

## Overview

### Useful For

Distinguishing primary from secondary membranous nephropathy

Monitoring patients with membranous nephropathy, over time, for trends in anti-PLA2R antibody levels

### Testing Algorithm

ELISA (PA2RE) testing is always performed initially. IFA testing (PA2RI) is performed based on the ELISA results. If ELISA results are greater than or equal 2 or less than or equal to 20 the IFA testing will reflex on.

### 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.

### Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
PA2RI	Phospholipase A2 Receptor IFA, S	Yes	No

### Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

### NY State Available

Yes

## Specimen

**Specimen Type**

Serum

**Specimen Required****Collection Container/Tube:****Preferred:** Serum gel**Acceptable:** Red top**Specimen Volume:** 1 mL**Collection Instructions:**

1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged and aliquoted within 2 hours of collection.

**Forms**If not ordering electronically, complete, print, and send a [Renal Diagnostics Test Request](#) (T830) with the specimen.**Reject Due To**

Gross hemolysis    Reject

Gross lipemia      OK

**Specimen Minimum Volume**

0.5 mL

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	14 days	
	Ambient		

**Clinical & 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).(1) There is also evidence that levels of anti-PLA2R autoantibodies correlate well with disease activity and progression.(2) The presence of anti-PLA2R antibodies could also

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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.<sup>(2)</sup> Mayo Clinic Renal Lab data suggest that there is a high-concordance between the enzyme-linked immunosorbent assay (ELISA) and indirect immunofluorescence assay PLA2R results; however, the ELISA assay alone may be preferred for monitoring patients with membranous nephropathy over time for trends in anti-PLA2R antibody levels.

**Reference Values**

Negative: <14 RU/mL

Borderline: > or =14-19 RU/mL

Positive: > 19 RU/mL

**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**

1. Beck L, Bonegio R, Lambeau G, et al: M-type phospholipase A2 receptor as target antigen in idiopathic membranous nephropathy. [N Engl J Med 2009;361:11-21](#)

2. Schlumberger W, Hornig N, Lange S, et al: Differential diagnosis of membranous nephropathy with autoantibodies to phospholipase A2 receptor 1. [Autoimmun Rev 2014 Feb;13\(2\)108-113](#)

**Performance**

**Method Description**

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)

**PDF Report**

No

**Specimen Retention Time**

7 days

**Performing Laboratory Location**

Rochester

**Fees & Codes****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**

83520

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
PA2RE	Phospholipase A2 Receptor ELISA, S	73737-9

Result ID	Reporting Name	LOINC®
PA2RE	Phospholipase A2 Receptor ELISA, S	73737-9