Identification of antibodies anti-n-DNA associated to Lupus Erythematosus systemic (LE) by agglutination to latex

**TEST SUMMARY**

When the latex reagent, which has been coated with native Deoxyribonucleic acid (n-DNA), is brought into contact with the serum sample, a clear agglutination will be observed if anti-DNA antibodies are present. (Positive result).

**SAMPLES**

Serum.
Stability at 2-8°C for 2 days.

**REAGENTS**

Latex
Particles of latex covered with Deoxyribonucleic acid; conservative and stabilizer .

Positive Control
Human base stabilized solution of antibodies anti-n-DNA with a titre that gives a clear agglutination.

Negative Control
Proteic solution doesn’t react with latex.

All reagents contain 0.095% of sodium azide.

**REAGENT PREPARATION AND STORAGE**

Reagents are ready for the use.
The latex suspension must be resuspended with much care. When the suspension becomes homogeneous by sweet inversion, it is necessary to fill and to empty the dosage’s pipette many times.
The components of this kit will remain stable until the expiration date stated on the label, when stored at 2-8°C. Do not freeze.

**MATERIAL REQUIRED BUT NOT SUPPLIED**

COD. AK00800 Slide and disposable stirrers.

**PRECAUTION**

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.
To use normal caution foreseen in a laboratory.

**QUALITATIVE PROCEDURE**

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Samples</th>
<th>Positive Control</th>
<th>Negative Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Control</td>
<td>50 µl (1 gt)</td>
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</tr>
<tr>
<td>Control</td>
<td>--</td>
<td>50 µl (1 gt)</td>
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</tr>
<tr>
<td>Latex</td>
<td>50 µl (1 gt)</td>
<td>50 µl (1 gt)</td>
<td>50 µl (1 gt)</td>
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</tbody>
</table>

Mixing using sticks and spreading homogeneously the mixture on the slide, then, shake slide for 3 minutes by a sweet rotating motion or by a stirrer at 100 r.p.m., and observe eventual agglutination using artificial light.

**RESULTS INTERPRETATION**

**POSITIVE:** A clear agglutination within 3 minutes.
**NEGATIVE:** No agglutination within 3 minutes.

**NOTE**

- If reaction’s times are bigger than 3 minutes, they can cause a supervaluation of samples concentrations.
- Human sera used in controls have been found negative in the reaction with HIV and HBsAg. However, they should be handled with care.
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

**CALIBRATION**

Positive and Negative control sera should be always used to distinguish an eventual background’s agglutination of reactive.

**TEST PERFORMANCE**

The reagent is designed to agglutinate in the presence of levels of anti-nuclear antibodies (ANA) commonly found in sistemic Lupus Erythematosus.

**Sensibility**

Test gave positive reactions with 92% of the samples having titres of ANA ≥ 1/20 by immunofluorescence method.

No false positive reactions were observed with latex reagent in testing performance of samples from healthy individuals.

**Interferences**

Highly lipemic or haemolyzed samples may interfere the agglutination reaction.

Those patients suffering from a variety of connective tissue diseases, may agglutinate the reagent.

**WASTE DISPOSAL**

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

**PACKAGING**

**CODE AK00800 (50TESTS)**

- Latex: 1 x 2.5 ml
- Positive Control: 1 x 0.25 ml
- Negative Control: 1 x 0.5 ml

**CODE AK00801 (50TESTS)**

- Latex: 1 x 2.5 ml
- Positive Control: 1 x 0.25 ml
- Negative Control: 1 x 0.5 ml
- Slide black spot: 9
- Stirrers: 25

**REFERENCES**


**MANUFACTURER**

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**SYMBOLES**

- IVD: Only for IVD use
- LOT: Lot of manufacturing
- REF: Code number
- K: Storage temperature interval
- J: Expiration date
- L: Warning, read enclosed documents
- A: Read the directions
- Biological risk