



PR3<sup>S</sup> and MPO<sup>S</sup>

**EliA**<sup>TM</sup>  
Excellence in Autoimmunity

## Detect more patients with **ANCA-associated vasculitis**

EliA PR3<sup>S</sup> and EliA MPO<sup>S</sup> – the fully automated tests with outstanding **sensitivity**

**Thermo**  
SCIENTIFIC

# EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> Outstanding performance for

**New  
technique  
for highest  
sensitivity**

## EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> – the perfect combination to help identifying ANCA-associated vasculitis

ANCA-associated diseases are caused by vasculitis of the small vessels in which antineutrophil cytoplasmic antibodies (ANCA) can be detected in the patients' blood. A rapid diagnosis of ANCA-associated small-vessel vasculitis is critically important, because life-threatening injury to organs often develops quickly and is mitigated dramatically by immunosuppressive therapy.

EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> (s = sensitivity) show greatly enhanced sensitivity, while maintaining exceptional specificity – using an anchor technique that provides better access to the antigen. As completely automated standardized tests, EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> deliver results with outstanding analytical and diagnostic accuracy combined with utmost practicality:

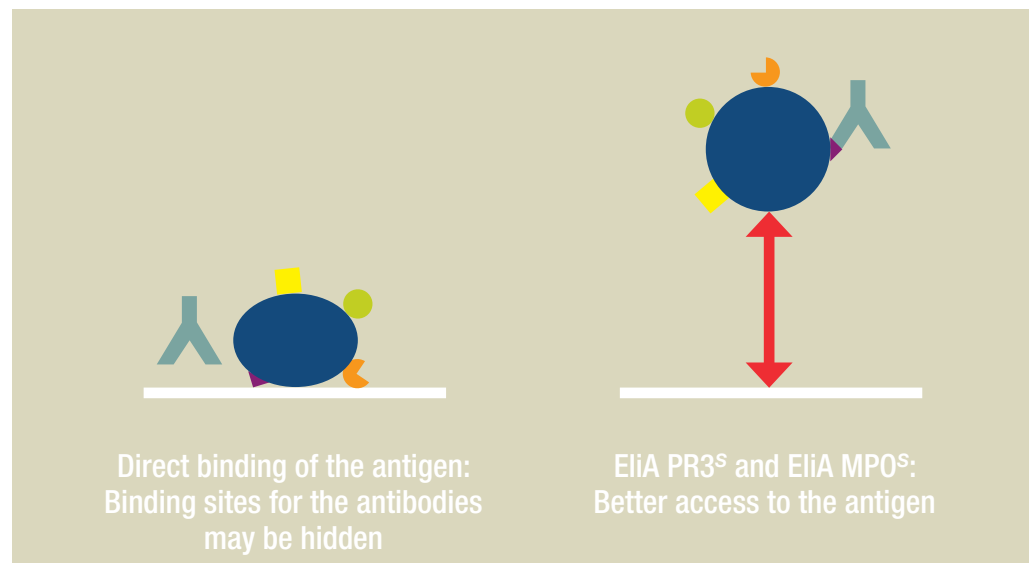


Figure 1: In both, EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup>, the antigens are bound indirectly to the EliA Well using a spacer in between well and antigen (anchor technique). This increases the sensitivity of the assays substantially, while the specificity is still exceptional.

**EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> – anchor technique leading to increased sensitivity and exceptional specificity.**

# or an even better clinical decision

## EliA PR3<sup>S</sup> and EliA MPO<sup>S</sup> – significant higher clinical value than directly coated assays

Miss fewer ANCA-associated vasculitides: EliA PR3<sup>S</sup> and EliA MPO<sup>S</sup> show dramatically increased sensitivity while keeping or – in the case of PR3<sup>S</sup> – even increasing specificity.

