Atlas Medical

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.

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Date: 2025.11.06 13:51:10 EET
Reason: MoldSign Signature
Location: Moldova

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.

REFERENCES

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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

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

GRAM STAIN PACK

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

15°C 30°C **Store at Room Temperature**

INTENDED USE

Gram Stain used for differentiate between gram positive and gram-negative bacteria.

INTRODUCTION

Gram staining is used to differentiate bacterial species into two large groups (Gram-positive and Gram-negative) based on the physical properties of their cell walls.

PRINCIPLE

Gram-positive bacteria have a thick mesh-like cell wall made of peptidoglycan (50-90% of cell wall), which stains Blue while gram-negative bacteria have a thinner layer (10% of cell wall), which stains pink. Gram-negative bacteria also have an additional outer membrane which contains lipids, and is separated from the cell wall by the periplasmic space. There are four basic steps of the Gram stain, which include applying a primary stain (crystal violet) to a heat-fixed smear of a bacterial culture, followed by the addition of a trapping agent (Gram's iodine), rapid decolorization with alcohol or acetone, and *counterstaining* with safranin or basic fuchsin.

Crystal violet (CV) dissociates in aqueous solutions into CV^+ and chloride (Cl^-) ions. These ions penetrate through the cell wall and cell membrane of both gram-positive and gram-negative cells. The CV^+ ion interacts with negatively charged components of bacterial cells and stains the cells Blue.

Iodine (I^- or I_3^-) interacts with CV^+ and forms large complexes of crystal violet and iodine (CV–I) within the inner and outer layers of the cell. Iodine is often referred to as a mordant, but is a trapping agent that prevents the removal of the CV-I complex and therefore color from the cell.

When a decolorizer such as alcohol or acetone is added, it interacts with the lipids of the cell membrane. A gram-negative cell will lose its outer membrane and the lipopolysaccharide layer is left exposed. The

CV–I complexes are washed from the gram-negative cell along with the outer membrane. In contrast, a gram-positive cell becomes dehydrated from an ethanol treatment. The large CV–I complexes become trapped within the gram-positive cell due to the multilayered nature of its peptidoglycan. The decolorization step is critical and must be timed correctly; the crystal violet stain will be removed from both gram-positive and negative cells if the decolorizing agent is left on too long (a matter of seconds).

After decolorization, the gram-positive cell remains Blue. and the gram-negative cell loses its Blue. color. Counterstain, which is usually positively charged safranin or basic fuchsin, is applied last to give decolorized gram-negative bacteria a pink or red color.

MATERIALS

MATERIALS PROVIDED

- Crystal Violet.
- Gram Iodine.
- Gram Decolouriser.
- Counterstain – Safranin O.

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

Packaging Content

- REF **8.17.009.0400 (1x100ml Crystal Violet, 1x100ml Iodine Solution, 1x100ml Decolouriser, 1x100ml Safranin O)**
- REF **8.17.008.1000 (1x250ml Crystal Violet, 1x250ml Iodine Solution, 1x250ml Decolouriser, 1x250ml Safranin O)**
- REF **8.17.009.1000 (1x250ml Crystal Violet, 1x250ml Iodine Solution, 1x250ml Decolouriser, 1x250ml Safranin O)**
- REF **8.15.032.0250 (1x250ml Crystal Violet)**
- REF **8.15.049.0250 (1x250ml Iodine Solution)**
- REF **8.15.051.0250 (1x250ml Decolouriser)**
- REF **8.15.125.0250 (1x250ml Safranin O)**

STORAGE AND STABILITY

- Store at room temperature.
- Stain Solution is stable up to the printed expiry date.
- Keep the bottles tightly closed to prevent air oxidation.

PRECAUTIONS

- The reagent may cause eye, skin and respiratory tract irritation; so protective clothing should be worn when handling this reagent.
- The reagent is intended for in vitro diagnostic use only.
- Do not use this reagent if the label is not available or damaged.
- Test materials and samples should be discarded properly in biohazards container.
- This reagent is considered toxic, so do not drink or eat beside it.
- Wash hands and test table top with water and soap once the testing is done.

PROCEDURE

1. immerse the heat fixed smears with Crystal Violet and allow to stain for up to 1 minute.
2. Wash with tap water.
3. Flood the smear with Gram Iodine for 2 minutes.
4. Wash with tap water.
5. Decolorize the smear for few second only.
6. Wash thoroughly with tap water.
7. Counterstain with Safranin O for up to 2 minutes.
8. Wash and allow to dry.
9. Examine under microscope using oil immersion objective

RESULTS

- Gram positive organisms (Blue).
- Gram negative organisms (Red).

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PPI2112A01
Rev C (27.03.2023)

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
	Flammable		

STAPHYLOCOCCUS LATEX KIT

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

2°C 8°C Store at 2- 8° C CE

INTENDED USE

Atlas Staphylococcus Latex Kit is a slide agglutination assay for the qualitative detection of coagulase (both clumping factor and protein A) to identify Staphylococcus aureus to the exclusion of other species of staphylococci. This test is for use on pure culture samples suspected of being S. aureus. Staphylococcus Latex Kit does detect methicillin resistant S. aureus (MRSA) strains that produce clumping factor and protein A. These materials are intended to be acquired, possessed and used only by health professionals.

