



REF 4097

January 02, 2009

# Antichromatin Latex

- 100 determinations -



IVD *In vitro* diagnostic device

Latex agglutination test for the detection of DNP antibodies associated with Systematic Lupus Erythematosus (SLE) in human serum

<b>REF</b>	Catalogue number	<b>LOT</b>	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction		Biological risk



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## INTENDED USE

Antichromatin Latex is used for the qualitative and semi-quantitative determination of DNP antibodies associated with Systematic Lupus Erythematosus (SLE) in human serum.

The test is intended to be used as an aid in the diagnosis of Systemic Lupus Erythematosus (SLE) through the detection and quantitation of serum antinucleoprotein factors associated with SLE.

The detection of antinuclear antibodies by laboratory methods include immunofluorescence, LE cell test and agglutination of coated particles. The antibodies that are believed to be most characteristic of SLE are those that are directed against deoxyribonucleoprotein (DNP). These antibodies are believed to cause the formation of the LE cell in vitro, with this unusual event occurring in 75-80% of those patients diagnosed as having SLE. It is not necessary to have a positive LE cell test for the diagnosis of SLE as this test had been found negative in certain individuals having symptoms suggestive for SLE. In these individuals, antinuclear antibodies may be demonstrated by methods other than the LE cell test.

## PRINCIPLE OF THE TEST

Antichromatin Latex is used for the detection of SLE associated antibodies in human serum.

The test is based on the agglutination reaction between latex particles coated with deoxyribonucleoprotein (DNP) being brought into contact with a serum, which contains antinuclear antibodies. Agglutination indicates a positive reaction. The reaction time for this occurrence is within one minute.

## TEST COMPONENTS for 100 determinations

<b>A</b>	<b>Latex reagent,</b>	4.0 ml
<b>LATEX</b>	Latex particles coated with DNP extracted from fetal calf thymus	ready for use dropper bottle
<b>P</b>	<b>Positive control</b>	1.0 ml
<b>CONTROL</b>	anti-DNP positive human serum	ready for use dropper bottle
<b>N</b>	<b>Negative control</b>	1.0 ml
<b>CONTROL</b>	negative human serum	ready for use dropper bottle
	<b>Agglutination slide</b>	1 ready for use
	<b>Disposable stirring sticks</b>	100 ready for use

## Materials required but not provided

- timer
- test Tubes and rack.
- serological pipettes
- high intensity light
- Glycine saline buffer (alternatively PBS)
- rocking shaker (optional)

## Size and storage

Antichromatin Latex has been designed for 100 determinations.

The expiry date of each component is reported on its respective label that of the complete kit on the box labels.

Upon receipt, all components of the Antichromatin Latex have to be stored at 2 - 8 °C, preferably in the original kit box. The Latex Reagent must be shaken vigorously for 30 seconds prior to using on each day's testing. Once shaken, the Latex reagent must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal. **Do not freeze!**

Do not use the latex reagents if it is marked with turbidity as this may indicate reagent deterioration or contamination.

After opening all kit components are stable for at least 3 months, provided proper storage.

Agglutination slide should be thoroughly rinsed with water and wiped with lint-free tissue after each use.

## PATIENT SAMPLES

Use fresh serum collected by centrifuging clotted blood. The test sera should not be heat inactivated.

If the test cannot be carried out on the same day, the serum may be stored between 2 - 8°C for no longer than 72 hours after collection. For longer periods the sample must be frozen.

As in all serological tests, hemolytic or contaminated serum must not be used. **Do not use plasma!**

## ASSAY PROCEDURE

### Qualitative evaluation

1. Allow all reagents and samples to reach room temperature prior to testing. Shake well all reagents before use.
2. Place **1 drop** (appr. 40 µl) of the positive control (P) on field no. 1 of the agglutination slide.
3. Place **1 drop** (appr. 40 µl) of the negative control (N) on field no. 2 of the agglutination slide.
4. Place **40 µl** of each undiluted patient sample to the following fields of the agglutination slide using different serological pipettes.
5. Gently resuspend the Latex reagent (A) and add **1 drop** (40 µl) to each test field.
6. Mix well using separate stirring sticks.
7. Gently rock the slide for **1 minute** by hand or use a rocking shaker (80-100 rpm).
8. Read immediately under direct light.

