, and CENP-C, respectively.(3) Several putative epitopes associated with these autoantigens have been described. The CENP-B antigen is believed to be the primary autoantigen and is recognized by all sera that contain centromere antibodies.

Reference Values
<1.0 U (negative)
> or =1.0 U (positive)

Reference values apply to all ages.

Interpretation
In various reported clinical studies, centromere antibodies occur in 50% to 96% of patients with calcinosis, Raynaud phenomenon, esophageal dysfunction, sclerodactyly, and telangiectasis (CREST) syndrome.

A positive test for centromere antibodies is strongly associated with CREST syndrome. The presence of detectable levels of centromere antibodies may antedate the appearance of diagnostic clinical features of CREST syndrome by several years.

Cautions
Centromere antibodies have also been described in some patients with primary biliary cirrhosis, and may occur in patients with rheumatoid arthritis or lupus erythematosus.

Clinical Reference

Performance

Method Description
Recombinant CENP-B antigen is coupled covalently to polystyrene microspheres, which are impregnated with
fluorescent dyes to create a unique fluorescent signature. Centromere antibodies, if present in diluted serum, bind to the CENP-B antigen on the microspheres. The microspheres are washed to remove extraneous serum proteins. Phycoerythrin (PE)-conjugated antihuman IgG antibody is then added to detect IgG anti-CENP-B bound to the microspheres. The microspheres are washed to remove unbound conjugate, and bound conjugate is detected by laser photometry. A primary laser reveals the fluorescent signature of each microsphere to distinguish it from microspheres that are labeled with other antigens, and a secondary laser reveals the level of PE fluorescence associated with each microsphere. Results are calculated by comparing the median fluorescence response for CENP-B microspheres to a 4-point calibration curve. (Package insert: BioPlex 2200 ANA Screen. Bio-Rad Laboratories, Hercules, CA 03/2012)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; 4 p.m.

Analytic Time

Same day/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

83516

LOINC® Information

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tr>
<td>CMA</td>
<td>Centromere Ab, IgG, S</td>
<td>31290-0</td>
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