ASO FL

AS 0050 CH	1 x 50 ml
AS 0100 CH	2 x 50 ml

INTENDED USE

Reagent for quantitative in vitro determination of antistreptolysin O in biological fluids.

SUMMARY OF TEST

Antistreptolysin O (ASO) is an antibody targeted against streptolysin O (SLO), a toxic enzyme produced by group A streptococcus bacteria. These bacteria cause strep throat and a variety of other infections, including skin infections (pyoderma, impetigo, cellulitis). In the course of a streptococcal infection, SLO stimulates the production of specific antistreptolysin antibodies, which act to neutralize the hemolytic properties of the antigen. Measurement of ASO is important in the investigation of post-streptococcal diseases, particularly acute post-streptococcal glomerulonephritis and rheumatic fever.

PRINCIPLE OF THE METHOD

Antibodies of the sample selectively react with Streptolysin O coated to latex, thus producing particle agglutination. The produced turbidity is proportional to the concentration of ASO in the sample, and can be measured at the wavelenght of 600 nm.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

ASO R1 **0050: 1 x 45 ml (liquid) white cap**
0100: 2 x 45 ml (liquid) white cap

Composition: Buffer pH 7.4, stabilizers and preservatives.

ASO R2 **0050: 1 x 7.5 ml (liquid) red cap**
0100: 2 x 7.5 ml (liquid) red cap

Composition: suspension of latex particles coated with Streptolysin O, stabilizers and preservatives.

Standard: ASO solution - 2 ml

Store all components at 2-8°C.

REAGENT PREPARATION

Use separate reagents ready to use.
Kindly shake R2 vial before use.
Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: use preferably within 60 days at 2-8°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

SPECIMEN

Serum, plasma.
Keep specimens away from direct light sources.
Samples are stable 2 days when stored at 2-8°C and 1 month at -20°C.

TEST PROCEDURE

Wavelength: 600 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	calibrator	sample
reagent R1	900 µl	900 µl	900 µl
water	10 µl	-	-
calibrator	-	10 µl	-
sample	-	-	10 µl

Mix, incubate at 37°C for 5 minutes.
Read against reagent blank the absorbances of calibrator (Ac_1) and sample (Ax_1).

dispense:	blank	calibrator	sample
reagent R2	150 µl	150 µl	150 µl

Mix, incubate at 37°C for 5 minutes.
Read against reagent blank the absorbances of calibrator (Ac_2) and sample (Ax_2).

RESULTS CALCULATION

serum/plasma sample:

$$\text{ASO (IU/ml)} = \frac{Ax_2 - Ax_1}{Ac_2 - Ac_1} \times \text{standard value}$$

EXPECTED VALUES

Adults < 200 IU/ml

Each laboratory should establish appropriate reference intervals related to its population

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA - MULTINORM CHEMA
with normal or close to normal control values,
QUANTIPATH CHEMA - MULTIPATH CHEMA
with pathological or close to pathological control values.

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity
the method is linear up to 400 IU/ml.
If the value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Hook effect
No Hook effect is observed with concentrations lower than 4100 IU/ml.

Sensitivity/limit of detection
The limit of detection is 10 IU/ml.

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 1000 mg/dl
bilirubin	≤ 60 mg/dl
lipids	≤ 2500 mg/dl
rheumatoid factor	≤ 250 IU/ml

Precision

intra-assay (n=10)	mean (IU/ml)	SD (IU/ml)	CV%
sample 1	74.7	1.56	2.09
sample 2	173.1	2.84	1.64

inter-assay (n=20)	mean (IU/ml)	SD (IU/ml)	CV%
sample 1	75.7	3.44	4.54
sample 2	172.7	4.58	2.65

Methods comparison
A comparison between CHEMA and a commercially available product gave the following results:

ASO competitor = x
ASO FL CHEMA = y
n = 43

$y = 0.93x + 2.88$ IU/ml $r^2 = 0.97$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Johnson G.D. *J. Clin. Path.* 1955, 8, 296.
Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006), 366.

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

CE