Atlas D-Dimer Latex Kit

IVD *For In Vitro Diagnostic Use Only.*

Store at 2°C to 8°C.

INTENDED USE

A manual slide latex agglutination test for the qualitative and semi-quantitative detection of circulating derivatives of cross-linked fibrin degradation products (XL-FDP) in human citrated plasma to exclude Venous Thromboembolism (VTE) in patients suspected of Deep Vein Thrombosis (DVP) and Pulmonary Embolism (PE).

INTRODUCTION

During blood coagulation, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerize to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, but only degradation products from cross-linked fibrin contain D-Dimer. Therefore, cross-linked fibrin degradation products (XL-FDP) are a specific marker of fibrinolysis.

PRINCIPLE

Atlas D-Dimer Latex is a rapid agglutination assay utilizing latex beads coupled with a highly specific D-Dimer monoclonal antibody. XL-FDP present in a plasma sample bind to the coated latex beads, which results in visible agglutination occurring when the concentration of D-Dimer is above the threshold of detection of the assay.

MATERIALS

MATERIALS PROVIDED

- D-Dimer Latex Reagent: a 0.83% suspension of latex particles coated with murine anti-D-Dimer monoclonal antibody, 10mg/mL BSA and 0.1% sodium azide.
- D-Dimer Positive Control: a solution containing purified human D-Dimer fragment, 5mg/mL BSA and 0.1% sodium azide.
- D-Dimer Negative Control: a buffer solution containing 5mg/mL BSA and 0.1% sodium azide.
- Dilution Buffer
- Reaction slide
- Stirring Sticks
- Instructions for Use.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Precision pipettes and tips - 20 µL and 100 µL
- Plastic test tubes and rack
- Stopwatch or timing device
- Disposable gloves
- Tissue (for wiping dropper bottle tips)

PACKAGING CONTENT

REF **8.00.17.0.0025 (D-Dimer Latex 1x0.5mL, 2x0.4mL Controls, 1x10mL Glycine Buffer)**

REF **8.00.17.0.0050 (D-Dimer Latex 1x1mL, 2x0.5mL Controls, 1x10mL Glycine Buffer)**

REF **8.00.17.0.0100 (D-Dimer Latex 1x2mL, 2x1mL Controls, 2x10mL Glycine Buffer)**

REF **8.00.17.2.0100 (D-Dimer Latex 1x2mL, 2x0.5mL Controls, 2x10mL Glycine Buffer)**

REF **8.00.17.0.0200 (D-Dimer Latex 1x4mL, 2x2mL Controls, 1x40mL Glycine Buffer)**

PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- Harmful if swallowed. Avoid contact with skin and eyes. Do not empty into drains.
- Wear suitable protective clothing.
- CAUTION: All reagents in Atlas D-Dimer Latex Kit contain sodium azide (0.1%) as preservative. Do not ingest or allow to contact skin or mucous membranes. Sodium azide may form explosive azides in metal plumbing. Use proper disposal procedures.
- CAUTION: The Positive Control in Atlas D-Dimer Latex Kit contain components of human origin. Each individual blood donation intended for the production of this reagent is tested for HBsAg, anti-HCV, anti-HIV1 and anti-HIV2. Only donations with negative findings are employed. As complete absence of infectious agents can never be assured, all materials derived from human blood should be treated as potentially infectious and handled with due care following the precautions recommended for biohazardous material.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Do not use these reagents if the label is not available or damaged.
- Test materials and samples should be discarded properly in a biohazard container.

STORAGE AND STABILITY

- Store at 2°C to 8°C.
- DO NOT FREEZE.
- Stability: Refer to outer package and vial labels for expiration date.
- Opened vials are stable until specified expiry date printed on vial label when stored refrigerated (2 - 8°C).
- Indication of Reagent Deterioration
  Reagent deterioration is indicated by failure of the Latex Reagent to agglutinate with the Positive Control, agglutination with the Negative Control, or evidence of microbial contamination.

SPECIMEN COLLECTION AND PREPARATION

- Use fresh plasma prepared by centrifugation of whole blood collected using tube contain sodium citrate anticoagulant. (The use of EDTA and heparin will result in an increased level of false positive reaction).
- The test works best on fresh plasma samples. If testing cannot be done immediately, plasma samples should be stored at -20ºC up to 2 weeks.
- Specimen may be tested directly for the presence of XL-FDP. Defibrination of the plasma is not recommended.
- Frozen specimen should be rapidly thawed at 37 °C and centrifuged before testing.

PROCEDURE

- Equilibrate reagents to room temperature (20°C to 25°C) before use.
- Latex Reagent should be mixed by inversion immediately prior to use.

Qualitative Method

1. Bring reagents and specimens to room temperature before use.
2. Place 20 µL of the reagent within a field on the reaction slide.
3. Accurately pipette 20 µL of undiluted plasma or of control solution next to the drop of Latex Reagent.
4. Mix the Latex Reagent and sample with a stirrer until the Latex is uniformly distributed.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for three minutes.
6. At exactly 3 minutes, check for agglutination under a strong light source.

NOTE

If test reading is delayed beyond 3 minutes, the latex suspension may dry out **giving a false agglutination pattern. If this is suspected, the specimen must be retested.**

Semi quantitative Method

1. Prepare serial dilutions of the test plasma with Buffer as follows:
1:2 dilution 100 µL plasma plus 100 µL Buffer solution
1:4 dilution 100 µL 1:2 dilution plus 100 µL Buffer solution
1:8 dilution 100 µL 1:4 dilution plus 100 µL Buffer solution
2. Test each dilution as described in the qualitative method.

