Enzyme immunoassays for the diagnosis of **rheumatoid arthritis**

**Cyclic Citrullinated Peptide (CCP)**

**Rheumatoid Factor (RF)**

**ELISA** kits are optimized and validated for detection of IgA, IgG and IgM antibodies in human serum and plasma.

ELISA kits are optimized and validated for detection of rheumatoid factor in human serum and plasma.
**INTRODUCTION**

Rheumatoid arthritis (RA) is an autoimmune disorder whose typical features are chronic osteosynovitis and erosion of articular cartilage and bone followed by joint destruction. It affects more than 5 million people worldwide. Usually appearing between the ages of 30 and 50, nearly three-fourths of all sufferers are women. The aetiology of rheumatoid arthritis is not completely understood. RA is a multifactorial disease where interactions between a number of genes and external environment factors play a considerable role.

**DIAGNOSIS OF DISEASE**

The most often used laboratory assay for RA is the determination of a Rheumatoid factor (RF).

Rheumatoid factors are immunoglobulins which bind to the C-terminal portion of the constant region of human heavy chain of IgG (Fc fragment). High levels of RF are indicative of rheumatoid arthritis whereas lower concentrations can be found in cases of other diseases such as Sjögren's syndrome, SLE and bacterial endocarditis. Screening for RF is typically performed by assays based on aglutination, turbidimetry, nephelometry or ELISA. These methods are semiquantitative and detect primarily RF of the IgM antibody class and not RF of other (IgA, IgG) classes.

Detection of individual IgA, IgG and IgM classes using the ELISA method enables quantitative determination with high sensitivity and specificity. RF can be present individually as well as in various combinations depending on clinical parameters and activity of disease. There is documented correlation between RF IgA, IgG levels and disease prognosis.

Determination of antibodies to Cyclic citrullinated peptides (CCP) is a highly specific test enabling even early diagnostics of rheumatoid arthritis. Anti-CCP antibodies can be detected several years before clinical manifestation of the disease; their presence indicating higher risk of an unfavourable disease process.
TEST PRINCIPLE

<table>
<thead>
<tr>
<th>Step</th>
<th>Test steps</th>
</tr>
</thead>
</table>
| 1    | Dilute samples  
• serum/plasma 1:10 (10 μl + 1 ml) |
| 2    | Pipette Controls (Calibrators) and diluted samples 100 μl  
Blank = 100 μl of Sample diluent |
| 3    | Incubate 30 min at 37 °C |
| 4    | Aspirate and wash the wells 5 times |
| 5    | Pipette Conjugate 100 μl  
• Blank = empty well |
| 6    | Incubate 30 min at 37 °C |
| 7    | Aspirate and wash the wells 5 times |
| 8    | Pipette Substrate (TMB-Complete) 100 μl  
• Including blank |
| 9    | Incubate 30 min at 37 °C |
| 10   | Pipette Stop Solution 100 μl  
• Including blank |
| 11   | Read colour intensity at 450 nm |

ANTIGENS

CCP  
Cyclic Citrullinated Peptides of 2nd generation

RF  
Purified human IgG immunoglobulin

CLINICAL APPLICATION

› Detection of rheumatoid arthritis and other diseases, e.g. Sjögren's syndrome, SLE or bacterial endocarditis.
› Quantitative results could be used to control therapy fertility and to determine a prognosis of the disease.

USER COMFORT

› Ready-to-use components  
› Colour-coded components  
› Interchangeable components  
› Breakable colour-coded microplate strips  
› CUT-OFF included  
› Calibrators included  
› Semiquantitative evaluation of results  
• (Index of Positivity)  
› Quantitative evaluation of results (U/ml)  
› Easy assay procedure

TEST CHARACTERISTICS

<table>
<thead>
<tr>
<th>Test</th>
<th>Diagnostic Sensitivity</th>
<th>Diagnostic Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>EIA CCP IgA</td>
<td>98.7%</td>
<td>98.8%</td>
</tr>
<tr>
<td>EIA CCP IgG</td>
<td>98.6%</td>
<td>98.6%</td>
</tr>
<tr>
<td>EIA RF IgA</td>
<td>93.1%</td>
<td>96.6%</td>
</tr>
<tr>
<td>EIA RF IgG</td>
<td>94.1%</td>
<td>93.7%</td>
</tr>
<tr>
<td>EIA RF IgM</td>
<td>95.1%</td>
<td>97.7%</td>
</tr>
<tr>
<td>EIA RF screen</td>
<td>98.0%</td>
<td>98.7%</td>
</tr>
</tbody>
</table>

ADVANTAGES

› Identical assay procedure  
› High diagnostic specificity and sensitivity  
› High reproducibility  
› High dynamics of antibody response  
› Short total assay time  
› Ready for automation  
› Customer support
### ORDERING INFORMATION

- **TestLine Clinical Diagnostics Ltd.**
  Krzikova 68, 612 00 Brno, Czech Republic
  Tel.: +420 549 121 203
  Fax: +420 541 243 390
  E-mail: sales@testlinecd.com
  www.testlinecd.com

- **Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.**

### ELISA

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Product</th>
<th>No. of Tests</th>
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<tbody>
<tr>
<td>CCPA96</td>
<td>EIA CCP IgA</td>
<td>96</td>
</tr>
<tr>
<td>CCPG96</td>
<td>EIA CCP IgG</td>
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</tr>
<tr>
<td>RFA096</td>
<td>EIA RF IgA</td>
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<tr>
<td>RFG096</td>
<td>EIA RF IgG</td>
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<td>RFM096</td>
<td>EIA RF IgM</td>
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<tr>
<td>RF0096</td>
<td>EIA RF screen</td>
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