## Semi-quantitative evaluation

1. Allow all reagents and samples to reach room temperature prior to testing. Shake well all reagents before use.
2. Set up at least five dilutions per patient sample: 1:2, 1:4, 1:8, 1:16, 1:32, etc. with glycine saline solution
3. Place **1 drop** (appr. 40 µl) of the positive control (P) on field no. 1 of the agglutination slide.
4. Place **1 drop** (appr. 40 µl) of the negative control (N) on field no. 2 of the agglutination slide.
5. Place **40 µl** of each sample dilution (refer 2.) to the following fields of the agglutination slide using different serological pipettes.
6. Gently resuspend the Latex reagent (A) and add **1 drop** (40 µl) to each test field.
7. Mix well using separate stirring sticks.
8. Gently rock the slide for **1 minute** by hand or use a rocking shaker (80-100 rpm).
9. Read immediately under direct light.

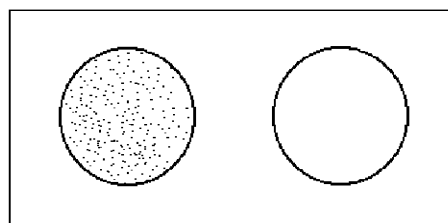
## EVALUATION OF RESULTS

### POSITIV

A positive reaction is indicated by any observable agglutination in the reaction mixture within one minute.

### NEGATIV

A negative reaction is indicated by a uniform milky suspension with no agglutination within one minute.



Positive

Negative

Sera that are positive in the screening test should be retested in the titration test (semi-quantitative test) to provide verification for borderline interpretations.

### Semi-quantitative test evaluation

The titer of the test is equal to the highest dilution, which shows a visible agglutination.

## Test validity

SLE Positive and Negative Control should be included in each test batch.

Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the Negative Control and agglutination with large aggregates is observed with the Positive Control.

## Limitations of the method

Reaction time is critical. If reaction time exceeds 1 minutes, drying of the reaction mixture may cause false positive result.

Those patients with scleroderma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may show reactivity when their serum is tested with the Antichromatin Latex test. In recent studies, it has been reported that many widely used drugs such as hydralazine, isoniazid, procainamide and a number of anticonvulsant drugs can induce a systemic lupus erythmatosis (SLE) syndrome.

Any clinical diagnosis should not be based on the results of in vitro diagnostic methods alone. Physicians are supposed to consider all clinical and laboratory findings possible to state a diagnosis.

## SAFETY PRECAUTIONS

- **This kit is for in vitro use only.** Follow the working instructions carefully. GA GENERIC ASSAYS GmbH and its authorized distributors shall not be liable for damages indirectly or consequentially brought about by changing or modifying the procedure indicated. The kit should be performed by trained technical staff only.
- The expiration dates stated on the respective labels are to be observed.
- Do not use or mix reagents from different lots. Do not use reagents from other manufacturers.
- All reagents should be kept at 2 - 8 °C before use in the original shipping container.
- Some of the reagents contain small amounts of Sodium azide (0.095%) as preservative. They must not be swallowed or allowed to come into contact with skin or mucosa.
- Positive and negative controls prepared using human sera found negative for hepatitis B surface antigen (HBsAg) and antibodies to HIV (Human Immunodeficiency Virus) and HCV (Hepatitis C Virus) by FDA required test. However, handle controls as if potentially infectious.
- Since the kit contains potentially hazardous materials, the following precautions should be observed:
  - Do not smoke, eat or drink while handling kit material,
  - Always use protective gloves,
  - Never pipette material by mouth,
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.
- In any case GLP should be applied with all general and individual regulations to the use of this kit.

Remarks: