Automation Hitachi™ **IVD**

TAS - ASO

Quantitative turbidimetric latex assay for the measurement of antibodies antistreptolisyn (ASO) in human serum

REF	Σ	REAGENTI	
101336150H	Content : 50 ml Manual : 50 test	R1:1x40 mL R2:1x10 mL	+4 +8

Test AUTOMATION

Hitachi 704 143

Hitachi 717, 902, 911, 912 200

1.0 CLINICAL SIGNIFICANCE(3-5)

ASO is a group of specific antibodies developed against an exoenzyme produced by β-heamolitic Streptococci of groups A, C and G.Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis, bacterial endocarditis and streptococcal infections. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as skin, heart, joints etc… and acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

2.0 METHOD PRINCIPLE

The latex particles coated with streptolisyn O (SLO) are agglutinated when they react with samples that containing specific antibodies antiestreptolisyn O (ASO). The latex particles agglutination is proportional to the concentration of the ASO in the sample and can be measured by turbidimetry (1).

3.0 SAMPLES

Fresh serum. Stable for 7 days at 2-8ºC or 3 months at –20ºC.Samples with presence of fibrin should be centrifuged before testing.Hemolyzed or contaminated samples are not suitable for testing.

4.0 REFRENCE VALUES

Adults	up to 200 IU/mL
Children (< 2 years)	up to 150 IU/mL
Children (school age)	up to 250 IU/mL

It is recommended that each laboratory establishes its own reference range.

5.0 REAGENTS

Reagent 1-Diluent Tris buffer 20 mmol/L, pH 8.2.

Reagent 2-Latex Latex particles coated with estreptolisyn O, pH 10.0.

6.0 PREPARATION OF THE REAGENTS

Working reagent (only for manual method)

Swirl the latex vial before use. Mix Latex and Diluent in a 1:4 ratio (i.e. 2 mL R2 + 8 mL R1) prior to use.

6.1 STORAGE AND STABILITY

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use the reagents after the expiration date.

Working reagent is stable during 20 days at 2-8 ºC. Shake gently the vial before use.Reagent deterioration: presence of particles and turbidity.

7.0 PRECAUTIONS IN USE

The reagents contain inactive components such as preservatives(Sodium azide or others), surfactants etc. The total concentration of these components is lower than the limits reported by 67/548/ECC and 88/379/EEC directives about classification, packaging and labelling of dangerous substances. However, the reagents should be handled with caution, avoiding swallowing and contact with skin, eyes and mucous membranes.The reagents from human donors have given negative results to anti-HIV 1/2, HBsAg and anti-HCV. It is recommended to handle with caution.The use of the laboratory reagents according to good laboratory practice is recommended.(9)

8.0 MATHERIAL NEEDED BUT NOT PROVIDED WITH THE KIT

- Automatic pipette to measure reagent and sample, Thermostatic bath at 37 ℃, Spectrophotometer or photometer thermostatable at 37 ℃ capable to read 540 ± 20 nm, Analysis cuvettes (optical path = 1 cm), - NaCl (9 g/L) solution, Calibrator, Plasma protein control Normal - Pathological .

9.0 PROCEDURE MANUAL

1. Prewarm the reagent and the photometer (cuvette holder) to 37 ºC.
2. Using distilled water zero the instrument at 540 nm.
3. Pipette into a cuvette:

Sample / Calibrator	10 µL
Working Reagent	1.0 mL

4. Mix well and insert the cuvette into the photometer. Record the absorbance (A1) immediately and after 2 minutes (A2) of the sample or calibrator addition.

10.1 PROCEDURE AUTOMATION (Hitachi 717)

TEST	(.....)
TEST NAME	ASO
2: CHEMISTRY PARAMETERS	
TEST	(....)
ASSAY CODE	3-23-35
SAMPLE VOLUME (uL)	3-0
R1 VOLUME	200-100-0
R2 VOLUME	50-20-0
WAVELENGHT	0-546
CALIB.METHOD	1-0-0
STD1 CONC – RACK POS.	0.0-1
STD2 CONC. – RACK POS.	(....)-2
UNIT	UI/ml
SD LIMIT	0.5
DUPLICATE LIMIT	300
SENSITIVITY LIMIT	0
ABS LIMIT	6000-0
PROZONE LIMIT	0-0
EXPECTED VALUES	0-200
PANIC VALUE	(....)-(....)
INSTRUMENT FACTOR	1.00
4: CHANNEL ASSIGNEMENT	
PHASE	(....)
TEST1 (....)	

10.0 RESULT CALCULATION

$$\frac{(A_2\text{-}A_1)_{\text{campione}}}{(A_2\text{-}A_1)_{\text{calibratore}}} \times \text{CAL conc.} = \text{IU/mL ASO}$$

11.0 QUALITY CONTROLS

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

12.0 ANALYTICAL PERFORMANCE

Linearity The method is linear up to 800 IU/mL, under the described assay conditions. Samples with higher concentrations should be diluted 1/5 with NaCl 9 g/L and retested again.

Detection limit Values less than 12 IU/mL give non-reproducible results.

Analytical sensitivity. 0.8 mA/IU ASO/mL

Prozone effect Prozone effect is not observed up to 4000 IU/mL.

12.5 Precision

	Media (mg/L)	CV (%)
Intra-serie N = 10	161.7	5.2
	411.3	4.3
	593	1.8
Inter-serie N = 10	161.7	4.6
	411.3	4.3
	593	3.7

Accuracy.Results obtained with this reagent did not show systematic differences when compared with commercial reagents of similar characteristics. Details of comparison are available on request.

Interferences.Bilirubin (40 mg/dL), hemoglobin (12 g/L), lipemia (10 g/L) and rheumatoid factors (800 IU/mL), do not interfere. Other substances may interfere8.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.

2. The linearity limit depends on the sample/reagent ratio, as well as the analyzer used. It will be higher by decreasing the sample volume, although the sensitivity of the test will be proportionally decreased.

3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

14.0 Waste Management

Please refer to local legal requirement.

15.0 REFERENCES

3. Haffejee I, Quarterly Journal of Medicine, New series 84; 305: 641 (1992).
4. Kassem AS et al. Pediatric Annals. 21 : 853 (1992).
5. Bisno DL. N Engl J Med 325 : 783 (1991).
6. Wannamaker LW. Circulation. 21: 598 (1960).
7. Klein GC et al. Appl Microbiol. 21: 758 (1971).
8. Young DS. Effects of drugs on clinical laboratory tests. 3th ed. AACC Press (1997).
9. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC…

16.0 LEGENDA SIMBOLI – DIRETTIVA 98/79/CE

Attenzione, consultare le istruzioni per l'uso	Σ N°determinazioni per kit	Fabbricante	
IVD Solo per uso diagnostico	Usare entro	Non riutilizzare	
2°C–30°C Conservare a 2-30℃	LOT Numero del lotto	REF Codice #	

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ASO_150H912-CE_ UK_0_200710 Rev. 0 - 20 JULY 2010