



RHEUMATOLOGY TESTING

# Rheumatoid arthritis testing with better performance



## Rheumatoid arthritis screening and diagnostic testing

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

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.<sup>1</sup>

## 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.<sup>3</sup> Labcorp offers tests for 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.<sup>4</sup> Diagnosis and classification of RA has relied heavily on anti-cyclic citrullinated peptide (Anti-CCP) and rheumatoid factor (RF) IgM.<sup>3</sup>



**Approximately 28% of patients are seronegative for both Anti-CCP and RF IgM in early RA and 12% seronegative in established RA.**<sup>5</sup> 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

|                        | SeroNeg RAdx4<br>(520305) | RA Profile w/ Reflex<br>to SeroNeg RAdx4<br>(520298) | RAdx6<br>(520304) | RheumAssure®<br>(504509) |
|------------------------|---------------------------|--|-------------------|--------------------------|
| Rheumatoid factor (RF) |                           | 1 ✓  | ✓                 | ✓                        |
| Anti-CCP, IgG and IgA  |                           | ✓  | ✓                 | ✓                        |
| Anti-MCV Ab            | ✓                         | 2 ✓  | ✓                 |                          |
| Anti-Sa Ab IgG         | ✓                         | ✓  | ✓                 |                          |
| Anti-CEP-1 Ab IgG      | ✓                         | ✓  | ✓                 |                          |
| Anti-CarP Ab           | ✓                         | ✓  | ✓                 |                          |
| 14-3-3 eta protein     |                           |  |                   | ✓                        |

### RAdx6 profile [520304]

The RAdx6 combines four novel markers (Anti-MCV Ab, 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.

- Anti-MCV and Anti-Sa have been shown to correlate with higher disease activity
- Disappearance or decrease of Anti-MCV 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 Anti-MCV, 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

### 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%<sup>4,6</sup>
- 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



## Rheumatoid arthritis screening and diagnosis tests

| Test No. | Test Name—Profiles  | Clinical Use  |
|----------|---|---|
| 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.      |
| 504509   | RheumAssure®  | Diagnose established and early RA. <sup>3,6</sup>   |

| Test No.           | Test Name—Individual Markers                                    | Clinical Use  |
|--------------------|---|---|
| <b>Traditional</b> |   |   |
| 006502             | 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 <sup>2</sup>  |
| 164914             | 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 <sup>7</sup>   |
| <b>Novel</b>       |   |   |
| 520375             | Anti-MCV Ab   | Highly specific for RA with a specificity of 95% and a sensitivity of 82%. <sup>8</sup> Have been found to correlate with early RA in seronegative patients, and its titer correlates to progression to radiographic joint erosion, more aggressive forms of RA and disease activity. <sup>9,10</sup> |
| 520081             | Anti-Sa Ab, IgG (RDL)   | Highly specific for RA with a specificity of >95% and a sensitivity of approximately 30%–40%. <sup>11</sup> 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                            |
| 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%. <sup>12,13</sup>  |
| 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   |
| 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 <sup>14</sup>   |

### 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.

