

NEW TEST TEST CHANGE

NOTIFICATION DATE: 06/28/2024

EFFECTIVE DATE: 07/16/2024

β2-glycoprotein 1 Antibodies, IgG, IgM, and IgA

On the effective date, as part of our commitment to providing best-in-class clinical diagnostic testing services, Northwell Health Laboratories will update the β2-glycoprotein 1 Antibodies, IgG, IgM, and IgA tests improving turnaround time. The current enzyme-linked immunosorbent assay (QUANTA Lite β2 GPI IgG, IgM, and IgA ELISA) will be replaced with a multiplex flow immunoassay (BioPlex 2200 APLS IgG, IgM, and IgA).

Measurement of β2-glycoprotein 1 antibodies can aid in the evaluation of patients with suspected cases of antiphospholipid syndrome (APS). APS is a systemic autoimmune disease characterized by arterial, venous, or microvascular thrombosis or pregnancy morbidity in patients with persistently elevated antiphospholipid antibodies (i.e., cardiolipin antibodies or β2-glycoprotein 1 antibodies and/or lupus anticoagulant). [1]

An in-house method comparison study conducted at Northwell Health Laboratories demonstrated acceptable qualitative clinical concordance between the two assays. *However, it is important to note that due to differences in immunoassay design and antibody epitope recognition, direct comparison of semi-quantitative values between the two assays is not feasible, as highlighted in the table below.*

Test Name	Beta 2 Glycoprotein 1 IgG Ab		Beta 2 Glycoprotein 1 IgM Ab		Beta 2 Glycoprotein 1 IgA Ab	
Test Requirements	New	Current	New	Current	New	Current
Methodology	Multiplex Flow Immunoassay	Enzyme-Linked Immunosorbent Assay	Multiplex Flow Immunoassay	Enzyme-Linked Immunosorbent Assay	Multiplex Flow Immunoassay	Enzyme-Linked Immunosorbent Assay
Assay Manufacturer	Bio-Rad Laboratories	Inova Diagnostics (WERFEN)	Bio-Rad Laboratories	Inova Diagnostics (WERFEN)	Bio-Rad Laboratories	Inova Diagnostics (WERFEN)
Result Interpretation	<20 U/mL: Negative ≥20 U/mL: Positive	≤20 SGU: Negative >20 SGU: Positive	<20 U/mL: Negative ≥20 U/mL: Positive	≤20 SMU: Negative >20 SMU: Positive	<20 U/mL: Negative ≥20 U/mL: Positive	≤20 SAU: Negative >20 SAU: Positive
Computer Interface Code	PDM #5905914	PDM #5905914	PDM #5905916	PDM #5905916	PDM #5905912	PDM #5905912
Test Order	B2G 1 IgG Ab	B2G 1 IgG Ab	B2G 1 IgM Ab	B2G 1 IgM Ab	B2G 1 IgA Ab	B2G 1 IgA Ab

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

1. Barbhuiya M et al. The 2023 ACR/EULAR Antiphospholipid Syndrome Classification Criteria. *Arthritis Rheumatol*, 75: 1687-1702. <https://doi.org/10.1002/art.42624>