Vasculitis

Detect more patients with ANCA-associated vasculitis

EliA™ PR3^{s} and EliA™ MPO^{s} – fully automated, high-sensitivity tests

ANCA-associated diseases are caused by vasculitis of the small vessels in which antineutrophil cytoplasmic antibodies (ANCA) can be detected in a patient's blood.[1,2] A rapid diagnosis of ANCA-associated small-vessel vasculitis is critically important because life-threatening injury to organs often develops quickly and can be rapidly mitigated by immunosuppressive therapy.[2]

The group of antineutrophil cytoplasmic autoantibody ANCA-associated vasculitides (AAVs) comprises microscopic polyangiitis (MPA), granulomatosis with polyangiitis (GPA), and eosinophilic granulomatosis with polyangiitis (EGPA).[3]

All of these diseases show features of vasculitis of the small vessels, but otherwise affect various different target organs with varying ANCA positivity.[3] During the active stage of the disease, ANCAs against myeloperoxidase (MPO) and/or proteinase 3 (PR3) can be detected in MPA and GPA patients.[2,3] Among patients with EGPA, less than 50% have ANCAs; the presence of ANCAs is associated with the typical manifestations of small vessel vasculitis, such as glomerulonephritis.[1,3] Taking the concentrations of antibodies into account improves clinical interpretation.[5] Literature suggests the potential to use ANCAs for the monitoring of relapse and remission states of already-diagnosed patients.[6,7]

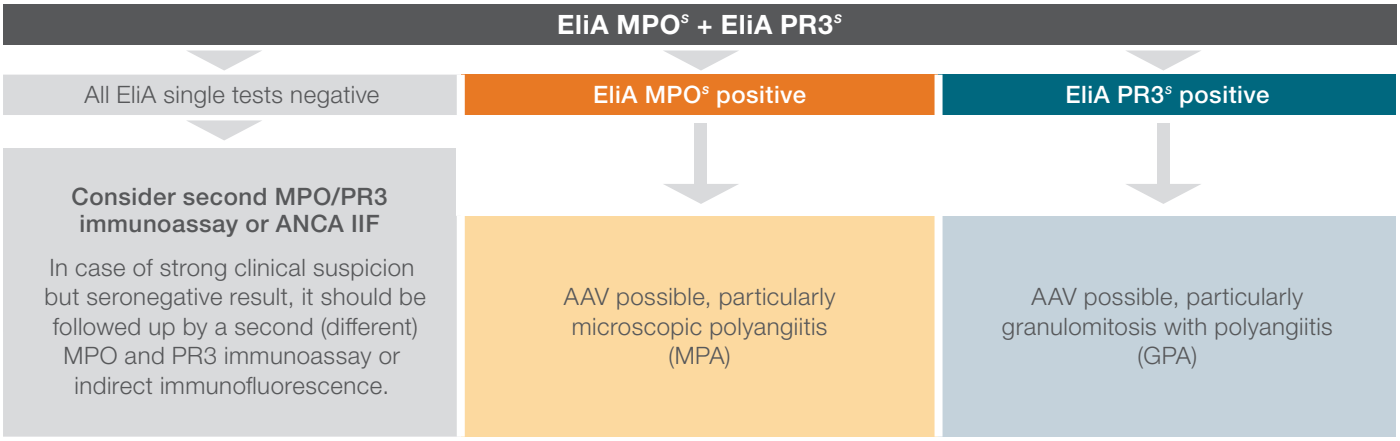

Figure 1. Gating strategy for EliA MPO^{s} and EliA PR3^{s}.[8]

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Gating strategy

The 2017 international consensus on ANCA diagnostics for AAV recommends that in the case of suspected GPA or MPA, anti-MPO and anti-PR3 antibodies should be determined using highly specific immunoassays.[8]

This guidance replaces the previous recommendation to perform a primary screening using indirect immunofluorescence (IIF).[8,9] Adherence to a strict gating strategy based on the clinical manifestations presented is critical here, as this strongly reduces the number of unnecessary ANCA test requests and improves the positive predictive value.[8]

