Hipro Biotechnology Co.,Ltd

EN
ENGLISH

ASO

Antistreptolysin O Test Kit
(Nephelometry Immunoassay Method)

Instructions for Use

Version: A/8

REF HP-ASO-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co., Ltd.
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Product Name

General Name：Antistreptolysin O Test Kit（Nephelometry Immunoassay Method）

Specification

Package Specification
25 Tests/ Kit.

Intended Use

This product is used to determine the content of Anti-Streptolysin"O" (ASO) in human blood, and specific reagent for the specific protein analyzer, applies only to the clinical in vitro assisted diagnosis.

Streptolysin "O" is one of the metabolites of group A hemolytic streptococcus, a hemolytic activity of the protein, highly immunogenic. Hemolytic streptococcus group A in the human body exists as normal flora. The ASO has certain basic values in the normal human body. ASO increased after Hemolytic streptococcus infected. Therefore, ASO has become an important indicator to determine the streptococcal infection. Patients with Hypercholesterolemia or macroglobulinemia may also appear the ASO elevated.

Test Principle

The ASO units conjugated Anti-Streptolysin"O" (ASO) in the latex surface. ASO in the sample and the antibody become to immune complexes by Latex condensation reaction. The immune complexes will produce the phenomenon of light scattering, is proportional to the intensity of scattered light and samples of ASO levels. Using specific protein analyzer to measure the intensity of scattered light, the concentration of ASO is determined by comparing the turbidity of samples to the standard concentration.

Component

The ASO test kit consists of two reagents R1 and R2, as shown on Figure 1.

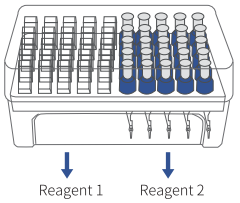


Figure 1

Name	Content	Quantity
Reagent 1 (R1)	Phosphate buffer	0.1mol/L
	Polyethylene glycol	2%
Reagent 2 (R2)	antibody sensitized latex	appropriate
	Phosphate buffer	0.1mol/L
IC card (optional)	/	1

Do not mix different batches of reagents.

Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated on the label. The test kit is stable for one year when unopened. Use up the test kit within one month after opening the package.

Do not freeze the test kit.

Do not mix different lots of the test kit.

Special Instrument Requirements

HP-083/4-I POCT Immunoassay System,
HP-083/4-II POCT Immunoassay System,
HP-AFS/1 Automatic Immunoassay System,
HP-AFS/3 Automatic Immunoassay System.

Specimen type

Serum samples, avoid hemolysis. Should be separated and tested in time after blood collection. store for 48 hours under 2-8 °C.

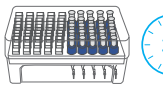
Procedures

HP-083/4-I&HP-083/4-II POCT Immunoassay System

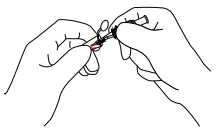
Note:

- Please read user manual of HP-083/4-I and HP-083/4-II before use.
- The analyzer will finish self check after start-up.
- Insert the IC card of ASO test kit to let analyzer read the parameter.
- The analyzer calibration can be done with app. It is recommended that analyzer calibration should be done for each new lot of test kit.

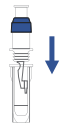
Step 1 Sample Preparation



1a Allow the test kit back to room temperature for 30 minutes before use.



1b Use the R2 with quantitative capillary to collect sample.

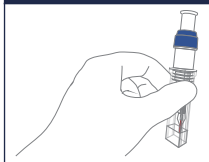


1c Insert the R2 into R1.

Note:

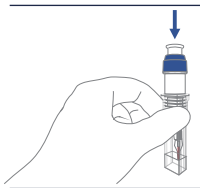
- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let the analyzer read the parameter before each assay test.
- The capillary of the R2 should be fully filled.

Step 2 Testing



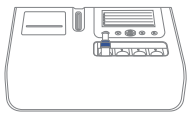
2a Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

Note:Do not hold the wide sides of R1.



