

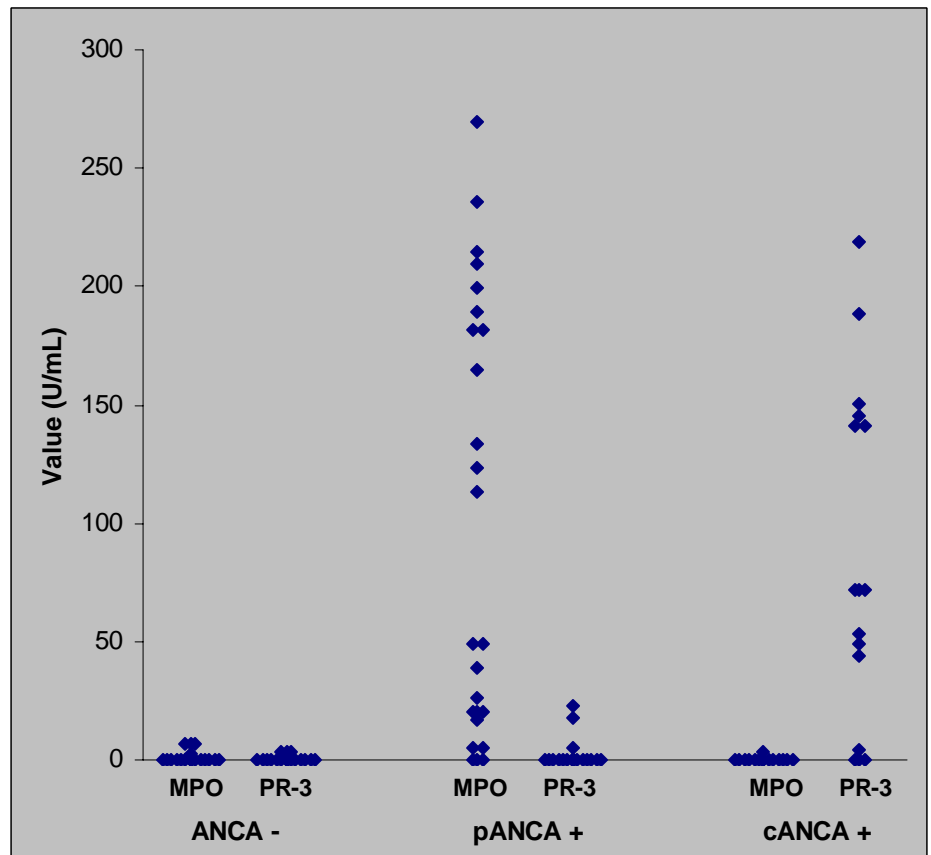
The REAADS Anti-MPO and Anti-PR-3 Test Kits are semi-quantitative enzyme-linked immunosorbent assays (ELISA) for the detection of IgG anti-myeloperoxidase (MPO) and anti-proteinase III (PR-3) antibodies in human serum. The REAADS Anti-MPO and Anti-PR-3 Test Kits are intended for in vitro diagnostic use as an aid in the diagnosis of certain systemic vasculitides such as microscopic polyarteritis, crescentic glomerulonephritis and Wegener's granulomatosis.



- Detects anti-MPO and anti-PR-3 IgG antibodies in human serum using native purified proteins
- MPO and PR-3 are the major target antigen for anti-perinuclear and anti-cytoplasmic antineutrophil cytoplasmic antibodies (pANCA and cANCA) respectively
- Results are reported in semi-quantitative units (U/mL)
- Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time

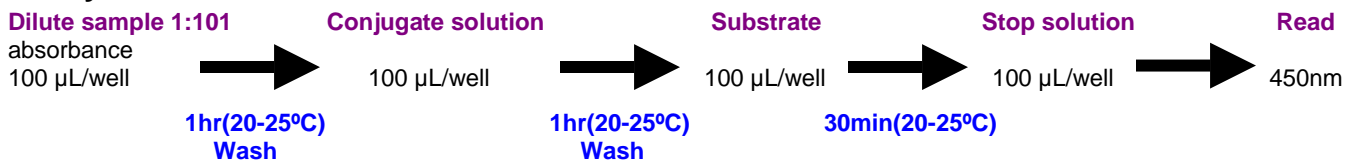
### Clinical Specificity and Sensitivity