**High clinical usefulness in ANCA-testing**

Tests with directly coated wells:

	EliA PR3 <sup>S</sup>	EliA PR3	Competitor assay
<b>Sensitivity</b>	79.0 %	51.0 %	69.0 %
<b>Specificity</b>	98.0 %	95.3 %	76.3 %
Positive predictive value (PPV)	96.3	87.9	94.5
Negative predictive value (NPV)	87.5	74.5	82.5
Positive likelihood ratio (LR+)*	39.5	10.9	25.9
Negative likelihood ratio (LR-)*	0.21	0.51	0.32

	EliA MPO <sup>S</sup>	EliA MPO	Competitor assay
<b>Sensitivity</b>	56.5 %	35.9 %	29.4 %
<b>Specificity</b>	99.3 %	99.3 %	99.3 %
Positive predictive value (PPV)	98.1	97.1	96.4
Negative predictive value (NPV)	78.8	71.6	9.6
Positive likelihood ratio (LR+)*	84.8	53.8	44.0
Negative likelihood ratio (LR-)*	0.44	0.64	0.71

**Table 1: Performance data of EliA PR3<sup>S</sup> / MPO<sup>S</sup> and of PR3 / MPO tests with directly coated antigen (internal study – number of patients included: PR3<sup>S</sup> – 100 GPA (glomerulonephritis with polyangiitis, Wegener’s granulomatosis) and 150 disease controls; MPO<sup>S</sup> – 80 MPA (microscopic polyangiitis), 12 NCGN (necrotizing crescentic glomerulonephritis) and 150 disease controls.)**

### \* Likelihood Ratios – indicating diagnostic evidence

Likelihood ratios use the sensitivity and specificity of a test to determine if the positive or negative result of a diagnostic test changes the probability of the patient actually being afflicted with the disease.

LR+ = Sensitivity / (1 - Specificity)    LR- = (1 - Sensitivity) / Specificity

Diagnostic evidence:

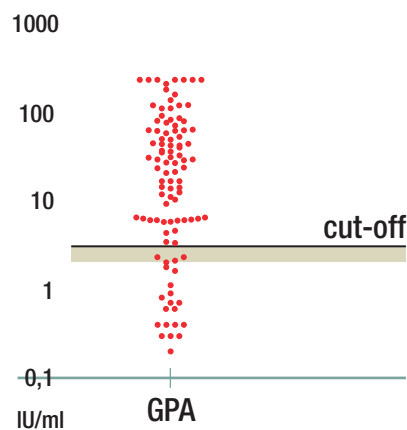
LR+ 0 - 2 none	LR- > 0.5 none
LR+ 2 - 5 weak	LR- 0.2 - 0.5 weak
LR+ 5 - 10 mod.	LR- 0.1 - 0.2 mod.
LR+ > 10 high	LR- < 0.1 high

# EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> Outstanding results for val

**Highly sensitive:  
Find more patients  
with ANCA-  
associated  
vasculitis**

## EliA PR3<sup>s</sup>: Detect more patients with GPA

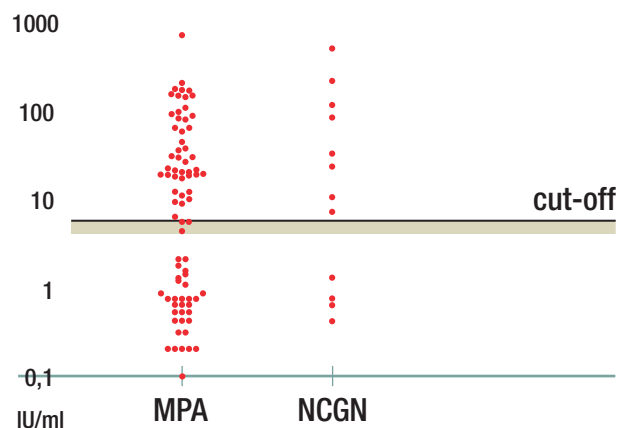
- 79 % of patients with GPA are clearly positive.\*



**GPA** glomerulonephritis with polyangiitis, Wegener's granulomatosis  
**MPA** microscopic polyangiitis  
**NCGN** necrotizing crescentic glomerulonephritis  
**NAAV** non-ANCA-associated vasculitis  
**CD** Crohn's disease  
**UC** ulcerative colitis  
**CTD** connective tissue diseases

## EliA MPO<sup>s</sup>: Detect more patients with MPA and NCGN

- 55 % of patients with MPA and 66 % of patients with NCGN are clearly positive in EliA MPO<sup>s</sup> (in total 56.5% positivity).\*

