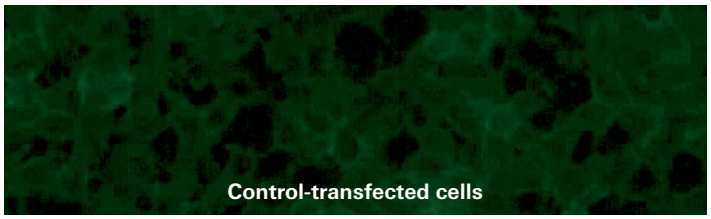
Anti-Phospholipase A2 Receptor IIFT (IgG)



- **High sensitivity and maximal specificity for primary membranous nephropathy (MN)**
- **Ideally suited for differentiation of primary and secondary MN**
- **Reliable test for qualitative and semiquantitative autoantibody determination**

Technical data

Antigen substrate	Transfected cells and control-transfected cells (EU 90)
Sample material	Serum or plasma
Sample dilution	Qualitative 1:10; semiquantitative: 1:10, 1:100, 1:1000 etc.
Reagents	Ready for use, with the exception of the PBS Tween buffer
Test procedure	30 min (sample) / 30 min (conjugate), room temperature
Microscopy	Objective: 20x, light source: EUROIMMUN LED, EUROStar Bluelight or mercury vapour lamp, 100 W Excitation filter: 450-490 nm, colour separator: 510 nm, blocking filter: 515 nm
Stability	18 months from the date of manufacture when stored at +2 °C to +8 °C
Test kit format	10 slides, each containing 3, 5 or 10 test fields
Order number	**FA 1254-####-50 G**
Related products	FC 1254-####-50 Anti-PLA2R IIFT EUROPattern (PLA2R- and control-transfected cells) FA 1254-####-1 IIFT: Membranous Nephropathy Mosaic 1 (PLA2R-, THSD7A- and control-transfected cells)

Clinical significance

Membranous nephropathy (MN) is a chronic inflammatory disease of the glomeruli which is accompanied by a progressive impairment of the kidney function. It is the most frequent cause of nephrotic syndrome in adults. MN is prevalent in all ethnic groups and genders, with men over 40 years of age and of white skin colour being more frequently affected. In young women with suspected MN, lupus nephritis should be considered. MN occurs very rarely in children. In around 20% of patients, MN is a secondary (accompanying) disease, which may result from infections, medication, drug or toxin intake, collagenosis, or other autoimmune diseases, and tumours. Secondary MN should be differentiated from primary MN (pMN). Whereas the therapy of secondary MN is based on the underlying disease, the treatment of pMN is aimed at the improvement of prognosis, especially with respect to nephrotic syndrome and hypertonia. If the origin of MN is unknown, which means it is neither autoantibody-associated nor secondary, it is called “idiopathic” (idiopathic membranous nephropathy, iMN). The underlying autoimmune mechanism of pMN is based on the production of autoantibodies against the transmembrane proteins phospholipase A2 receptor (PLA2R) and thrombospondin type-1 domain-containing 7A (THSD7A). These proteins are expressed on the podocyte surface. As a result of the binding of antibodies, the podocytes are damaged and protein enters the primary urine. While autoantibodies against PLA2R can be detected in the serum of up to 75% of pMN patients, the prevalence of anti-THSD7A varies from 2.5% to 14%, depending on the pMN cohort. In rare cases, autoantibodies against PLA2R and THSD7A may also occur together. The connection between THSD7A-positive pMN and the presence of malignant tumours is currently being researched.

Diagnostic application

The Anti-Phospholipase A2 Receptor (PLA2R) IIFT is a well-established screening test for qualitative and semiquantitative serological detection of anti-PLA2R antibodies. Autoantibodies of class IgG against PLA2R are highly specific for the detection of pMN. In healthy persons and patients with secondary MN anti-PLA2R autoantibodies are only very rarely found. Therefore, the detection of these antibodies is helpful in the differentiation of primary and secondary MN. The “IIFT: Membranous Nephropathy Mosaic 1” allows simultaneous determination of anti-PLA2R and anti-THSD7A autoantibodies, which increases the serological detection rate.

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Evaluation

Fluorescence pattern (positive reaction): Antibodies against phospholipase A2 receptor (PLA2R) react with the transfected cells of the substrate. They cause a fluorescence of the cytoplasm, partly including the cell membrane. The cell nuclei are only weakly stained.

Reference range

Titer 1:< 10 The following antibody prevalences were determined using a panel of samples from healthy blood donors (origin: Germany):

Substrate	Antibodies against	Conjugate	Prevalence	Cut-off	Number of samples
PLA2R-transfected cells	PLA2R	IgG	0%	1:10	178

Sensitivity and specificity

A total of 560 clinically characterised samples (275 from patients with primary membranous nephropathy (MN), 285 from control groups) were investigated for anti-PLA2R antibodies (IgG) in different clinical studies. Primary MN diagnosis was based on kidney biopsy. The disease was considered as idiopathic/primary when no secondary cause of MN was suspected on the basis of clinical and laboratory criteria. The samples were drawn eight weeks after biopsy, before treatment. Patients who had been or were being treated with immunosuppressive drugs at that time were excluded, as were patients with a history of medication and neoplasia. With the Anti-PLA2R IIFT using the cut-off dilution of 1:10, a sensitivity of 77.1% was found in MN, which is the expected value of approx. 75% reported in scientific literature. The specificity was 100%.

Cohort (n = 560)	n	Anti-PLA2R IIFT positive
Primary MN	275	212
Clinical sensitivity	**275**	**77.1%**
Secondary MN	68	0
Non-membranous MN	63	0
Systemic lupus erythematosus	30	0
Systemic sclerosis	30	0
Psoriasis arthritis	30	0
Rheumatoid arthritis	14	0
Thyroiditis	50	0
Clinical specificity	**285**	**100%**

Literature

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