ASO
Agglutination Slide Test

INTENDED USE
Kit for the Qualitative and semi-quantitative determination of Anti-Streptolysin-O (ASO) in Human Serum.

TEST PRINCIPLE
The latex reagent is coated with Streptolysin-O Antigen. The specimen containing ASO, on mixing with latex reagent agglutinates, showing the positive test result. If ASO is absent there will be no agglutination, which is a negative test result.

MATERIALS PROVIDED
1. Reagent 1: Latex Reagent
2. Reagent 2 : Positive Control
3. Reagent 3 : Negative Control
4. Glass slide with drawn circles (Optional)
5. Disposable sample droppers (Optional)
6. Disposable mixing sticks (Optional)
7. Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED
1. Vortex mixer
2. Normal saline
3. Micropipettes and microtips
4. Tissue paper
5. Stopwatch

WARNING AND PRECAUTIONS
1. Firmly shake the latex reagent vial properly to get the homogenous latex particles before testing.
2. Do not freeze the latex reagent.
3. Cap the vial properly after use to avoid drying of the latex reagent.
4. Drying of the samples and latex reagent mixture at the periphery of the circle could lead to erroneous results.
5. Positive & negative controls are ready to use & should not be diluted while using in test procedure.
6. This package insert must be read completely before performing the test, Failure to follow the package insert may give inaccurate test results.
7. Do not use expired test kit.
8. Bring all components to room temperature (15°C-30°C) before use.
9. Do not use the components of any other type of test kit as a substitute for the components in this kit.
10. Apply standard biosafety precautions for handling and disposal of potentially infective material:
    - Handle all specimens as potentially infectious.
    - Wear gloves while handling specimens and performing the test.
    - Clean up spills thoroughly using an appropriate disinfectant.
11. Do not smoke, drink or eat in areas where specimens or kit is being handled.
12. Dispose off all left over specimens and materials used to perform the test as biohazardous waste.

STORAGE AND EXPIRATION
Please refer to the outer box for details. The kit components are stable up to expiry date indicated on the component label.

SPECIMEN COLLECTION AND HANDLING
Fresh serum is the preferred specimen. Plasma and hemolysed/lipaemic serum should not be used.

TEST PROCEDURE
A. QUALITATIVE TEST
1. Bring all the reagents and specimens to room temperature before use. Shake the latex reagent gently to ensure homogenous suspension.
2. Place one drop (approximately 35-40 µl) of test specimen on to the glass slide using disposable droppers provided in the kit.
3. Add one drop of latex reagent to the test specimen on the glass slide by holding the latex reagent vial vertically. Do not let the dropper tip touch the liquid on the glass slide.
4. Using a mixing stick, mix the test specimen and latex reagent uniformly over the entire circle.
5. Immediately start a stopwatch.
6. Results should be read at a normal reading distance in good light. Do not examine for agglutination after 2 minutes. Do not use magnifying lens.

INTERPRETATION OF RESULTS
1. Agglutination is a positive result and indicates presence of Anti-Streptolysin (ASO) in the test specimen (serum).
2. No agglutination is a negative test result and indicates absence of Anti-Streptolysin (ASO) in the test specimen (serum).
3. Agglutination with Positive Control and no agglutination with Negative Control validates test results.
4. Distinct agglutination within 2 minutes indicates ASO concentration of more than or equal to 200 IU/ml.
5. Do not interpret results after 2 minutes.
6. Sera with positive results should be retested in the semi-quantitative test.

B. SEMI QUANTITATIVE TEST
1. Dilute the specimen serially 1:2, 1:4, 1:8, 1:16, using normal saline.
2. Place one drop of each dilution of serum specimen using sample droppers on to separate circles of glass slide and proceed further as in qualitative test A proceed from step 3.

INTERPRETATION OF RESULTS
The highest dilution which shows clear-cut agglutination within 2 minutes, indicates the ASO titre. The approximate ASO concentration can be obtained by multiplying the titre with sensitivity of the test.
ASO in IU/ml = D X S
where, D = Highest dilution showing clear cut agglutination.
S = Sensitivity of the test i.e, 200 IU/ml.

INTERFERENCES
Bilirubin (20 mg/dl), hemoglobin (10 g/L) and lipids (10 g/L) do not interfere. Other substances may interfere.

LIMITATIONS
The incidence of false positive result 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 other tests along with the clinical examination history.

PERFORMANCE CHARACTERISTICS
Analytical sensitivity : 200 IU/ml
Prozone effect : No prozone effect was detected up to 1500IU/ml
Diagnostic sensitivity : 98%
Diagnostic specificity : 97%

DISCLAIMER
Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result. The manufacturer and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

REFERENCES

1. Young DS. Effects of drugs on clinical laboratory test, 4th ed. AACC Press, 1995.
2. Ahmed Samir et al. Pediatric Annals 1992; 2: 835-842.
3. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279.

SYMBOLS AND EXPLANATIONS

Symbol	Explanations	Symbol	Explanations
	Instructions for use		Storage temperature
IVD	For in-vitro diagnostic use		Expiry date
	Do not reuse	REF	Ref./Catalogue number
	Keep away from sunlight		Manufactured by
	No. of tests		Manufacturing date
CE	Conformite Europeenne	EC REP	Authorized Representative

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IFU/ASO/102 R-00
Date of issue - 2020-12-12

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