QUALITY CONTROL

- It is recommended that both Positive and Negative Controls be included in each batch of tests to ensure proper functioning of the system. Control solutions should be tested by the same procedures as patient samples.
- D-Dimer Positive Control consists of a solution of human D-Dimer at a level of approximately ≥ 0.80 mg/L (≥ 800ng/mL).

RESULTS

A. Qualitative Assay

For the qualitative assay protocol, the following pattern of results should be obtained:

Undiluted Plasma D-Dimer (XL-FDP) concentration

- Less than 0.15 mg/L (150ng/mL): Negative result
- Greater than 0.15 mg/L (150ng/mL): Positive result

B. Semiquantitative Assay

Approximate levels of XL-FDP, containing the D-Dimer domain, for specimen dilutions are shown in Table 1. As with all semiquantitative tests, some variability in dose-response can be expected.

Approximate Range of D-Dimer (XL-FDP) mg/L (ng/ml)	Sample Dilution			
	Undil.	1:2	1:4	1:8
< 0.2 (< 200)	-	-	-	-
0.2 – 0.4 (200 – 400)	+	-	-	-
0.4 – 0.8 (400 – 800)	+	+	-	-
0.8 – 1.6 (800 – 1600)	+	+	+	-
1.6 – 3.2* (1600 – 3200*)	+	+	+	+

"+" = agglutination, "-" = no agglutination

* Levels of XL-FDP greater than 3.20 mg/L (3200 ng/mL) can be estimated by further dilutions beyond 1:8.

EXPECTED VALUES

A positive result, indicating active fibrinolysis, should be obtained with D-Dimer Latex Test when XL-FDP (D-Dimer) levels are at or greater than approximately 0.20 mg/L (200ng/mL). Plasma specimens from normal subjects are expected to give negative results because their plasma XL-FDP concentrations are typically less than 0.20 mg/L (200ng/mL). Due to many variables that may affect results, each laboratory should establish its own normal range.

Elevated levels of XL-FDP (containing the D-Dimer domain) have been demonstrated in patients by a combination of immunoprecipitation and gel electrophoresis techniques. Monoclonal antibodies allow the specific detection of the D-Dimer domain. Monoclonal antibody based D-Dimer assay is of diagnostic value in disseminated intravascular coagulation (DIC) and acute vascular diseases, including pulmonary embolism (PE) and deep venous thrombosis (DVT), conditions that are difficult to detect reliably by clinical examination.

The amount of XL-FDP detected in a specimen will depend on several interrelated factors in vivo, such as the severity of the thrombotic episode, the rate of cross linked fibrin formation, and the time elapsed after the thrombotic event until blood is drawn from the patient.

Elevated levels of XL-FDP as an indication of reactive fibrinolysis have also been reported in surgery, trauma, sickle cell disease, liver disease, severe infection, sepsis, inflammation, and malignancy. D-Dimer levels also rise during normal pregnancy but very high levels are associated with complications.

LIMITATIONS

Clinical diagnosis should not be based on the result of D-Dimer Latex alone. Clinical signs and other relevant test information should be included in the diagnostic decision.

SPECIFIC PERFORMANCE CHARACTERISTICS

- Diagnostic Sensitivity: 100.00% (95% CI (97.34% to 100.00%))
- Diagnostic Specificity: 94.38% (95% CI (89.91% to 97.27%)).
- Positive Predictive Value: 93.20% (95% CI (88.24% to 96.16%)).
- Negative Predictive Value : 100%
- Accuracy: 96.83% (95% CI (94.24% to 98.47%)).
- Intra-assay (within run) reproducibility was determined for 10 replicates of 3 plasma samples that contained different levels of XL-FDP. The results were equivalent for all replicates.
- Inter-assay (run-to-run) reproducibility was determined using 10 plasma samples with XL-FDP titers ranging from 1 to 16. In 10 runs, the replicates of these specimens did not vary by more than one titer.
- In an anticoagulant study of 50 parallel citrated, EDTA and heparin plasma samples, the test result showed that the following:
  - Plasma prepared from whole blood anticoagulated with sodium citrate is recommended.
  - The use of EDTA and heparin sodium will result in an increased level of false positive reaction.
- No assay interference was demonstrated with Atlas D-Dimer Latex with spiked specimens containing potential interfering substances at the following concentrations:
  - Bilirubin 0.2 mg/mL
  - Hemoglobin 5.0 mg/mL
  - Lipids (triglycerides) 30 mg/mL
  - Protein (gamma globulin) 0.06 g/mL

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3. Whitaker, A.N. et al. Identification of D-Dimer-E complex in Disseminated Intravascular Coagulation. Thromb. Res. 18 (3-4): 453-459; 1980.
4. NCCLS Publication H21-A3 - Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline Third Edition; 1998.
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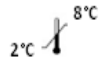
REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control

Atlas Medical CE

RPR Carbon Antigen

IVD ***For In-Vitro diagnostic and professional use only***



Store at 2 to 8 °C

***INTENDED USE**

A manual rapid plasma reagin carbon test for the qualitative and semi-quantitative detection of non-treponemal antibodies against Syphilis in human serum and plasma to provide serological evidence of past/current Syphilis infections when preceeded by a positive treponemal test. Not to be used as a screening tool for blood or tissue donations.