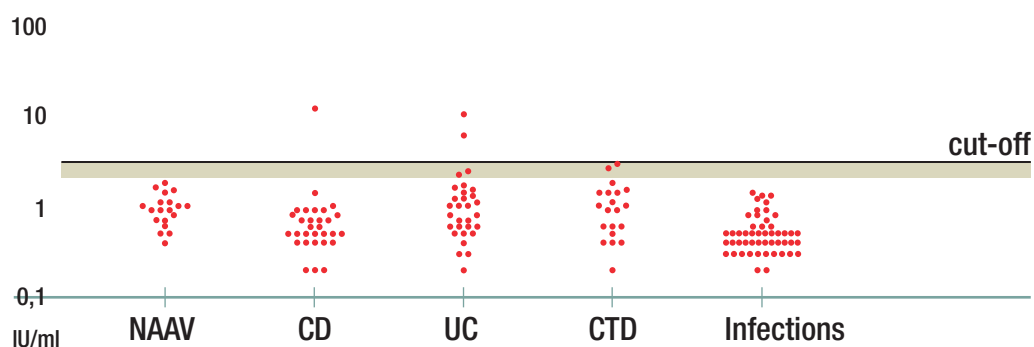


**EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> offer excellent diagnostic support.**

# uable diagnostic guidance

## EliA PR3<sup>S</sup>: Less false positives in control panels

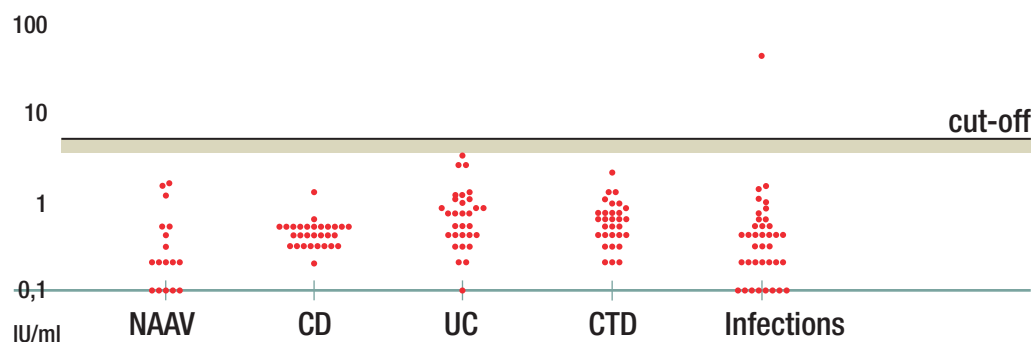
- 98 % of control patients are correctly negative.\*
- EliA PR3<sup>S</sup> showed only three false positives in inflammatory bowel diseases, which are known to be anti-PR3-positive in some cases.



**Highly specific:  
Reduce false positives to the max**

## EliA MPO<sup>S</sup>: Exceptional specificity

- > 99 % of controls are correctly negative.\*
- EliA MPO<sup>S</sup> was positive in only one control, a patient with Epstein-Barr virus. This serum was also positive in other anti-MPO tests and showed a typical p-ANCA pattern on granulocytes.



### Standardized tests:

EliA PR3<sup>S</sup> and EliA MPO<sup>S</sup> fulfill international standardization requirements:

- Calibrated against CDC reference sera #16 and #15
- Quantitative results are given in International Units

\* Internal study – for number of patients included, see Table 1

# EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> Outstanding efficiency for i

**Ensure  
operational  
excellence –  
every day**



## **Increase efficiency and optimize workflow through fully automated Phadia® Laboratory Systems**

Serum and plasma samples are processed automatically by the Phadia Laboratory Systems (Phadia 100 / 250 / 2500 / 5000) leading to a reduced workload for the lab personnel. Minimize your operational costs, simplify your planning and optimize the workflow in your lab.

## **Improve the service for your customers through fast delivery of results**

Even small sample series can be run cost-efficiently because of the monthly stored IgG standard curve. Results of urgent samples can be run with the STAT function in short time.

## **Consolidate different tests through a comprehensive panel of automated allergy and autoimmunity tests**

EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> can easily be performed from the same sample in one run and even simultaneously with other markers of interest such as GBM antibodies or antinuclear antibodies.

**EliA PR3<sup>s</sup> and EliA MPO<sup>s</sup> – fully automated,  
fast and cost-efficient testing.**

# Improved lab procedures

## Your advantages in routine testing with EliA PR3<sup>S</sup> and EliA MPO<sup>S</sup>:

**For the laboratory** Improved efficiency with more reliable results – benefitting both clinicians and patients.

**For the doctor** Increased confidence in management of patients with ANCA-associated vasculitis. Greater ease of differentiation between life-threatening ANCA-associated vasculitis and other renal diseases or other ANCA-positive non-vasculitic diseases.

