ASO VISILATEX – SLIDE ASSAY

CAT NO	DESCRIPTION	PACK SIZE
LATASO4	ASO VISILATEX – LATEX REAGENT ONLY	1L

Intended Use:

ASO Visilatex is a rapid slide agglutination procedure intended to be used for the direct detection and semi quantitation of Anti Streptolysin O (ASO). This reagent is for In vitro diagnostic use by trained professionals only.

Summary and Principle:

A suspension of latex particles coated with Streptolysin O antigen is added to a test sample. The presence of absence of a visible agglutination indicates the presence or absence of ASO in the samples tested.

Reagent Composition:

ASO Latex Reagent	**Polystyrene Latex particles coated with Streptolysin O antigen stabilized in a buffered saline**
	Sodium Azide 0.95 g/l
Positive Control	**Serum Base with ASO activity of >200 IU/ml**
Negative Control	**Serum base with ASO activity of <100 IU/ml**

Warnings and Precautions:

- The reagent contains Sodium azide. Do not allow contact with skin or mucous membranes.
- Components of different human origin have been tested and found to be negative for the presence of antibodies to HIV 1+2 and HCV as well as for HBsAg. However, controls should be handled as potentially infectious.

Reagent Preparation and Stability:

Unopened reagents are stable up to expiry when stored at 2 - 8°C.
The reagents and controls are provided liquid stable. Once opened store at 2 - 8°C tightly capped. Do not freeze.

Materials required but not provided:

Pipettes, Saline solution (0.9% NaCl for semi quantitation), mechanical rotor adjustable to 100 rpm.

Specimen Collection:

Collect clear serum by separation after standard venepuncture technique. Samples that cannot be tested immediately may be stored at 2 - 8°C up to 1 week. For longer term storage keep serum samples at -20°C for up to 3 months.
Before use, bring all samples to room temperature (+25°C)

Procedure:

Qualitative Assay:

1. Ensure that the test reagents and the samples are at room temperature.
2. Mix the Latex reagent gently by aspirating and expulsion of the reagent using the dropper several times.
3. Place 1 drop of serum (40 µl) in one of the circles on the card. On separate additional circles place 1 drop of Positive Control and Negative Control.
4. Add 1 drop (40 µl) of ASO Latex reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide by means of a mechanical rotor (100 rpm) for a period of 2 minutes.
7. Observe immediately under a suitable light source for any degree of agglutination.

Interpretation:

- Non Reactive: Smooth suspension with no visible agglutination as shown by negative control
- Reactive: Any degree of agglutination visible macroscopically.

Semi-Quantitative Assay:

1. For each sample to be tested pipette 40 µl of 0.9% saline into each of the circles (6 circles) of a reaction card. Do not spread the saline.
2. To circle 1 add 40 µl of sample. Mix well by repeated aspiration and expulsion and transfer 40 µl of the mixture to the saline solution in the second circle. Mix as above.
3. Continue with the 2-fold serial dilutions up to the last circle and discard 40 µl from the last circle. Final sample dilutions will be 1/2, 1/4, 1/8, 1/16, 1/32, 1/64.
4. Test each dilution as described in the steps 4-7 for the qualitative assay.

Interpretation:

- Non Reactive: Smooth suspension with no visible agglutination as shown by Negative Control
- Reactive: Any degree of agglutination visible macroscopically. The titre of the sample is reported as the highest dilution that shows agglutination. If the highest dilution is still reactive, repeat the test starting with a 1/16 dilution. As the diluent, use a 1/50 dilution of Negative Control serum in 0.9% saline solution to make the new dilution series starting at 1/16. The approximate amount of ASO found in the sample can be estimated by multiplying the titre of the hightest positive dilution by the minimum detectable unit (the analytical sensitivity).

Expected Values:

95% of healthy adults have ASO titres of 200 IU/ml or less. Highest titres have been found in school children with titres up to 250 IU/ml. Since a single ASO determination does not provide much information, it is recommended that titrations at bi-weekly intervals are carried out for a period of 4-6 weeks. The ASO titres resulting from ordinary streptococcal infections and acute rheumatic fever differ in that the titre of the latter condition is usually much higher and persists for a longer period of time.

Quality Controls:

Positive and Negative Controls should be run regularly following the steps outlined in the qualitative assay. The Positive Control should produce clear agglutination. If it does not, discard the kit and use a fresh one for further assays.

Performance Characteristics:

- The minimum detectable limit (analytical sensitivity) is ~200 IU/ml as tested against a ASO International Calibrator (WHO).
- Diagnostic Sensitivity: 98%.
- Diagnostic Specificity: 97%.
- No prozone effect was observed up to 1500 IU/ml.

Limitations:

- False positive reactions may occur in serum from patients with other conditions including scarlet fever, early and acute periods of rheumatoid arthritis and tonsillitis.
- Biologically false negative reactions can occur in early primary infections in children from 6 months to 2 years.

Note:

- The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15 - 25°C.
- Delays in reading the results may result in over-estimation of the antibody present. Do not interpret results after 2 minutes.
- A positive result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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Sources of Error:

- Bacterial contamination of controls and specimens as well as freezing and thawing of the antigen may lead to false positive results.
- Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until all reactants are removed and then with distilled water. Allow to air dry, avoiding the use of organic solvents as they may impair the special finish on the slide.
- The ASO latex antigen must not be used beyond its expiry date because prolonged storage can affect the sensitivity of the suspension.

References:

1. Haffejee. Q J Med. 1992; 384: 641-658.
2. Samir et al. Pediatric Annals. 1992; 21: 835-842.
3. Spaun J et al. Bull Wld Hlth Org. 1961; 24: 271-279.
4. Klein, G.C Manual of Clinical Immunology, Chapter 33, American society for Microbiology, Washington DC. (1976)
5. Young D.S.et al., Effect of Drugs on Clinical Laboratory Tests, 3rd ed., AACC Press Washington DC 1990.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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