Third-generation anti-CCP 3.1 test and 14-3-3 eta provides improved sensitivity and can aid in early diagnosis of rheumatoid arthritis (RA)\(^1,2\)

### Anti-CCP 3.1 Clinical Utility
- Anti-cyclic citrullinated peptide (Anti-CCP) is commonly used along with rheumatoid factor (RF) to diagnose rheumatoid arthritis (RA).
  - Anti-CCP, when used in combination with RF, provides greater sensitivity than RF alone.\(^3\)
  - Anti-CCP 3.1 offers greater sensitivity than earlier CCP tests and has been shown to correctly identify 83% of RA patients who were found to be RF negative.\(^1\)
- Anti-CCP (also called anti-citrullinated protein antibody [ACPA]) is now included in Rheumatoid Arthritis Classification Criteria for RA diagnosis.\(^4\)
- Assessment of anti-CCP antibodies has been shown to identify patients who are more likely to develop joint damage, including a significant number of patients without RF.\(^3,6\)
- Anti-CCP 3.1 is the first assay approved for early detection of RA
  - Improved detection within 2 years of onset\(^7\)

### Anti-CCP 3.1 Scientific Excellence
- Anti-CCP 3.1 offers a sensitivity of 70.3% and a specificity of 97.8%.\(^7\)
- Enhanced sensitivity is achieved by utilizing both IgG and IgA antibodies.\(^7\)
  - Prior assays only detected IgG antibodies.
  - Use of multiple citrullinated epitopes improves early RA detection by increasing the likelihood for a corresponding antibody reaction.

### 14-3-3 eta
The 14-3-3 eta protein is a joint-derived, proinflammatory mediator that is implicated in the joint erosion process and pathogenesis of RA.\(^8\)
- Positive serum 14-3-3 eta levels are associated with higher rates of joint damage as measured by radiographic assessments using the Sharp/van der Heijde Score.\(^2,8\)
- Serum testing shows that 14-3-3 eta is elevated in both early and established RA.\(^8\)
- 14-3-3 eta is highly specific for RA. Serum 14-3-3 eta may be especially helpful in identifying patients with early RA, as it provides a 15% incremental benefit to the diagnostic sensitivity of markers including, Rheumatoid Arthritis (RA) Factor and Cyclic Citrullinated Peptide (CCP) Antibodies.\(^2\)
- A higher level of 14-3-3\(\eta\) also helps to identify RA patients who are most likely to exhibit rapid progression and need earlier, tailored therapy.\(^2\)

### CCP 3.1 Offers Increased Clinical Sensitivity over CCP 2\(^7\)

<table>
<thead>
<tr>
<th></th>
<th>CCP 2</th>
<th>CCP 3.1</th>
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<tbody>
<tr>
<td>Overall</td>
<td>64.6%</td>
<td>70.3%</td>
</tr>
<tr>
<td>Early RA</td>
<td>54.7%</td>
<td>64.0%</td>
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</tbody>
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\(^1\) Anti-CCP 3.1 offers a sensitivity of 70.3% and a specificity of 97.8%.\(^7\)
\(^2\) Enhanced sensitivity is achieved by utilizing both IgG and IgA antibodies.\(^7\)
\(^3\) Anti-CCP 3.1 offers a sensitivity of 70.3% and a specificity of 97.8%.\(^7\)
\(^4\) Anti-CCP (also called anti-citrullinated protein antibody [ACPA]) is now included in Rheumatoid Arthritis Classification Criteria for RA diagnosis.\(^4\)
\(^5\) Assessment of anti-CCP antibodies has been shown to identify patients who are more likely to develop joint damage, including a significant number of patients without RF.\(^3,6\)
\(^6\) Anti-CCP 3.1 is the first assay approved for early detection of RA.
\(^7\) Improved detection within 2 years of onset\(^7\)
\(^8\) The 14-3-3 eta protein is a joint-derived, proinflammatory mediator that is implicated in the joint erosion process and pathogenesis of RA.\(^8\)
References


7. QUANTA Lite™ CCP 3.1 IgG/IgA ELISA (directional insert), INOVA Diagnostics, Inc October 2009. Revision 2.