INTRODUCTION

Although staphylococci are commonly found on the skin and mucous membranes, they have been associated with many human and animal infections. *S. aureus*, coagulase positive staphylococci, has been identified as a cause of suppurative infections, food poisoning, toxic shock syndrome and has been isolated from nearly all anatomical sites.

PRINCIPLE

The coagulase tube test has long been accepted as the standard procedure routinely used for the identification of S. aureus. This and other procedures typically require 24 to 48 hours to complete. Staphylococcus Latex Kit is a test of this nature, utilizing plasma-coated latex particles that will simultaneously bind both clumping factor and protein A. The aggregation of the latex reagent upon mixing with a culture sample, within 45 seconds, represents a positive reaction. This test is easily visible to the unaided eye and has been shown to correlate 91% in one study, and 100% in another study, with the tube coagulase test.

KIT COMPONENTS

Materials Provided

- **Test Latex Reagent:** Suspended inert plasma-coated latex particles, with 0.1% Sodium Azide as preservative.
- **Negative Control (Non-reactive):** Suspensions of non-viable control organisms with 0.2% Sodium Azide and 0.2% Gentamicin Sulfate as preservatives.
- **Positive control (Reactive):** Suspensions of non-viable control organisms with 0.2% Sodium Azide and 0.2% Gentamicin Sulfate as preservatives.
- One Glass slide (6-wells).
- Package insert.

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

Materials Needed But Not Provided

- Stirring Sticks.
- Timing Device

PACKAGING CONTENT

REF **8.00.12.0.0100 (1x4.0ml Test Latex, 1x1.0ml Negative Control Latex, 1x1.0ml Positive Control, Glass Slide)**

REAGENT PREPARATION

Latex reagents are ready to use. Bring to room temperature and mix slowly the latex reagents to obtain a homogenous suspension.

PRECAUTIONS AND WARNINGS

- The reagents are intended for *in vitro* diagnostic and professional use only.
- Latex reagent and controls contains 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.
- Do not pipet by mouth.
- Do not smoke, eat, drink or apply cosmetics in areas where patient 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.
- Bacterial contamination of reagents or specimens may cause false positive results.

STORAGE CONDITIONS

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

SPECIMEN AND SAMPLE PREPARATION

- Use only pure, 24-hour cultures, grown on 5% sheep blood agar plates.
- Handle cultures using standard biohazard techniques.
- 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.

PROCEDURE

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

Assay protocol – qualitative

1. Add a drop of the latex reagent to a well of the test slide.
2. Using a disposable stirrer, collect a visible amount of an isolated colony about 2 mm in size from the overnight culture grown on 5% sheep blood agar plate.
3. Emulsify the culture sample in the latex reagent on the slide. Discard the stirrer into an appropriate biohazard container.
4. Add one free-falling drop of positive or negative controls from the dropper vial supplied. Note the location of each sample by using the numbers of each slide well.
5. Gently tilt and rotate the slide in a complete circular motion for up to 45 seconds, or until agglutination is evident, whichever comes first. Positive reactions usually occur within 15-20 seconds.
6. View the mixture on the slide, using only a high intensity light source. Do not use a magnifying lens. Record the results.

READING THE RESULTS

NEGATIVE: Sandy appearance or no visible agglutination after 45 seconds.

POSITIVE: Visible agglutination as compared to the negative control.

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. If control samples do not yield the expected response, the assay is considered invalid and the assay should be repeated. If the repeated assay does not elicit the expected results for the control samples, discontinue use of the kit and contact your distributor.

To check for auto agglutination, add one drop of latex reagent to a slide. No degree of agglutination should occur.

LIMITATIONS

- Strains of some S. aureus which do not possess clumping factor and protein A may give negative results in the test. Additional biochemical tests may be necessary to assist in identification.
- Occasionally a culture sample may cause latex reagent to appear stringy or speckled and not demonstrate typical agglutination. This result necessitates further biochemical testing to identify the organism.
- False positive results may occur with S. saprophyticus for protein A and therefore cause misidentification as S. aureus. Protein A determinations should not be performed alone, especially on cultures from urine.
- Less than heavy suspensions of the test organism can be used, but reactions tend to be weaker and slower in agglutinating and may lead to erroneous results.
- Rough strains of staphylococci and yeasts frequently cause nonspecific reactions and should therefore be distinguished by morphological criteria.
- Some streptococci possess plasma protein-binding factors;

and several species, such as members of the enterobacteriaceae, nonspecifically agglutinate latex particles.

- Gram stains should be performed to ensure that only organisms with staphylococcal morphology are tested.
- Media such as mannitol salt agar, containing high salt concentrations, inhibit protein A production and can cause false negative reactions.
- Temperature of the REAGENTS and samples is crucial to test outcome. It should be between 20 and 30°C.
- Reaction times longer than specified might cause false positive results due to a drying effect.
- In accord with all diagnostic methods, a final diagnosis should not be made on the results 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 -	Negative control	CONTROL +	Positive 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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	Keep away from sunlight		Keep dry
CONTROL +	Positive control	CONTROL -	Negative control

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