PRINCIPLE OF THE METHOD
The ASO reagent is a suspension of polystyrene latex particles coated with stabilized Streptolysin O. The reagent has been adjusted in the way that the presence of an ASO titer of 200 IU/mL or higher in the serum gives a visible agglutination of the latex particles without previous sample dilution.

REAGENTS
Latex : Latex particles coated with streptolysin O, pH, 8.2.
Preservative
Control + : Human serum with an ASO concentration > 200 IU/mL. Preservative
Control - : Animal serum. Preservative

PRECAUTIONS
Reagents containing sodium azide may combine with copper and lead plumbing to form highly explosive metal azides. Dispose of reagent by flushing with large amounts of water to prevent azide buildup.

The positive and negative controls were prepared from human sera, which have been tested and found to be non-reactive for the presence of HbsAg, HCV and HIV(1/2) antibodies. However, no test method can offer complete assurance that infectious agents are absent. Therefore all human specimens should be considered potentially infectious.

CALIBRATION
The ASO-latex sensitivity is calibrated against the ASO International Calibrator (WHO).

STORAGE AND STABILITY
The reagent and control sera are stable up to the expiry date when stored at +2 to 8°C. Do not freeze!

SAMPLES
Use fresh clear serum specimens. Plasma, lipemic serum or microbial contamination may cause erroneous results. If the test cannot be performed immediately, store the specimen at +2 to +8°C for up to 8 days. For longer storage, up to 3 months, freeze the serum at −20°C.

Samples with presence of fibrin should be centrifuged.

PROCEDURE
Qualitative Test :
1. Bring reagents and specimens to room temperature before use.
2. Place one drop (50 µl) of the positive control on field #1 of the reaction slide. Place one drop (50 µl) of the negative control on field #2. Using a pipette, place one drop (50 µl) of each undiluted test specimen on successive fields.
3. Gently resuspend the Latex Reagent and add one drop (50 µl) to each test field. Use stick to spread reaction mixture over entire test field. Use different sticks for each sample.
4. Rotate the slide (80-100 r.p.m.) for 2 minutes and read immediately under direct light.

Semi-quantitative Test :
1. Bring reagents and specimens to room temperature before use.
2. Using saline, dilute the specimens 1:2, 1:4, 1:8, 1:16, or as needed.
3. Proceed for each dilution as in the qualitative method.

Dilutions 1/2 1/4 1/8 ...
Sample serum 100µl
Saline 100µl 100µl 100µl ...
Volume of the sample 50 µl 50 µl 50µl ...

READING AND INTERPRETATION
A negative reaction is indicated by a uniform milky suspension with no agglutination as observed with the negative control (2). A positive reaction is indicated by any observable agglutination in the reaction mixture. The specimen reaction should be compared with the positive control (1).

Interpretation :
Positive (1) negative (2)
Agglutination within 2 min. No Agglutination within 2 minutes

The titer of the serum is the reciprocal of the highest dilution that exhibits a positive reaction.

Concentration will be reciprocal of positive reading dilution x 200:

IU/ml 400 800 1600

Normal Levels : Adults < 200 IU/ml
Elevated serum titers happen as a result of infectious coming from beta-hemolytic Streptococci, producers of Streptolysin O.

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.

PERFORMANCE CHARACTERISTICS
1. Analytical sensitivity: 200 (± 50) IU/mL, under the described assay conditions
2. Prozone effect: No prozone effect was detected up to 1500 IU/mL.
3. Diagnostic sensitivity: 98 %.
4. Diagnostic specificity: 97 %.

INTERFERENCES
Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipids (10 g/L), rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere.

NOTES
Contaminated sera and a longer reaction time than 3 minutes may cause false positive agglutination. As with all diagnostic methods, the 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.
False positive results may be obtained in conditions such as, rheumatoid arthritis, scarlet fever, tonsillitis, several streptococcal infections and healthy carriers.
Early infections and children from 6 months to 2 years may cause false negative results.

Langdorp, 09.2012