

NEW TEST TEST CHANGE

NOTIFICATION DATE: JULY 17, 2024

EFFECTIVE DATE: JULY 30, 2024

Cyclic Citrullinated Peptide Antibodies (anti-CCP)

On the effective date, Northwell Health Laboratories will implement a change in the assay methodology for the measurement of Cyclic Citrullinated Peptide antibodies (anti-CCP) to improve turnaround time. The current enzyme-linked immunosorbent assay (QUANTA Lite CCP3 IgG ELISA) will be replaced with an electrochemiluminescence immunoassay (Elecsys Anti-CCP).

Cyclic Citrullinated Peptide antibody is a highly specific biomarker for the diagnosis of rheumatoid arthritis (RA), a chronic inflammatory disease characterized by joint swelling, joint tenderness, and destruction of synovial joints. [1] The presence of anti-CCP antibodies can aid in the early diagnosis and management of RA, even before clinical symptoms appear.

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.*** Be aware of this change in methodology when reviewing patient histories and previous anti-CCP results. Adjustments in clinical interpretation is necessary as, highlighted in the table below.

Test Requirement	New	Previous
Methodology	Electrochemiluminescence Immunoassay	Enzyme-Linked Immunosorbent Assay
Assay Manufacturer	Roche Diagnostics	Inova Diagnostics (WERFEN)
Result Interpretation	<17 U/mL: Negative ≥17 U/mL: Positive	≤19 Units: Negative 20 – 39 Units: Weak Positive 40-59 Units: Moderate Positive >60 Units: Strong Positive
Computer Interface Code	PDM #5916102	PDM #5916102
Test Order	CCP	CCP

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

References:

1. Daniel Aletaha et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum.* 2010 Sep;62(9):2569-81. doi: 10.1002/art.27584