INTRODUCTION

Syphilis is a disease caused by infection with the spirochete Treponema pallidum. The infection is systemic and the disease is characterized by periods of latency. These features, together with the fact that T pallidum cannot be isolated in culture, mean that serologic techniques play a major role in the diagnosis and follow-up of treatment for syphilis.

Syphilis is categorized by an early primary infection in which patients may have non-specific symptoms, and potentially, genital lesions. Patients tested by serology during the primary phase may be negative for antibodies, especially if testing is performed during the first 1 to 2 weeks after symptom onset. As the disease progresses into the secondary phase, antibodies to T pallidum reach peak titers, and may persist indefinitely regardless of the disease state or prior therapy. Therefore, detection of antibodies to nontreponemal antigens, such as cardiolipin (a lipoidal antigen released by host cells damaged by T pallidum) may help to differentiate between active and past syphilis infection. Nontreponemal antibodies are detected by the rapid plasma reagin (RPR) assay, which is typically positive during current infection and negative following treatment or during late/latent forms of syphilis.

PRINCIPLE

RPR utilises carbon particles coated with cardiolipin antigen to detect reagin antibodies present in serum or plasma of syphilitic persons.

Specimens that contain reagin cause aggregation of the carbon particles which appear as dark clumps against a white background. The aggregation can be read macroscopically. Non-reactive samples typically appear as a smooth non-aggregated pattern which may form buttons in the centre of the test area.

MATERIALS

MATERIALS PROVIDED

- **RPR carbon antigen reagent**: A particulate carbon suspension coated with lipid complexes, with 0.95 g/L sodium azide.
- **Positive Control**: Human syphilitic serum reactive with the test reagent, with 0.95 g/L Sodium azide. **(Optional).**
- **Negative control**: non-reactive phosphate buffer containing 5% BSA pH7.4, with 0.1% of Sodium azide. **(Optional).**
- **RPR test cards or white glass slide (Optional).**
- **Plastic sticks (Optional).**
- **Package insert**.

NOTE: This package insert is also used for individually packed reagent.

MATERIALS NEEDED BUT NOT PROVIDED

- Rotator (100rpm).
- Timer.
- Calibrated micropipettes and tips.

PACKAGING CONTENT

REF **8.00.18.0.0100 (2mL Reagent, 1x0.5ml Positive Control, 1x0.5mL Negative Control)**

REF **8.00.18.0.0500 (10mL Reagent, 1x1ml Positive Control, 1x1mL Negative Control)**

REF **8.00.18.3.1000 (2x10ml Reagent, 1x2ml Positive Control, 1x2ml Negative Control)**

STORAGE AND STABILITY

- All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C.
- *Do Not Freeze.
- *Signs of deterioration:
  - RPR Carbon: Visible agglutination.
  - Controls: Presence of particles and turbidity.

PRECAUTIONS AND WARNINGS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- *The test is not for near-patient or self-testing.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all negative and positive in the manner as patient specimens .
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Components of different human origin have been tested and found to be negative for the presence of antibodies anti- HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
- *Do not touch, drink, or ingest the reagent.
- *Do not use black glass slides during testing.
- *Perform the test in a well-lit area with good visibility.
- *Failure in following the instructions may give incorrect results or face safety hazards.
- *Wash the area of contact with water immediately if contact occurs.
- *Wash of the hands and the test table top with water and soap.
- *Do not use the reagent if displaying any signs of deterioration.
- *Always use a fresh pipette tip and stirring sticks for each test.
- *Handle the used disinfectant with care.
- *Glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- *Do not use the reagents if the label is missing, damaged, or unclear.
- *Do not use leaked vials and making proper disposal of them.
- *Use forceps, scoops, or other mechanical devices for removing broken glass from the working area. A dustpan and brush should be used to clean up shards/small pieces of broken glass. Broken glass must be disposed of in a sharps container.
- *The reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide bulidup.
- *Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

- Fresh serum or plasma. The samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolized or lipemic samples.
- *Samples may be stored at 2-8° C for up to 7 days. For long term storage sera should be stored at -20° C up to 30 days.

REAGENT PREPARATION

RPR reagent is ready to use. No preparation is required.

PROCEDURES

QUALITATIVE PROCEDURE

- **Mix well the RPR reagent before use.**

1. Bring the reagents and samples to room temperature.
2. Dispense **50 µL of each sample** into a separate circle on the card. Use a separate tip for each sample.
3. Dispense **1 drop of each of positive and negative controls** into two additional circles.
4. Gently shake the dispensing vial and slightly press to remove air bubbles from the needle and the drop obtained is correct.

5. Dispense **1 drop (17.5 µl) of RPR antigen** to each circle next to the sample to be tested.
6. *Close the reagent vial tightly.
7. *Spread the specimen evenly over the test circle.
8. Place the card on a mechanical rotator and rotate at 100 r.p.m. for 8 minutes.
9. Observe macroscopically for agglutination within a minute after removing the card from the rotator.

SEMI-QUANTITATIVE PROCEDURE

- **Mix well the RPR reagent before use**.

1. Make doubling dilutions from Undiluted to 1:16 normal saline.
2. Place 50 µl of each dilution in to a separate circle on the test card.
3. Spread each dilution evenly over the test circle.
4. Continue as from Qualitative procedure .
   The titer of the sample is expressed as the final dilution which shows aggregation of the carbon particles.

INTERPRETATION OF TEST RESULTS

1. **Strong Reactive:** Large clumps of carbon particles with a clear background.

2. **Reactive:** Large clumps of carbon particles somewhat more disperse than Strong Reactive pattern.