2b Press the piston on R2.

2c Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.



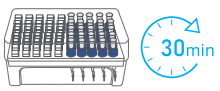
2d Insert the R1 into test channel of HP-083/4-II and the analyzer will finish the test and print out results automatically.

HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

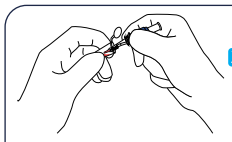
Note:

- Please read user manual of HP-AFS/1 and HP-AFS/3 before use.
- The analyzer will finish the self check after start-up.
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.

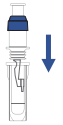
Step 1 Sample Preparation



3a Allow the test kit back to room temperature for 30 minutes before use.



3b Use the R2 with quantitative capillary to collect sample.

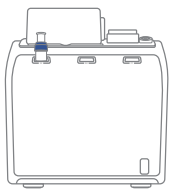


3c Insert the R2 into R1.

Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing



4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.
2. New lots of reagent.
3. New operator training.
4. The results can not match the clinical symptoms.
5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

Normal reference range is 0 ～ 200 IU/ml.

Recommended that each laboratory establish its own reference range.

Interpretation

The results ⩾ 200 IU/mL suggested that group a streptococcal infection was found. it is suggested to find out the specific cause

The test results of this reagent are only for clinical reference. the clinical diagnosis and treatment of patients should be considered in combination with their symptoms / signs, medical history, other laboratory tests and treatment responses.

Limitations

Hemoglobin＞5g/L, triglyceride＞5mmol/L, bilirubin＞510 μmol/L had effect on the test result.

Performance Characteristics

1. Linearity range: 30-600 IU/mL.

2. Detection limit: ⩽16 IU/mL.

The limit of detection means the lowest detectable analyte level that can distinguish the concentration. Calculate based on the minimum standard above the two standard deviation of the data (Blank table, 1+2SD, within-run precision, n=20).

3. Precision

Test the control material by Antistreptolysin O Test Kit 2 times per day for 20 days (n=80) according to EP5-A2 of CLSI.

The data as below:

a.

HP-083/4-II POCT Immunoassay System					
Sample	Mean IU/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	106	4.75	4.5	4.42	4.2
Control 3	389	9.60	2.5	13.25	3.4

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean IU/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	105	5.09	4.8	4.45	4.2
Control 3	392	12.5	3.2	10.07	2.6

c.

HP-AFS/1 Automatic Immunoassay System					
Sample	Mean IU/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	110	4.69	4.3	4.06	3.7
Control 3	380	13.2	3.5	11.21	3.0

4.Methodology comparison

Compared to Hitachi 7100 ASO TIA(x) by test the same samples, the relative data as below:

HP-AFS/3 Automatic Immunoassay System				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Serum	50	Y= 0.93X+0.18	0.95

The concentration of sample is about 50 IU/mL -600 IU/mL.

Precautions

⚠ **Attention:**

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infection.

Do not use the kits beyond shelf life.

Do not mix different batches of reagents.

⚠ **Warning:**

To avoid error, do not forced to take out the cuvette from the device. Follow the device operation manual strictly, If the problem cannot be solved, contact the manufacturer for further technical support.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
	Use-By date		Do not freeze
LOT	Batch code		Biological risks
	Manufacturer		Do Not Reuse
	Temperature Limit		
	Contains sufficient for <n> tests		
	Do not use if package is damaged		
	Consult Instructions for use		
	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

Galiving,P.et al; Clin.lab.assays 4: 73-95(1983)

Approval Date&Revision Date

Approval Date：Sep 9,2015
Revision Date：May 6,2016
Revision Date：May 1, 2017
Revision Date：Feb 1,2019
Revision Date：Apr 1,2019
Revision Date：Jan 1, 2021
Revision Date：Apr 1, 2021
Revision Date：Jan 1, 2023
Revision Date：Dec 22,2023

CE IVD

尺寸：24*25cm展开尺寸，横向三折页再垂直方向两次对折