Serum samples from 63 patients with various systemic vasculitis diseases were tested to determine clinical specificity and sensitivity of the REAADS Anti-MPO and PR-3 Test Kits. All samples were first tested by IIF method for the presence of pANCA or cANCA antibodies. Since MPO is the major antigen target for pANCA antibodies and PR-3 is the major target antigen for cANCA antibodies, it was anticipated that the results of the ELISA testing would correlate with the respective IIF pattern. 22 of the vasculitis patients were negative by IIF and both ELISA assays. 25 patients resulted positive by IIF for a pANCA pattern, where 64% were also positive for anti-MPO by ELISA. 16 patients were positive for a cANCA pattern by IIF, and 75% of these samples also tested positive for anti-PR-3 by ELISA. None of the pANCA positive samples were positive for anti-PR-3 or the cANCA positives for anti-MPO antibodies. Results are presented in the graph.



In 1982 Davis et al. described the presence of antineutrophil cytoplasmic antibodies (ANCA) in serum of patients with necrotising glomerulonephritis. The use of indirect immunofluorescence (IIF) identified two distinct pattern types described in 1988 by Falk et al, pANCA (perinuclear) and cANCA (cytoplasmic), in renal patients with systemic vasculitis. The major pANCA target antigen is myeloperoxidase and the major cANCA target antigen is proteinase III (PR-3). Several other antigens (lactoferrin, elastase, cathepsin G) are associated with ANCA reactivity to lesser degrees. Although the use of an ELISA can identify the presence of antibodies specific for MPO and PR-3, it is still recommended to use an IIF method for patient screening. Testing positive IIF samples by ELISA can provide useful additional information. ELISA assays that identify the presence of anti-MPO and anti-PR-3 antibodies can be used not only to confirm IIF positive patterns, but also distinguish specific systemic vasculitides. Anti-PR-3 antibodies are detected in the majority of active Wegener's granulomatosis patients. These same patients only occasionally tested positive for the anti-MPO antibodies. Diseases such as microscopic polyarteritis and crescentic glomerulonephritis are more likely associated with the presence of anti-MPO antibodies.

### Assay Procedure



### Correlation with Indirect Immunofluorescence (IIF) method

A comparison analysis was performed on 94 systemic vasculitis patient samples with the REAADS Anti-MPO and Anti-PR-3 Test Kits against an IIF method resulting in a 95% relative agreement. Of the 55 samples that were positive by both methods, 27 were anti-MPO/p-ANCA positive and 27 were anti-PR-3/cANCA positive. Ten samples that pANCA and 4 that were cANCA positive by IIF resulted negative on the ELISA assays. Two samples were anti-MPO positive and negative by IIF.

ELISA vs. IIF Correlation		IIF method	
		Positive	Negative
REAADS	Positive	54	2
	Negative	14	24

### Kit Contents

96 antigen coated microwells in frame	12 x 8 strips
Calibrator-1 (0 U/mL) (ready to use)	1.5 mL
Calibrator-2 (100 U/mL) (ready to use)	1.5 mL
Positive Control	0.2 mL
Negative Control	0.2 mL
Conjugate Reagent (IgG)	15 mL
Assay Diluent	50 mL
Wash Concentrate (10x)	100 mL
Substrate (ready to use)	20 mL
Stop Solution (ready to use)	20 mL



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### REAADS Anti-MPO and Anti-PR-3 Test Kit

Product # Anti-MPO 10886  
 Anti-PR-3 10881

Quantity: 96 tests  
 Storage: 2-8°C  
 Stability: 15 months