3. **Weak Reactive:** Small clumps of carbon particles with light grey background.

4. **Trace Reactive:** Slight clumping of carbon particles typically seen as a button of aggregates in the centre of the test circle or dispersed around the edge of the test circle.

5. **Non-Reactive:** Typically a smooth grey pattern or a button of non-aggregated carbon particles in the centre of the test circle.

<u>*LIMITATION OF THE TEST</u>

- Pregnancy may give a false positive reaction.
- Hepatitis and Brucellosis may give a false positive reaction.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

PERFORMANCE CHARACTERISTICS

Sensitivity: 100%.
Specificity: 100%.
Precision: 100%
Hook effect: no prozone effect up to the titer level studied: 1/16.
Interferences: There is no effect from Hemoglobin/Bilirubin and Rheumatoid factor on the results of RPR carbon antigen at the studied concentrations:
Bilirubin: ≤15 mg/dL.
Hemoglobin: ≤10 g/L.
Rheumatoid factor: ≤300 IU/ml.

REFERENCES

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control

<u>*: Indication of the introduced modifications.</u>

ASO LATEX KIT

IVD For in -*vitro* diagnostic and professional use only

Store at 2-8°C. CE

INTENDED USE

ATLAS ASO latex Test is used for the qualitative and semi-quantitative measurement of antibodies to Antistreptolysin-O in human serum.

INTRODUCTION

The group A ß-hemolytic streptococci produce various toxins that can act as antigens. One of these exotoxins streptolysin-O, was discovered by Todd in 1932.

A person infected with group A hemolytic streptococci produces specific antibodies against these exotoxins, one of which is antistreptolysin-O. The quantity of this antibody in a patient's serum will establish the degree of infection due to the hemolytic streptococcal.

The usual procedure for the determination of the antistreptolysin titer is based on the inhibitory effect that the patient's serum produces on the hemolytic power of a pre-titrated and reduced streptolysin-O. However, the antigen-antibody reaction occurs independently of the hemolytic activity of streptolysin-O. This property enables the establishment of a qualitative and quantitative test for the determination of the antistreptolysin-O by agglutination of latex particles on slide.

PRINCIPLE

ASO test method is based on an immunologic reaction between streptococcal exotoxins bound to biologically inert latex particles and streptococcal antibodies in the test sample. Visible agglutination occurs when increased antibody level is present in the test specimen.

MATERIALS

MATERIALS PROVIDED

- ASO Latex Reagent: Latex particles coated with streptolysin O, pH, 8,2. Preservative**.**
- ASO Positive Control (Red cap): Human serum with an ASO concentration > 200 IU/mL.Preservative.
- ASO Negative Control (Blue cap) Animal serum. Preservative
- Glass Slide.
- Stirring Sticks.

Note: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL.
- Glycine Buffer 20x (1000 mmol/l): add one part to nineteen parts of distilled water before use.

Packaging contents

REF **8.00.02.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

PRECAUTIONS

- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- For In Vitro diagnostic use.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (40µl). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

REAGENT PREPARATION:

The ASO Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- **DO NOT FREEZE.**
- The ASO Latex Reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagents deterioration: Presence of particles and turbidity.

SAMPLES

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- **DO NOT USE PLASMA.**

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. Mix the ASO-latex reagent vigorously or on a vortex mixer before using and add one drop (40 µL) next to the sample to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

Semi-quantitative method

1. Make serial two-fold dilutions of the sample in 9 g/L saline solution.

2. Proceed for each dilution as in the qualitative method.

QUALITY CONTROL

- Positive and Negative Controls should be included in each test batch.
- Acceptable performance is indicated when a uniform milky suspension with no agglutination is observed with the ASO Negative Control and agglutination with large aggregates is observed with the ASO Positive Control.

CALCULATIONS

The approximate ASO concentration in the patient sample is calculated as follows:

200 x ASO Titer = IU/mL

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates an ASO concentration equal or greater than 200 IU/mL

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

REFERENCE VALUES

Up to 200 IU/mL(adults) and 100 IU/mL (children < 5 years old). Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity:

200 (±50) IU/ml.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

SENSITIVITY

98%.

SPECIFICITY

97%.

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10 g/L)
- Bilirubin(20 mg/dL)
- Lipids (10 g/L)
- Rheumatoid factors (300 IU/mL)
- Other substances may interfere.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the ASO Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative ASO concentration; therefore, screening reactions should not be graded.
- False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers.
- Early infections and children from 6 months to 2 years may cause false negative results. A single ASO determination does not produce much information about the actual state of the disease.
- Titrations at biweekly intervals during 4 or 6 weeks are advisable to follow the disease evolution.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

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PPI2325A01
Rev A (05.01.2023)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control

RF LATEX KIT

IVD For In-*Vitro* diagnostic and professional use only

Store at 2-8°C CE

INTENDED USE

Atlas RF latex test for the qualitative and semi-quantitative measurement of RF in human serum.

INTRODUCTION

Rheumatoid factors (RF) are antibodies directed against antigenic sites in the Fc fragment of human and animal IgG. Their frequent occurrence in rheumatoid arthritis makes them useful for diagnosis and monitoring of the disease.

One method used for rheumatoid factor detection is based on the ability of rheumatoid arthritis sera to agglutinate sensitized sheep red cells, as observed by Waaler and Rose. A more sensitive reagent consisting of biologically inert latex beads coated with human gamma globulin was later described by Singer and Plotz. The RF kit is based on the principle of the latex agglutination assay of Singer and Plotz. The major advantage of this method is rapid performance (2-minutes reaction time) and lack of heterophile antibody interference.

