

NEW TEST TEST CHANGE

NOTIFICATION DATE: 06/28/2024

EFFECTIVE DATE: 07/16/2024

Cardiolipin Antibodies, IgG, IgM, and IgA

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

Measurement of cardiolipin 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 β 2-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	Cardiolipin Ab IgG		Cardiolipin Ab IgM		Cardiolipin Ab IgA	
	New	Current	New	Current	New	Current
Test Requirements						
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 GPL-U/mL: Negative ≥20 GPL-U/mL: Positive	<12.5 GPL: Negative 12.5-20 GPL: Indeterminate > 20 GPL: Positive	<20 MPL-U/mL: Negative ≥20 MPL-U/mL: Positive	<12.5 MPL: Negative 12.5-20 MPL: Indeterminate > 20 MPL: Positive	<20 APL-U/mL: Negative ≥20 APL-U/mL: Positive	<12.5 APL: Negative 12.5-20 APL: Indeterminate >20 APL: Positive
Computer Interface Code	PDM #5901410	PDM #5901410	PDM #5901405	PDM #5901405	PDM #5901400	PDM #5901400
Test Order	CARDIGG	CARDIGG	CARDIGM	CARDIGM	CARDIGA	CARDIGA

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

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

