RHEUMATOLOGY TESTING

Rheumatoid arthritis testing with better performance

labcorp

Rheumatoid arthritis screening and diagnostic testing

Rheumatoid arthritis (RA) affects an estimated 1.5 million people in the United States.[1] RA is the most common type of autoimmune arthritis.[2]

RA can happen at any age and the risk for developing the disease increases as we age; women are about two to three times more likely to have the disease.[1]

Rheumatoid arthritis diagnosis and prognosis

Early rheumatoid arthritis (RA) diagnosis and initiation of disease-suppressing therapy may improve clinical outcomes and reduce the accrual of joint damage and disability.[3] Labcorp offers several RA-specific markers that, when used in combination, provide industry-leading sensitivity and an early diagnosis of RA.

Prognosis is dependent on early, accurate diagnosis and establishing an effective treatment plan.[4] Diagnosis and classification of RA has relied heavily on anti-cyclic citrullinated peptide (Anti-CCP) and rheumatoid factor (RF) IgM.[3]

Approximately 28% of patients are seronegative for both Anti-CCP and RF IgM in early RA and 12% seronegative in established RA.[5] New markers are available to better identify early RA patients, stratify patients for risk of joint destruction, and to monitor disease activity and effectiveness of treatment.

Profiles

	RheumAssure® (504509)	SeroNeg RAdx4 (520305)	RA Profile w/ Reflex to SeroNeg RAdx4 (520298)	RAdx6 (520304)
Rheumatoid Factor (RF)	✓		[1] ✓	✓
Anti-CCP, IgG and IgA	✓		✓	✓
14-3-3 eta	✓	✓	[2] ✓	✓
Anti-Sa Ab IgG		✓	✓	✓
Anti-CEP-1 Ab IgG		✓	✓	✓
Anti-CarP Ab		✓	✓	✓

RheumAssure® 504509

Labcorp's RheumAssure panel contains rheumatoid factor (RF), cyclic citrullinated peptide (CCP) antibodies, and 14-3-3 eta protein tests.

- Used together, these three markers are able to diagnose established RA with a sensitivity of 88-96% and early RA with a sensitivity of 78-92%[4,6]

- Elevation of one or more RheumAssure markers is consistent with an RA diagnosis and if all three markers are negative, a diagnosis is less likely

RAdx6 profile 520304

The RAdx6 combines four novel markers (14-3-3 eta, Anti-Sa, Anti-CEP-1 and Anti-CarP) with two traditional markers (Anti-CCP and RF-IgM) to enhance diagnosis in early or established RA, and help predict disease severity.

- Disappearance or decrease of 14-3-3 eta and/or Anti-Sa with treatment is associated with less radiographic progression

- In preclinical RA, Anti-CEP-1 with Anti-CCP antibodies significantly raises the risk of imminently developing clinical RA

- Anti-CarP may predict the development of RA independently of Anti-CCP and may be present years before the onset of symptoms in RA

SeroNeg RAdx4 profile 520305
RA Profile (RF and Anti-CCP) with reflex to SeroNeg RAdx4 520298

Diagnostic and prognostic panels designed to complement traditional RF and Anti-CCP testing. The profile consists of 14-3-3 eta, Anti-Sa, Anti-CEP-1 and Anti-CarP.

- Enhances RA diagnosis and helps predict disease severity

- Helps identify RA in Anti-CCP-negative and IgM-RF-negative patients and in the diagnosis of early RA

Rheumatoid arthritis screening and diagnosis tests

Test No.	Test Name—Profiles	Clinical Use
504509	RheumAssure®	Diagnose established and early RA.[3,6]
520304	RAdx6 Profile	Enhance the diagnosis of early and established RA. Helps predict disease severity.
520305	SeroNeg RAdx4 Profile	Enhance the diagnosis in established and early RA in individuals seronegative for RF and Anti-CCP Ab.
520298	RA Profile (RF and Anti-CCP) with reflex to SeroNeg RAdx4	RF and Anti-CCP are performed and reported. If both are negative the SeroNeg RAdx4 is performed.

Test No.	Test Name—Individual Markers	Clinical Use
Traditional		
006502 520129 (RDL)	Rheumatoid Factor	Nonspecific diagnostic marker for RA that may also be present in healthy elderly persons or in patients with other autoimmune, infectious disease, or chronic inflammatory diseases.[2]
164914 520008 (RDL)	Anti-CCP (Cyclic Citrullinated Peptide) Antibodies, IgG and IgA	More specific than a RF diagnosis and Labcorp's Anti-CCP, version 3.1, provides greater sensitivity than earlier CCP tests.[7]
Novel		
504550	14-3-3 eta, Rheumatoid Arthritis	Highly specific for RA and provides a 15% incremental benefit over RF and Anti-CCP. Higher levels predict poorer clinical and radiographic outcomes, both at baseline and after initiation of treatment.[8]
520133	Anti-CEP-1 Ab, IgG (RDL)	Predict onset of symptoms in preclinical RA years before onset and confirms the diagnosis of RA with a specificity of 98% and sensitivity of 37%-62%.[9,10]
520081	Anti-Sa Ab, IgG (RDL)	Highly specific for RA with a specificity of >95% and a sensitivity of approximately 30%–40%.[11] Can help identify patients that are Anti-CCP and IgM-RF antibody negative and predict a more aggressive, rapid disease course associated with a poor prognosis.
520311	Anti-CarP Ab	May predict the development of RA independently of Anti-CCP and may be present years before the onset of symptoms in RA.

References
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For rheumatology questions, including specimen collection requirements, or for access to technical or medical consultation, **call the rheumatology hotline at 800-338-1918**

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