In 2022, the new ACR/EULAR classification criteria for AAVs have been released which, based on the DCVAS study panel, provide a scoring system for anti-MPO and anti-PR3 test results. They suggest a positive / negative scoring of parameters in the classification of GPA, MPA, and EGPA.[11-13]

Table 1. Granulomatosis with polyangiitis (GPA).
Based on n=724 GPA patients and n=813 controls

Positive test result	Classification score*
anti-MPO antibodies	–1
anti-PR3 antibodies	+5

Table 2. Granulomatosis with microscopic polyangiitis (MPA).
Based on n=291 MPA patients and n=822 controls

Positive test result	Classification score*
anti-MPO antibodies	+6
anti-PR3 antibodies	–1

Table 3. Eosinophilic granulomatosis with polyangiitis (EGPA).
Based on n=226 EGPA patients and n=887 controls

Positive test result	Classification score*
anti-PR3 antibodies	–3

*These classification criteria and attributed scoring always need to be taken in concordance with the clinical manifestations and further biopsy criteria mentioned in the classification guidelines. These classification criteria should not be used as diagnostic criteria. The sum of the scoring points including other criteria must be >= 5 for GPA and MPA and >=6 for EGPA classification.[11-13]

EliA PR3^{s} and EliA MPO^{s} – fully automated, fast, cost-efficient testing

Clinical data

The EliA™ PR3^{s} and EliA™ MPO^{s} immunoassays display an enhanced sensitivity while maintaining high specificity by utilizing an anchor technique that provides enhanced access to the antigen in the second generation of capture ELISA,[2] versus conventional first generation direct ELISA tests.[4] As completely automated, standardized tests, EliA PR3^{s} and EliA MPO^{s} deliver results with reliable analytical and diagnostic accuracy (Table 4 and Table 5).[14]

Table 4. Performance characteristics of EliA MPO^{s} test in comparison with competitor ELISA-based methods. Based on n=80 MPA patients and n=142 controls, a Thermo Fisher Scientific internal study.[14] LR+ = positive likelihood ratio. LR- = negative likelihood ratio.

	EliA MPO^{s}	Competitor W	Competitor E
Sensitivity (%)	**55.00**	**23.80**	**53.80**
Specificity (%)	**99.30**	**100.00**	**97.90**
LR+	78.10	-	25.40
LR-	0.45	0.77	0.47

Table 5. Performance characteristics of EliA PR3^{s} test in comparison with competitor ELISA-based methods. Based on n=100 GPA patients and n=150 controls, a Thermo Fisher Scientific internal study.[14] LR+ = positive likelihood ratio. LR- = negative likelihood ratio.

	EliA PR3^{s}	Competitor W	Competitor E
Sensitivity (%)	**79.00**	**71.00**	**74.00**
Specificity (%)	**98.00**	**97.30**	**94.00**
LR+	39.50	26.63	12.33
LR-	0.21	0.30	0.28

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Advantages of routine testing with EliA PR3^{S} and EliA MPO^{S}

For the laboratory

- Improved efficiency with reliable results benefitting both clinicians and patients.[2]

For the healthcare system

- Clear results the first time, reducing the need for re-testing and enabling earlier diagnoses and more cost-effective treatments for patients.

For the clinician

- Increased confidence in management of patients with ANCA-associated vasculitis.
- Greater ease of differentiation between 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 faster treatment.

Technical and ordering information

			Interpretation of test results		
Product	**Article No.**	**Package size**	**Negative**	**Equivocal**	**Positive**
EliA™ PR3^{s} Well	14-5536-01	4 x 12 wells	< 2.0 IU/mL	2.0–3.0 IU/mL	> 3.0 IU/mL
EliA™ MPO^{s} Well	14-5537-01	4 x 12 wells	< 3.5 IU/mL	3.5–5.0 IU/mL	> 5.0 IU/mL
EliA™ ANCA/GBM Positive Control 200	83-1149-01	6 vials x 2 results	n.a.	n.a.	n.a.
EliA™ ANCA/GBM Positive Control 250	83-1034-01	6 vials x 2 results	n.a.	n.a.	n.a.
EliA™ ANCA/GBM Positive Control 2500/5000	83-1075-01	6 vials x 2 results	n.a.	n.a.	n.a.

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