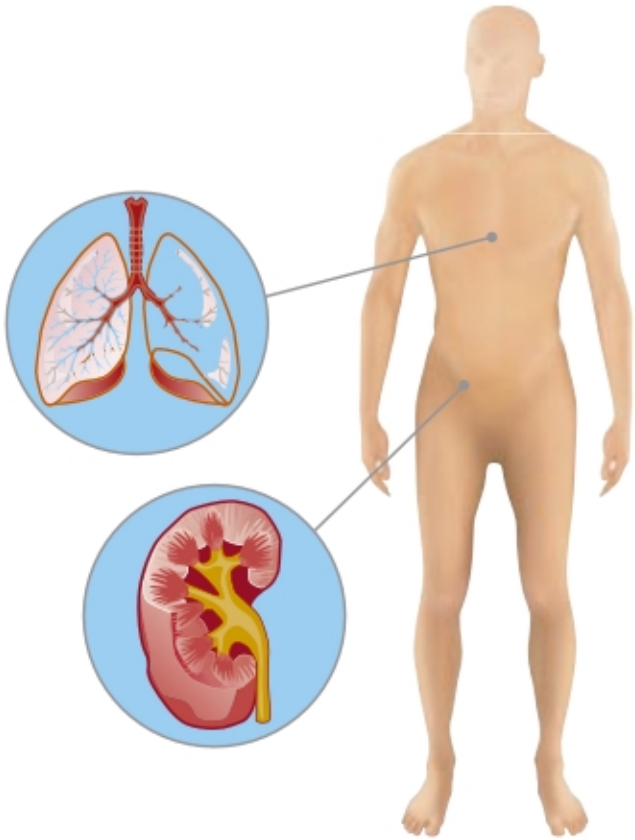
EURO-DIAGNOSTICA

Calibrated against International Standards

Wieslab® Capture PR3-ANCA ELISA and Capture MPO-ANCA ELISA

The Ultimate Serological Tool for Standardized Vasculitis Diagnosis

- Break-apart wells
- Superior sensitivity for autoimmune vasculitis
- High specificity
- Stable assay format
- Results expressed in IU/mL



Wieslab® Capture PR3-ANCA ELISA and Capture MPO-ANCA ELISA

ANCAs (anti-neutrophil cytoplasmic antibodies) are a family of autoantibodies related to vasculitis and inflammatory disorders. Since 1985, when c-ANCA was shown to be related to Wegener's granulomatosis (WG), interest in ANCAs has increased steadily, and today these antibodies are considered to be major diagnostic tools for the investigation of systemic vasculitis.

The granulocyte contains a great number of granules, each with many different proteins. It was early shown that antibodies from systemic vasculitis patients bind to the alpha fraction of the azurophil granules. The most important proteins were found to be proteinase 3 (PR3) and myeloperoxidase (MPO). PR3 is a serine protease with a molecular weight of 29kD, and MPO is a dimer with a molecular weight of 140kD. Thus antibodies to proteinase 3 are termed PR3-ANCA, and antibodies to myeloperoxidase are termed MPO-ANCA.

The first method to detect ANCA was indirect immunofluorescence (IIF) performed on ethanol fixed granulocytes. As more and more evidence indicated that vasculitis is primarily related to ANCA against PR3 or MPO a need for specific ELISA methods were required. Today, ELISAs have to a large extent replaced IIF for serological diagnosis of these diseases. The Wieslab® capture PR3-ANCA and capture MPO-ANCA ELISA kits have been shown to be superior to the traditional direct assays. In particular, the capture PR3 assay has been shown to have superior sensitivity and specificity for vasculitis. In part, these characteristics may be explained by optimal presentation of the antigen due to its complex with a specific monoclonal capture antibody. Now, Euro-Diagnostica takes a further step by introducing these revised kits calibrated against the first International PR3-ANCA and MPO-ANCA standards, respectively.

More than 80% of WG patients manifest PR3-ANCA and 5-15% MPO-ANCA. Also in microscopic polyangiitis (MP), most patients with active MP are characterized by positive ANCA test results, MPO-ANCA being more frequent than PR3-ANCA.

An international workgroup has developed an international standard for PR3-ANCA and MPO-ANCA serology. The revised Wieslab® Capture PR3-ANCA and Capture MPO-ANCA kits are standardized against the CDC International standards (PR3-ANCA code IS2721 Human Reference Serum 16, MPO-ANCA code IS2720 Human Reference Serum 15).

Assay principle

The wells of the microtitre plate are coated with purified anti-PR3 or anti-MPO monoclonal antibody in complex with its antigen, proteinase 3 and myeloperoxidase, respectively. This allows for a defined and homogeneous antigen presentation, which in turn give more consistent results and lower inter-lot variation. During the first incubation, specific antibodies in diluted serum, will bind to the antigen coating.

The wells are then washed to remove unbound antibodies and other components.

A conjugate of alkaline phosphatase-labelled antibodies to human IgG binds to the antibodies in the wells in the second incubation.

After a further washing step, detection of specific antibodies is obtained by incubation with substrate solution. The amount of bound antibodies correlates to the colour intensity and is measured in terms of absorbance (optical density (OD)). The absorbance is then calculated against a calibrator curve and the results are given in IU/mL adapted to the CDC International standard.

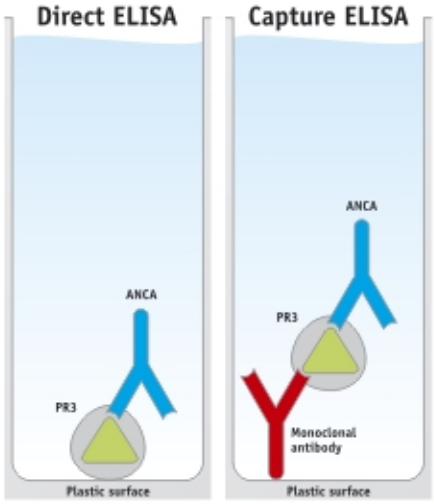
Clinical performance

Capture PR3-ANCA

	n	Neg	Equivocal	Pos
Blood donors	120	120	0	0
WG	83	3	1	79
MP	79	56	2	21
SLE	14	13	1	0
RA	14	14	0	0
Sjögren's syndrome	12	11	0	1
GBM	55	51	0	4

Capture MPO-ANCA

	n	Neg	Equivocal	Pos
Blood donors	120	120	0	0
WG	54	46	2	6
MP	79	32	1	46
GBM	55	42	4	9
SLE	14	14	0	0
RA	14	13	0	1
Sjögren's syndrome	12	12	0	0



Capture ELISA principle compared to Direct ELISA.

Technical features

- Capture ELISA format
- Calibrated against International Standards (IU)
- Alkaline phosphatase/pNPP detection system
- Read at 405 nm
- 60 + 30 + 30 minutes incubation
- Stop solution
- Colour coded reagents
- Ready-to-use reagents except wash solution

Abreviations:
WG = Wegener's granulomatosis
MP = microscopic polyangiitis
SLE = systemic lupus erythematosus
RA = rheumatoid arthritis
GBM = glomerular basement membrane

>> *Read more at www.eurodiagnostica.com*

CapPR3 IU	ELISA kit in capture format for the quantitative determination of PR3-ANCA (96 wells)
CapMPO IU	ELISA kit in capture format for the quantitative determination of MPO-ANCA (96 wells)

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