**For the patient** Improved quality of life due to quicker diagnosis and therefore faster treatment.

**For the healthcare system** Clear results first time which reduces the need for re-testing, enabling earlier diagnosis and cost-effective treatment for patients.

**Literature:** 1. Wiik AS. Autoantibodies in ANCA-associated Vasculitis. *Rheum Dis Clin North Am* 2010;36:479. 2. Csernok E, Lamprecht P, Gross WL. Diagnostic significance of ANCA in Vasculitis. *Nature Clin Pract Rheumatol* 2006;2(4):174-175. 3. Westman KW, Selga D, Isberg PE, et al. High proteinase 3-anti-neutrophil cytoplasmic antibody (ANCA) level measured by the capture enzyme-linked immunosorbent assay method is associated with decreased patient survival in ANCA-associated vasculitis with renal involvement. *J Am Soc Nephrol* 2003;14:2926-2933.

EliA PR3<sup>S</sup> and EliA MPO<sup>S</sup> – leave routine to the instrument and ensure outstanding efficiency!

# EliA PR3<sup>S</sup> and EliA MPO<sup>S</sup>: technical data

EliA PR3<sup>S</sup> and EliA MPO<sup>S</sup> on one instrument in the same run from one sample tube.

<b>Antigens</b>	proteinase 3 and myeloperoxidase, both purified from human granulocytes			
<b>Dilution</b>	EliA PR3 <sup>S</sup> : 1:100 (automated) EliA MPO <sup>S</sup> : 1:50 (automated)			
<b>Sample material</b>	Serum, Plasma (EDTA, citrate, heparin)			
<b>Standardization</b>	Six point standard curve for IgG. IgG Calibrators are traceable to the International Reference Preparation 67/86 of Human Serum IgA, IgG and IgM from WHO. EliA PR3 <sup>S</sup> is calibrated against the CDC PR3-ANCA Human Reference Serum #16; EliA MPO <sup>S</sup> against the CDC MPO-ANCA Human Reference Serum #15 (international standards, results in IU/ml).			
<b>Cut-off / measuring range</b>	negative	equivocal	positive	measuring range
EliA PR3 <sup>S</sup> :	< 2.0 IU/ml	2.0 – 3.0 IU/ml	> 3.0 IU/ml	0.2 – 177 IU/ml
EliA MPO <sup>S</sup> :	< 3.5 IU/ml	3.5 – 5.0 IU/ml	> 5.0 IU/ml	0.2 – 134 IU/ml
<b>Normal distribution</b> (Mean / 95 % / 99 % percentile)	EliA PR3 <sup>S</sup> : 0.3 IU/ml / 0.6 IU/ml / 0.7 IU/ml EliA MPO <sup>S</sup> : 0.6 IU/ml / 0.9 IU/ml / 1.5 IU/ml			
<b>Reproducibility</b>	EliA PR3 <sup>S</sup> : Intra-run CV* 3.9 – 10.5 %		Inter-run CV* 0.0 – 7.0 %	
	EliA MPO <sup>S</sup> : Intra-run CV* 2.5 – 6.1 %		Inter-run CV* 1.9 – 4.9 % *for details see directions for use	
<b>Ordering information</b>	<b>Package size</b>	<b>Article No.</b>		
EliA PR3 <sup>S</sup> Well	4 x 12 determinations	14-5536-01		
EliA MPO <sup>S</sup> Well	4 x 12 determinations	14-5537-01		
<b>EliA Controls</b>				
EliA ANCA/GBM Positive Control 100	6 vials for single use			83-1039-01
EliA ANCA/GBM Positive Control 250	6 vials for single use			83-1034-01
EliA ANCA/GBM Positive Control 2500/5000	6 vials for single use			83-1075-01
EliA IgG/IgM/IgA Negative Control 100	6 vials for single use			83-1042-01
EliA IgG/IgM/IgA Negative Control 250	6 vials for single use			83-1037-01
EliA IgG/IgM/IgA Negative Control 2500/5000	6 vials for single use			83-1074-01

For EliA specific reagents and general reagents please refer to the Product Catalog Allergy & Autoimmunity



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