Overview

Useful For
Distinguishing primary from secondary membranous nephropathy

Highlights
Anti-phospholipase A2 receptor (PLA2R) antibodies are highly specific for the diagnosis of primary membranous nephropathy.

As many as 70% to 75% of patients with primary membranous nephropathy are positive for anti-PLA2R.

A titer increase, decrease, or disappearance generally precedes a change in clinical status.

Profile Information

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<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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<tbody>
<tr>
<td>SCOPE</td>
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<tr>
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<td>ELISA, S</td>
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Method Name
EURO: Enzyme-Linked Immunosorbent Assay (ELISA)

SCOPE: Indirect Immunofluorescence Assay (IFA)

NY State Available
Yes

Specimen

Specimen Type
Serum SST

Specimen Required

Collection Container/Tube: Serum gel

Specimen Volume: 1 mL

Forms
If not ordering electronically, complete, print, and send a Renal Diagnostics Test Request (T830) with the specimen.

Specimen Minimum Volume
0.5 mL
Reject Due To

<table>
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<tr>
<th>Condition</th>
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<td>Gross hemolysis</td>
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<tr>
<td>Gross lipemia</td>
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Specimen Stability Information

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<th>Time</th>
<th>Special Container</th>
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Clinical and Interpretive

Clinical Information

Membranous nephropathy (MN) is a rare disease in which immune complexes deposit at the glomerular basement membrane, causing damage to the filtration barrier, resulting in proteinuria. Recent studies have shown that in approximately 70% of patients with primary MN (pMN), the immune complexes consist of autoantibodies against the podocyte protein M-type phospholipase A2 receptor (PLA2R). There is also evidence that levels of anti-PLA2R autoantibodies correlate well with disease activity and progression. The presence of anti-PLA2R antibodies could also potentially be used to differentiate pMN from other causes of nephrotic syndrome if a biopsy is not possible. Among patients with chronic kidney disease (CKD) awaiting kidney transplantation, higher levels of anti-PLA2R could predict those more likely to recur after transplantation.

Reference Values

ELISA:

- Negative: <14 RU/mL
- Borderline: > or =14-<20 RU/mL
- Positive: > or =20 RU/mL

IFA: Negative

Interpretation

Therapy outcome can be monitored by measuring the anti-phospholipase A2 receptor (PLA2R) antibody titer. A titer increase, decrease, or disappearance generally precedes a change in clinical status. Thus, the determination of the antibody titer has a high predictive value with respect to clinical remission, relapse, or risk assessment after kidney transplantation.

Cautions

This test should not be used as a stand-alone test but an adjunct to other clinical information. A diagnosis of primary or secondary membranous nephropathy (MN) should not be made on a single test result. The clinical symptoms, results on physical examination, and laboratory tests (eg, serological tests), when appropriate, should always be taken into account when considering the diagnosis of primary versus secondary MN.
Absence of circulating anti-phospholipase A2 receptor (PLA2R) autoantibodies does not rule out a diagnosis of primary MN.

**Clinical Reference**


**Performance**

**Method Description**

**Enzyme-Linked Immunosorbent Assay (ELISA):**

The test kit provides microtiter strips each with 8 break-off reagent wells. In the case of positive samples, specific IgG antibodies (also IgA and IgM) will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled antihuman IgG (enzyme conjugate) catalyzing a color reaction. (Package insert: EUROIMMUN Anti-PLA2R ELISA [IgG] Kit, EUROIMMUN US, Morris Plains, NJ, V 9/23/2014)

**Indirect Immunofluorescence Assay (IFA):**

Diluted patient samples are incubated with combinations of substrates. If the reaction is positive, specific antibodies of classes IgA, IgG, and IgM attach to the antigens. In a second step, the attached antibodies are stained with fluorescein-labelled antihuman antibodies and made visible with a fluorescence microscope. (Package insert: EUROIMMUN Anti-PLA2R IFA Kit, EUROIMMUN US, Morris Plains, NJ, V 9/23/2014)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Monday, Wednesday, Friday

**Analytic Time**

3 days

**Maximum Laboratory Time**

7 days

**Specimen Retention Time**

7 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.
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
EURO-83520
SCOPE-86255

LOINC® Information

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