

NEW TEST TEST CHANGE

NOTIFICATION DATE: 01/13/2025

EFFECTIVE DATE: 01/21/2025

Proteinase 3 Antibody (PR3)

Effective 01/21/2025, Northwell Health Laboratories will change the **Proteinase 3 Antibody (PR3)** test method to improve result turnaround time. The current enzyme-linked immunosorbent assay (QUANTA Lite PR-3 IgG ELISA) will be replaced with a multiplex flow immunoassay (BioPlex 2200 Vasculitis Kit).

Anti-neutrophil cytoplasmic antibodies (ANCA), targeting proteins like proteinase 3 (PR3) and myeloperoxidase (MPO), are associated with a distinct form of small-vessel vasculitis known as ANCA-associated vasculitis (AAV), including polyangiitis (GPA) and microscopic polyangiitis (MPA). PR3 antibodies are closely associated with GPA and usually exhibit the cytoplasmic indirect immunofluorescence ANCA (c-ANCA) staining pattern. [1,2]

A method comparison study at Northwell Health Laboratories showed acceptable qualitative agreement between the assays. *However, due to design and epitope recognition differences, quantitative values from the two assays cannot be directly compared.* Please consider this methodological change when reviewing patient histories and prior PR3 results, especially for patients undergoing serial monitoring. Adjustments in clinical interpretation are necessary, as detailed in the table below.

Test Requirement	New	Previous
Methodology	Multiplex flow immunoassay	Enzyme-linked immunosorbent assay
Assay Manufacturer	Bio-Rad Laboratories	Inova Diagnostics (Werfen)
Result Interpretation	<1.0 AI: Negative ≥1.0 AI: Positive	≤20 Units: Negative 21 – 30 Units: Weak Positive >30 Units: Moderate/Strong Positive
Specimen Collection	1 mL Serum (0.5 mL minimum)	1 mL Serum (0.5 mL minimum)
Computer Interface Code	PDM # 5700380	PDM # 5700380
Test Order	PROT3	PROT3

If you have any questions, please contact Client Services at (800) 472-5757.

References:

1. Hellmich B, et al. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. *Ann Rheum Dis* 2024;83:30–47. doi:10.1136/ard-2022-223764
2. Bossuyt, X, et al. Revised 2017 international consensus on testing of ANCA in granulomatosis with polyangiitis and microscopic polyangiitis. *Nat Rev Rheumatol* 13, 683–692 (2017). <https://doi.org/10.1038/nrrheum.2017.140>