PRINCIPLE

The RF reagent is based on an immunological reaction between human IgG bound to biologically inert latex particles and rheumatoid factors in the test specimen. When serum containing rheumatoid factors is mixed with the latex reagent, visible agglutination occurs.

MATERIALS

MATERIALS PR0VIDED

- RF Latex Reagent: Latex particles coated with human gamma-globulin, pH, 8,2. Preservative.
- RF Positive Control Serum (Red Cap): Human serum with a RF concentration > 30 IU/Ml. Preservative.
- *RF Negative Control (Blue Cap): Non-reactive buffer containing BSA and 0.1% sodium azide.
- *Glycine Buffer 20X (1000 mmol/L) (Optional): add one part to nineteen parts of distilled water before use.
- *Black glass Slide
- Stirring sticks

NOTE: This package insert is also used for individually packed reagent.

MATERIALS REQUIRED BUT NOT PROVIDED

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Pipettes 50 µL
- *9 g/L saline.

Packaging contents

REF **8.00.04.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

PRECAUTIONS

- *For *in vitro* diagnostic and professional use only. The test is not for near-patient or self-testing.
- All reagents contain 0.1 %(w/v) sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Reagents containing sodium azide may be combined with copper and lead plumbing to form highly explosive metal azides. Dispose of reagents by flushing with large amounts of water to prevent azide buildup.
- Components prepared using human serum found negative for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) by FDA required test. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent *(35µL ±5µL). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- *Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV, and antibody to HIV (1/2). However, handle cautiously as potentially infectious.
- *Wash the area of contact with water immediately if contact occurs.
- *Do not drink or ingest the reagent.
- *Do not use the reagent if the label is missing, damaged, or unclear.
- *Do not use white or transparent glass slides during testing.
- *Perform the test in a well-lit area with good visibility.
- *Close the vial after each test.
- *Failure in following the instructions may give incorrect results or face safety hazards.
- *Handle the used disinfectant with care.
- *Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

REAGENT PREPARATION:

- The RF Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

STORAGE AND STABILITY

- Reagents are stable until specified expiry date on bottle label when stored refrigerated (2-8°C).
- Do not freeze.
- Always keep vials in vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- The RF latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Reagents deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION AND STORAGE

- Use fresh serum collected by centrifuging clotted blood.
- If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- Do not use PLASMA.

PROCEDURE

Qualitative method

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop of each Positive and Negative controls into separate circles on the slide test.
3. *Swirl the reagent gently before use and add one drop (35 µL ±5µL) next to the sample to be tested.
4. *Close the vial tightly after use.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
6. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

***Semi-quantitative method**

Prepare serial two-fold dilutions of the sample in 9 g/L saline/glycine buffer (1X):

1. Allow the reagents and samples to reach room temperature.
2. Add (40 µL) of 9 g/L saline/glycine buffer (1X) into 6 circles of the black glass slide.
3. Add (40 µL) of the serum sample to the first circle.
4. Mix well using the pipette and then transfer (40 µL) from the first circle to the second circle, repeat until finishing the six circles.
5. Swirl the reagent vial.
6. Add one drop of RF reagent (35µL ±5µL) next to the samples in each circle.
7. Close the reagent vial.
8. Mix the drops with a stirrer, spreading them over the entire surface of the circle.
9. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates a RF concentration equal or greater than 8 IU/mL (Note 1).

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate RF concentration in the patient sample is calculated as follows:

8 x RF Titer = IU/mL

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.
- All result different from the negative control result, will be considered as a positive.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity

8 (6-16) IU/ml, under the described assay conditions.

PROZONE EFFECT

No prozone effect was detected up to 1500 IU/ml.

DIAGNOSTIC SENSITIVITY

100%.

DIAGNOSTIC SPECIFICITY

100%.

The diagnostic sensitivity and specificity have been obtained using 139 samples compared with the same method of a competitor.

***PRECISION**

100%.

INTERFERENCES

NON-INTERFERING SUBSTANCES:

- Hemoglobin (10g/L)
- Bilirubin (20mg/dl)
- Lipids (10g/L)

Other substances may interfere.

LIMITATIONS

- Reaction time is critical. If reaction time exceeds 2 minutes, drying of the reaction mixture may cause false positive result.
- Freezing the RF Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative RF concentration; therefore, screening reactions should not be graded.
- Increased levels of RF may be found in some diseases other than rheumatoid arthritis such as infectious mononucleosis, sarcoidosis, lupus erythematosus, Sjogren's syndrome.
- Certain patients with rheumatoid arthritis will not have the RF present in their serum.
- The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.
- Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

REFERENCE VALUES

Up to 8 IU/mL. Each laboratory should establish its own reference range.

NOTES

1. Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control

***: Indication of the introduced modifications.**

CRP LATEX KIT

IVD For *in vitro* diagnostic and professional use only

2°C 8°C Store at 2-8°C. CE

INTENDED USE

Atlas CRP Latex kit is a manual slide latex agglutination test for the qualitative and semi-quantitative detection of C-reactive protein (CRP) in human serum to aid in the diagnosis of individuals with suspected inflammation.

