

Bio-Rad Laboratories
The Clear Choice in Autoimmune Testing



Anti-PR3 (c-ANCA)

Autoimmune EIA

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Simple, Objective, Sensitive, Specific

Bio-Rad offers the most comprehensive menu of EIA assays available today, with a constantly expanding menu that includes new clinically relevant assays.

The Bio-Rad Kallestad™ Anti-Proteinase 3 (anti-PR3) test is a semi-quantitative/qualitative enzyme-linked immunosorbent assay (ELISA) for the detection of autoantibodies specific for proteinase 3 antigen in human serum or plasma. It is intended to aid in the diagnosis of Wegener's granulomatosis and other conditions associated with raised anti-neutrophil cytoplasmic antibodies (ANCA). Autoantibody levels represent one parameter in a multicriterion diagnostic process.

Product Highlights

- Common assay protocol and reagents
- Color-coded breakaway wells
- Semi-quantitative and qualitative result interpretations
- Easy-to-automate



Clinical Utility

The systemic vasculitides are inflammatory diseases of blood vessels and comprise a heterogeneous group of disorders, the causes of which are generally unknown. The diseases have diverse presentations, and are often rapidly progressive, causing irreversible damage to kidney and lung blood vessels. Davies¹ first observed anti-neutrophil cytoplasmic antibodies (ANCA) in vasculitis patients in 1982. ANCA are autoantibodies specific for proteins located in the primary and secondary granules of neutrophils and in the peroxidase-positive lysosomes of peripheral blood monocytes. They were originally detected by indirect immunofluorescence on ethanol-fixed neutrophils, producing characteristic staining patterns with accentuation of the fluorescent activity within the nuclear lobes. Two major patterns of immunofluorescent staining have been observed: a classical or cytoplasmic staining designated c-ANCA, and a perinuclear pattern designated

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Anti-Proteinase 3 (PR3/c-ANCA)

p-ANCA which was described in association with renal systemic vasculitis.² Other staining patterns have been described and are generally noted as atypical or snowdrift patterns.^{3,4} The nature of the antigens and clinical significance of the antibodies responsible for these atypical fluorescent patterns is currently unclear.

The association between ANCA and Wegener's granulomatosis (WG), a systemic necrotising vasculitis was formally described by Woude in 1985, and confirmed by other workers.^{5,6} The target autoantigen associated with c-ANCA was identified in 1990 as proteinase 3,⁷ a 29kD neutrophil serine protease of azurophil granules, previously characterized by Kao.⁸ Proteinase 3 has been confirmed as the major autoantigen in WG.^{9,10}

The presence of c-ANCA denotes a spectrum of disease varying from idiopathic pauci-immune necrotising glomerulonephritis to extended WG. Extended WG is characterized by granulomatous inflammation of the respiratory tract, systemic vasculitis and necrotising crescentic glomerulonephritis; c-ANCA are present in over 90% of WG patients.¹¹⁻¹³ It is also detected in 67-86% of patients with so-called limited WG without renal involvement, and in 40-50% of patients with pauciimmune necrotising glomerulonephritis.¹⁴

Not all c-ANCA-positive sera react with the PR3 antigen; reported sensitivity of anti-PR3 antibodies is 70-100%.^{4,14-16} c-ANCA-positive serum may contain antibodies against antigens other than PR3¹⁴ but the role of these antibodies is unclear. Prognostically, antibody titre rises are thought to predict relapse and to help differentiate relapse from opportunistic infection.^{17,18} Recent evidence suggests that in a large minority of patients, c-ANCA/anti-PR3 titres do not follow disease activity.¹⁹

As the clinical spectrum of ANCA-related diseases increases and further target antigens are identified and characterized, the introduction of antigen-specific ELISAs using highly purified antigen extracts may play a valuable role in the identification of disease sub-types.

Result Interpretation	
Qualitative Absorbance Ratio	Result Interpretation
< 0.95	Negative
≥ 0.95 to 1.0	Borderline – Repeat Testing Recommended
> 1.0	Positive
Semi-Quantitative	
< 2U/mL	Negative
≥ 2U/mL	Positive

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Ordering Information

Catalog No. Description

31023 Bio-Rad Kallestad™ Anti-Proteinase 3 (anti-PR3/c-ANCA)96 tests



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