Overview

Useful For
Evaluating patients with vasculitis, glomerulonephritis, and lymphoproliferative diseases
Evaluating patients with macroglobulinemia or myeloma in whom symptoms occur with cold exposure

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRY_S</td>
<td>Cryoglobulin, S</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>CRY_P</td>
<td>Cryofibrinogen, P</td>
<td>No</td>
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Reflex Tests

<table>
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<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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<tbody>
<tr>
<td>IMFXC</td>
<td>Immunofixation</td>
<td>No</td>
<td>No</td>
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</tbody>
</table>

Testing Algorithm
If cryoglobulin has a positive result after 1 or 7 days, then immunofixation will be performed at an additional charge. Positive cryoglobulins of 0.1 mL or above of precipitate will be typed once.

Method Name
CRY_S, CRY_P: Quantitation and Qualitative Typing Precipitation at 1 Degree C
Includes cryofibrinogen.
IMFXC: Immunofixation

NY State Available
Yes

Specimen

Specimen Type
Plasma EDTA
Serum Red

Specimen Required
Both plasma and serum are required.

Cryofibrinogen
Collection Container/Tube: Lavender top (EDTA)

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:
1. Tube must remain at 37 degrees C.

2. Centrifuge at 37 degrees C. (Do not use a refrigerated centrifuge. If absolutely necessary, ambient temperature is acceptable.) It is very important that the specimen remain at 37 degrees C until after separation of plasma from red cells.

3. Place plasma into an appropriately labeled plastic vial.

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Cryoglobulin

Collection Container/Tube: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 5 mL

Collection Instructions:
1. Tube must remain at 37 degrees C.

2. Allow blood to clot at 37 degrees C.

3. Centrifuge at 37 degrees C. (Do not use a refrigerated centrifuge. If absolutely necessary, ambient temperature is acceptable.) It is very important that the specimen remain at 37 degrees C until after separation of serum from red cells.

4. Place serum into an appropriately labeled plastic vial.

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Additional Information: Analysis cannot be performed with <3 mL of serum. Smaller volumes are insufficient to detect clinically important trace (mixed) cryoglobulins. Less than 3 mL will require draw of a new specimen.

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

--Hematopathology/Cytogenetics Test Request Form (T726)

--Benign Hematology Test Request Form (T755)

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Specimen Minimum Volume
Serum: 3 mL
Plasma: 0.5 mL

Reject Due To
Test Definition: CRGSP
Cryo Panel, S and P

Gross hemolysis | OK
Gross lipemia | OK
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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<tbody>
<tr>
<td>Plasma EDTA</td>
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<tr>
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<td>Frozen</td>
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<tr>
<td>Serum Red</td>
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<tr>
<td></td>
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Clinical and Interpretive

Clinical Information
Cryoglobulins are immunoglobulins that precipitate when cooled and dissolve when heated. Because these proteins precipitate when cooled, patients may experience symptoms when exposed to the cold. Cryoglobulins may be associated with a variety of diseases including plasma cell disorders, autoimmune diseases, and infections. Cryoglobulins may also cause erroneous results with some automated hematology instruments.

Cryoglobulins are classified as:

- Type I (monoclonal)
- Type II (mixed--2 or more immunoglobulins of which 1 is monoclonal)
- Type III (polyclonal--in which no monoclonal protein is found)

Type I cryoglobulinemia is associated with monoclonal gammopathy of undetermined significance, macroglobulinemia, or multiple myeloma.

Type II cryoglobulinemia is associated with autoimmune disorders such as vasculitis, glomerulonephritis, systemic lupus erythematosus, rheumatoid arthritis, and Sjogren's syndrome. It may be seen in infections such as hepatitis, infectious mononucleosis, cytomegalovirus, and toxoplasmosis. Type II cryoglobulinemia may also be essential, ie, occurring in the absence of underlying disease.

Type III cryoglobulinemia usually demonstrates trace levels of cryoprecipitate, may take up to 7 days to appear, and is associated with the same disease spectrum as Type II cryoglobulinemia.

A cryoprecipitate that is seen in plasma but not in serum is caused by cryofibrinogen. Cryofibrinogens are extremely rare and can be associated with vasculitis. Due to the rarity of clinically significant cryofibrinogenemia, testing for cryoglobulins is usually sufficient for investigation of cryoproteins.

Reference Values

CRYOglobulin
Negative (positives reported as percent)

If positive after 1 or 7 days, immunotyping of the cryoprecipitate is performed at an additional charge.

CRYOFIBRINOGEN
Negative
Quantitation and immunotyping will not be performed on positive cryofibrinogen.

Interpretation
An interpretive report will be provided.

Cautions
Failure to follow specimen handling instructions may cause false-negative results.

Not useful for general screening of a population without a clinical suspicion of cryoglobulinemia.

Clinical Reference

Performance

Method Description
The normal proteins of plasma and serum do not precipitate in the cold. An aliquot of plasma and of serum are incubated for 24 hours at 1 degree C. If a precipitate develops in the serum, the specimen is centrifuged and the percent precipitate is reported. Negative specimens are kept at 1 degree C for 7 days and rechecked. All positive cryoglobulins are analyzed by immunofixation to determine if the precipitate is a monoclonal protein, polyclonal protein, or a mixed cryoglobulin. Precipitates that occur in plasma and not serum are reported as positive for cryofibrinogen. Cryofibrinogen-positive specimens are not quantitated or immunotyped. Slowly forming fibrin clots (as may occur in hemophilia) are distinguished from cryoprecipitates by their inability to redissolve on warming.(Lerner AB, Watson CJ: Studies of cryoglobulins. I. Unusual purpura associated with the presence of a high concentration of cryoglobulin [cold precipitable serum globulin]. Am J Med Sci 1947;214:410-415)

PDF Report
No

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

Analytic Time
2 days

Maximum Laboratory Time
10 days

Specimen Retention Time
Negative: 7 days; Positive: until reported
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 uses a standard method. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
82585
82595
86334-Immunofixation (if appropriate)

LOINC® Information

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<td>Cryo Panel, S and P</td>
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