INTRODUCTION

C-reactive protein (CRP) is an evolutionarily conserved constitutive protein produced primarily by hepatocytes in minute amounts. At baseline levels, CRP mediates important biological functions. Its clinical significance as a component of the acute phase response emerged upon linking elevated blood levels of CRP to trauma, infection and inflammatory non-infectious disorders including autoimmune diseases. Its concentration can increase up to 1000-fold in severe inflammatory insults. CRP quickly rises in blood upon the onset of an acute stimulus (within 6 hours), and may double every 8 hours reaching a peak at 50 hours. Likewise, blood CRP rapidly drops upon cessation of the stimulus in an exponential manner. Although non-discriminatory of the root cause, elevated serum CRP has been established as an important marker of inflammation.

PRINCIPLE

The C-Reactive Protein test is based on the principle of the latex agglutination. When latex particles complexed with human anti-CRP are mixed with a patient's serum containing C- reactive protein, a visible agglutination reaction will take place within 2 minutes.

KIT COMPONENTS

Materials Provided

- **CRP Latex Reagent:** Latex particles coated with goat IgG anti-human CRP (approximately 1 %), pH 7.4. **MIX WELL BEFORE USE.**
- **CRP Positive Control (Red Cap):** Diluted human serum with CRP concentration > 20mg/L.
- **CRP Negative Control (Blue Cap):** Non-reactive buffer containing BSA and 0.1% sodium azide.
- **Glycine Buffer 20X (1000 mmol/L) (Optional):** add one part to nineteen parts of distilled water before use.
- **Black Glass Slide.**
- **Stirring Sticks.**
- **Package insert.**

NOTE: This package insert is also used for individually packed reagent.

Materials Required But Not Provided

- Mechanical rotator with adjustable speed at 80-100 r.p.m.
- Calibrated 50 µL micro-pipette.
- 9 g/L saline.

Packaging Contents

REF **8.00.00.0.0100 (1x4ml Latex Reagent, 1x1ml positive control, 1x1ml negative control)**

REAGENT STORAGE AND STABILITY

- Reagents are stable until specified expiry date on vial label when stored refrigerated (2 - 8°C).
- **DO NOT FREEZE.**
- The CRP latex reagent, once shaken must be uniform without visible clumping. When stored refrigerated, a slight sedimentation may occur and should be considered normal.
- Do not use the latex reagent or controls if they become contaminated.
- Always keep vials in a vertical position. If the position is changed, gently mix to dissolve aggregates that may be present.
- Reagent deterioration: Presence of particles and turbidity.

PRECAUTIONS AND WARNINGS

- For *in vitro* diagnostic and professional use only. The test is not for near-patient or self-testing.
- All reagents contain 0.1% (w/v) Sodium azide as a preservative.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- This kit is NOT to be used in CRP-guided therapy.
- Components containing human serum were tested for hepatitis B surface antigen (HBsAg), HCV and antibody to HIV (1/2) as required by FDA; and found to be negative. However, handle controls as if potentially infectious.
- Accuracy of the test depends on the drop size of the latex reagent (35 µL ±5µL). Use only the dropper supplied with latex and hold it perpendicularly when dispensing.
- Use a clean pipette tip and stirring stick for each specimen, and glass slides should be thoroughly rinsed with water and wiped with lint-free tissue after each use.
- Check reactivity of the reagent using the controls provided.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.
- Use forceps, scoops, or other mechanical devices for removing broken glass from the working area. A dustpan and brush should be used to clean up shards/small pieces of broken glass. Broken glass must be disposed of in a sharps container
- Wash the area of contact with water immediately if contact occurs.
- failure in following the instructions may give incorrect results or incur safety hazards
- Handle the used disinfectant with care.
- Close the vial after each test.
- Perform the test in a well-lit area with good visibility.
- Do not use white or transparent glass slides during testing.
- Do not touch, drink, or ingest the reagent.
- Certain nutritional supplements may effect on CRP levels.
- Any serious incident that occur in relation to the device shall be reported to the manufacturer and the competent authority. (Feedback@atlas-medical.com)

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

- Use fresh serum collected by centrifuging clotted blood.
- Samples with presence of fibrin should be centrifuged before testing. Do not use highly hemolyzed or lipemic samples.
- **Do not use plasma**.

SPECIMEN STORAGE AND STABILITY

If the test cannot be carried out on the same day, store the specimen for 7 days at 2-8°C and for 3 months at -20°C. Frozen samples should be completely thawed and brought to room temperature before testing. Avoid repeated freezing and thawing of the samples.

REAGENT PREPARATION

The CRP Latex reagent is ready to use. No preparation is required. Mix gently before use to ensure a uniform suspension of particles.

PROCEDURE

NOTE: The latex and sample volumes are very critical for correct test performance. Please adhere to the volumes stipulated in this package insert.

QUALITATIVE TEST:

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place (40 µL) of the sample and one drop (40 µL ±5µL) of each Positive and Negative controls into separate circles on the slide test.
3. Swirl the CRP latex reagent gently and add one drop (35 µL

±5µL) next to the samples and controls to be tested.
4. Close the reagent vial tightly.
5. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample and each control.
6. Place the slide on a mechanical rotator at 80-100 r.p.m. for **2 minutes**. False positive results could be obtained if the test is read later than two minutes.

B. SEMI-QUANTITATIVE TEST:

Prepare serial two-fold dilutions of the sample in 9 g/L saline/glycine buffer (1X):

1. Allow the reagents and samples to reach room temperature.
2. Add (40 µL) of 9 g/L saline/glycine buffer (1X) into 6 circles of the black glass slide.
3. Add (40 µL) of the serum sample to the first circle.
4. Mix well using the pipette and then transfer (40 µL) from the first circle to the second circle, repeat until finishing the six circles.
5. Swirl the reagent vial.
6. Add one drop of CRP reagent (35µL ±5µL) next to the samples in each circle.
7. Close the reagent vial.
8. Mix the drops with a stirrer, spreading them over the entire surface of the circle.
9. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes.

