Anti-dsDNA Farr Radioimmunoassay (IgA/IgG/IgM)

- Reliable detection of anti-dsDNA antibodies in plasma or serum
- Very high diagnostic efficiency owing to excellent sensitivity and specificity

Technical data

Antigen
- Iodine-125-labelled plasmid-dsDNA; ssDNA-free

Sample dilution
- Serum or plasma, 20 μl; undiluted

Calibration
- Quantitative, in international units per millilitre (IU/ml)

Calibrators A-F (variable concentrations; see QC certificate)
- Cut-off value: 7 IU/ml

Reagents
- Calibrators, controls, sample diluter: lyophilised; tracer, ammonium sulfate: ready to use

Test procedure
- 1 hour (sample incubation). Temperature 37 °C

Measurement
- ¹²⁵I; Gamma-Counter

Test kit format
- 100 reagent vessels

Order no.
- RA 1571-10001

Clinical significance

The detection of autoantibodies against deoxyribonucleic acid (DNA) is the most specific marker for the diagnosis of systemic lupus erythematosus (SLE). Generally, two types must be distinguished: antibodies against native, double-stranded DNA (dsDNA, nDNA) and antibodies against denatured, single-stranded DNA (ssDNA). The prevalence of antibodies against dsDNA amounts to 20 to 90% depending on the detection method and disease activity. Antibodies against dsDNA are also occasionally detected in patients with other autoimmune diseases and infections and, in rare cases, in clinically healthy people. 85% of people in the latter group develop SLE within 5 years from initial detection of anti-dsDNA. However, SLE cannot be entirely excluded if anti-dsDNA antibodies are not detected. It is known to a large extent that anti-DNA antibodies play a role in the pathogenesis of SLE. During the course of disease immunocomplexes of double-stranded DNA and the corresponding autoantibodies are deposited in the capillaries of the subcutis, the kidneys and other organs. Here they lead to tissue damage through activation of the complement system. There is now evidence that the primary target antigen of the pathogenetically relevant autoantibodies is not "naked" DNA, but dsDNA complexed with nucleosomes. Antibodies against dsDNA are among the most important criteria for diagnosis of SLE due to their high specificity of 70% to 98%, depending on the method of detection. A high concentration of autoantibodies against dsDNA in Farr RIA is considered a very reliable marker for the diagnosis of SLE. Changes of the anti-dsDNA autoantibody concentration correlate with the activity of SLE, especially with the activity of a lupus nephritis, and are therefore important for the prognosis of SLE and for therapy monitoring.

Diagnostic application

ELISA, Farr RIA (using ammonium sulfate precipitation) and Chriithidia luciliae IIFT are the methods mainly used for the determination of autoantibodies against dsDNA. These methods often vary in sensitivity and specificity because they detect different antibody fractions. Therefore, many laboratories prefer a combination of two methods which are complementary in their diagnostic significance. Due to its good sensitivity and specificity, the Farr RIA has an outstanding, high diagnostic efficiency.
In the first analysis step, the patient samples to be investigated are incubated with Iodine-125-labelled dsDNA. If the sample is positive, specific antibodies bind to the dsDNA. In order to precipitate these antigen-antibody complexes, the sample is then incubated with an ammonium sulfate solution in the second analysis step. After centrifugation, the unbound Iodine-125-labelled dsDNA is removed from the tubes by decantation or aspirating off the liquid. The remaining radioactivity is measured using a gamma counter. The measurement signal level is proportional to the dsDNA antibody concentration in the sample and can be determined using a calibration curve with known dsDNA antibody concentrations.

### Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation (CV) using 4 sera at different points on the calibration curve. The intra- and inter-assay CVs are based on 20 determinations each.

<table>
<thead>
<tr>
<th>Intra-assay variation, n=20</th>
<th>Inter-assay variation, n=20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample</strong></td>
<td><strong>Mean value (IU/ml)</strong></td>
</tr>
<tr>
<td>1</td>
<td>5.9</td>
</tr>
<tr>
<td>2</td>
<td>11.4</td>
</tr>
<tr>
<td>3</td>
<td>24.7</td>
</tr>
<tr>
<td>4</td>
<td>55.9</td>
</tr>
</tbody>
</table>

### Method comparison:

The concentration of Anti-dsDNA antibodies was investigated in 100 sera (origin: Germany) by using both the EUROIMMUN RIA (x) and the Amerlex RIA (y) (Trinity Biotech). The results of the linear regression analysis showed the following correlation characteristics: \( y = 0.80 \times + 1.95, r = 0.98 \). I here was a very high correlation between both assays.

### Literature