CALCULATIONS

The approximate CRP concentration in the patient sample is calculated as follows:

Sensitivity x CRP Titer = mg/L

(Sensitivity indicated on the label of the latex vial)

INTERPRETATION OF THE RESULT

Examine macroscopically the presence or absence of visible agglutination immediately after stopping the rotator.

The presence of agglutination indicates a CRP concentration equal or greater than the reagent sensitivity (mg/L CRP) (indicated on the label of the latex vial).

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

REFERENCE VALUES

Each laboratory should establish its own reference range.

QUALITY CONTROL

- Positive and Negative controls are recommended to monitor the performance of the kit, as well as providing a comparative pattern for better result interpretation.
- Any result that differs from the negative control result is considered positive.

LIMITATIONS OF THE TEST

- Reaction time is critical. If reaction time exceeds two (2) minutes, the reaction mixture may dry causing particles, which can be mistaken for false positive results.
- Freezing the CRP Latex Reagent will result in spontaneous agglutination.
- Intensity of agglutination is not necessarily indicative of relative CRP concentration; therefore, reactions should not be graded.
- A false negative can be attributed to a prozone phenomenon (antigen excess). It is recommended, therefore, to check all suspected negative sera by retesting with a 1:10 dilution in 9 g/L saline/glycine buffer (1X).

PERFORMANCE CHARACTERISTICS

- **Sensitivity:** 6 mg/L.
- **Prozone effect:** No prozone effect was detected up to 1600 mg/L.
- **Diagnostic sensitivity: 100 %** in comparison with a commercial latex kit.
- **Diagnostic specificity: 100 %** in comparison with a commercial latex kit.
- **Precision : 100%**
- **Interferences:**

  No interference was observed with the following substances at the concentrations indicated:
  - Hemoglobin (<15 g/dl)
  - Bilirubin (<20 mg/dl)
  - Lipids (<13 g/dL)
  - Other substances interfere, such as RF (>75IU/ml).

NOTES

- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

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PPI2327A01
Rev B (10.02.2024)

REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control

Atlas Medical CE

ATLAS SLE SLIDE TEST

IVD For *in vitro* diagnostic and professional use only

Store at 2°-8°C

INTENDED USE

Atlas SLE Slide Test is a slide agglutination assay for the qualitative and semi quantitative detection of anti-deoxyribonucleoprotein (anti-DNP) in human serum. No initial dilution of patient samples is required for this test. These materials are intended to be acquired, possessed and used only by health professionals.

INTRODUCTION

The detection of antinuclear antibodies, by such laboratory methods as immunofluorescence, LE cell test, and agglutination of coated particles, can aid in the diagnosis of such autoimmune diseases as systemic lupus erythematosus (SLE). The antibodies most associated with SLE are those directed against DNP. These antibodies are believed to cause the formation of the LE cell *in vitro*, occurring in 75-80% of patients diagnosed as having SLE. Given that 20-25% of SLE patients do not exhibit the formation of LE cells, other methods can be used to detect antinuclear antibodies.

PRINCIPLE

Atlas SLE Slide Test provides a means of detecting anti-DNP in human serum. SLE Slide reagent is a stabilized buffered suspension of polystyrene latex particles that have been coated with DNP. When the latex reagent is mixed with the serum containing antibodies to DNP, agglutination occurs. Using dilutions of a reactive patient sample, the anti-DNP titer can be determined.

MATERIALS

MATERIALS PROVIDED

- SLE Latex Reagent: Suspended inert latex particles coated with DNP, with 0.1% sodium azide as preservative.
- SLE Positive Human serum or defibrinated plasma (liquid), with 0.1% sodium azide as preservative.
- SLE Negative Control: Non-reactive buffer containing BSA and 0.1% sodium azide.
- Stirring sticks.
- Glass slide.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Timing device.
- 13 x 75 mm test tubes
- Volumetric pipet to deliver 0.25 ml
- Saline (0.9% NaCl solution)
- Mechanical rotator (optional)

PACKAGING CONTENTS

REF **8.00.11.0.0025 (1x1 mL Latex, 1x0.5 mL Positive Control, 1x0.5 mL Negative Control)**

REF **8.00.11.0.0050 (1x2 mL Latex, 1x0.5 mL Positive Control, 1x0.5 mL Negative Control)**

REF **8.00.11.0.0100 (1x4 mL Latex, 1x1 mL Positive Control, 1x1 mL Negative Control)**

PRECAUTIONS

- For *in vitro* diagnostic use.
- Latex reagent and controls contain sodium azide. Azides in contact with lead and copper plumbing may react to form highly explosive metal azides. When disposing of reagents containing azide, flush down the drain with large quantities of water to prevent azide build-up.
- The controls contain human serum or plasma which has been tested at the donor level for HBsAg and for HIV-1, HIV-2 and HCV antibodies and found to be nonreactive. As no known test offers complete assurance that infectious agents are absent, the controls should be considered potentially infectious and universal precautions should be used.
- Do not pipet by mouth.
- Do not smoke, eat, drink or apply cosmetics in areas where plasma/serum samples are handled.
- Any cuts, abrasions or other skin lesions should be suitably protected.
- In order to obtain reliable and consistent results, the instructions in the package insert must be strictly
- followed. Do not modify the handling and storage conditions for reagents or samples.
- Do not use past the expiration date indicated on the kit.
- Do not interchange components of one kit with those of another kit.
- Turbidity or precipitation in controls is indicative of deterioration and the component should not be used.
- Bacterial contamination of reagents or specimens may cause false positive results.

STORAGE & STABILITY

- Store all reagents at 2-8°C in an upright position when not in use.
- Do not freeze reagents.

SPECIMEN COLLECTION and STORAGE

- Use only serum that is free from contamination. Test samples should not be heat-inactivated.
- It is preferable to test samples on the day of their collection. If samples cannot be tested immediately, maintain them in their original tubes at 2-8°C and test within 48 hours.
- Serum samples stored longer than 48 hours should be stored at -20°C or below until testing. Avoid repeated freezing and thawing of specimens.
- If necessary before testing, centrifuge the specimens at a force sufficient to sediment cellular components.
- Samples to be sent out for testing should be placed on ice packs and packaged like any other biohazardous material that could potentially transmit infection.

REAGENT PREPARATION

- Allow all reagents and samples to warm to room temperature (20-30°C) before use. Do not heat reagents in a water bath.
- All reagents are ready for use as supplied. Gently mix the reagents before use; avoid foaming.
- Gently mix the latex reagent before each use to ensure homogeneity.

PROCEDURES

A. Method I (Qualitative)

1. Dispense (35 µL) of each serum sample onto a separate circle on the test slide. Add one drop of Positive and negative controls from the dropper vials supplied onto a separate circle on the test slide.
2. Dispense one drop of latex reagent (35 µL) to each serum specimen and to each control.
3. Using the flat end of the stirring sticks, mix each specimen and control serum with the latex reagent, in a circular manner, over the entire area in the circles of the card.

4. Gently tilt and rotate the card for one (1) minute and observe for agglutination. All test results should be compared to both positive and negative controls.

INTERPRETATION OF RESULTS (QUALITATIVE)

Agglutination indicates a reactive SLE sample. Sera that elicit a reactive result should be retested and tittered using the "Semi quantitative Assay Protocol".

B. Method II (Semi-Quantitative)

1. Prepare serial dilutions of patient serum, in saline, in test tubes as follows:

Tube	Dilution	Composition
1	1:2	0.25 ml of serum + 0.25 ml saline.
2	1:4	0.25 ml from tube 1 + 0.25 ml saline.
3	1:8	0.25 ml from tube 2 + 0.25 ml saline.
4	1:16	0.25 ml from tube 3 + 0.25 ml saline.
5	1:32	0.25 ml from tube 4 + 0.25 ml saline.
6	1:64	0.25 ml from tube 5 + 0.25 ml saline.

Note: Testing on additional dilutions should be performed as needed.

2. Using each dilution as a separate test specimen, apply the samples to the slide as described in Step 1 of the "Qualitative method" and proceed with Steps 2 through 4 of the "Qualitative method". Include undiluted sample if not tested previously on that day with the same lot of latex reagent.

INTERPRETATION OF RESULTS (SEMI-QUANTITATIVE)

The highest dilution in which visible agglutination occurs is considered the endpoint titer.

QUALITY CONTROL

Quality Control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included. If control samples do not yield the expected response, the assay should be considered invalid and the assay repeated. If the repeat assay does not elicit the expected results for the control samples, discontinue use of the kit and contact your local distributer.

EXPECTED VALUES

Serum samples from 155 individuals were tested using the **SLE Slide Test**. Of the 155 individuals, 29 had active SLE, 23 had clinically inactive SLE, 8 had connective tissue diseases and the remaining 95 were either clinically normal or had some nonrelated disease (including anemia, infectious mononucleosis and rheumatic heart disease) and were used as controls. Results from testing with the **SLE Slide Test** were compared with the results from testing of the samples using a standard LE cell preparation assay and a fluorescent ANA assay.

Of the 29 active SLE patients, 82% were positive using the SLE Slide Test, 86% were positive by the LE cell prep, and 82% positive by the ANA test. For the 23 clinically inactive SLE patients, 19% were positive by both the SLE Slide Test SLE and the LE cell prep; and 71% were positive by the ANA test. None of the 8 patients having connective tissue disease tested positive with the SLE Latex Test, whereas 17% and 50% tested positive by the LE cell prep and the ANA procedures, respectively. Of the controls, 1% tested positive by both the SLE Latex Test and the LE cell prep, while 6% tested positive by the ANA assay.

LIMITATION

1. Serum from patients with scleroderma, rheumatoid arthritis, dermatomyositis, and a variety of connective tissue diseases may elicit agglutination in the SLE slide test.
2. Because extremely high levels of antibodies might affect the degree of agglutination, positive samples should be reassayed using the semi quantitative procedure.
3. Contaminated, lipemic, or grossly hemolyzed sera should not be used because of the possibility of nonspecific results.
4. Plasma samples should not be used because of the possibility of nonspecific results.
5. Samples yielding indeterminate results may be resolved by repeating the test utilizing a two (2) minute slide rotation period. Reaction times longer than two minutes might cause false positive results due to a drying effect.
6. Drugs such as hydralazine, isoniazid, procainamide and a number of anticonvulsant drugs can induce an SLE syndrome.
7. In accord with all diagnostic methods, a final diagnosis should not be made on the result of a single test, but should be based on a correlation of test results with other clinical findings.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control