



mAlb

Microalbuminuric Test Kit (Nephelometry Immunoassay Method)

Instructions for Use

Version: A/6

REF HP-mAlb-25

Manufacturer

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EC REP

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Product Name

General Name: Microalbuminuric Test Kit (Nephelometry Immunoassay Method)

Specification

Package Specification 25 Tests/ Kit.

Intended Use

This product is used to determine the content of Microalbuminuric (mAlb) in the urine samples, and specific reagent for the specific protein analyzer, applies only to the clinical in vitro assisted diagnosis.

MALB are some protein who is difficult to detect by conventional qualitative or quantitative methods. The body protein does not normally excreted through the urinary excretion, is primary kidney disease and other diseases caused by kidney disease, is the most important one of the pathophysiology of symptoms of the disorder. mAlb is the main indicator to assess the renal glomerular dysfunction.

MAlb is the most sensitive indicators of the routine inspection of early kidney lesions; is often to see the increase in early diabetic and hypertensive patients.

Test Principle

The mAlb units conjugated Anti- Micro albumin (mAlb) antibody in the latex surface. mAlb 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 mAlb levels. Using specific protein analyzer to measure the intensity of scattered light, the concentration of mAlb is determined by comparing the turbidity of samples to the standard concentration.

Component

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

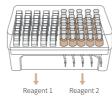


Figure	
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	Name	Content	Quantity
		Phosphate buffer	10mmol/L
	Reagent 1	Polyethylene glycol	<4%
(R1)		sodium chloride	150mmol/L
Reagent 2 anti mAlb antiserum		anti mAlb antiserum	Appropriate
	IC card (optional)	/	1

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

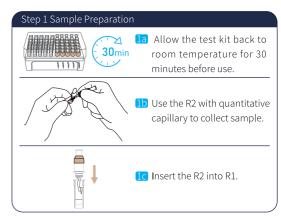
Quantitative urine sample in the 24 hours, or at any time urine samples; store at 2-8°C for 2 days or -20°Cfor 2 months (avoid repeated freezing and thawing); pre-test centrifuge.

Procedures

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

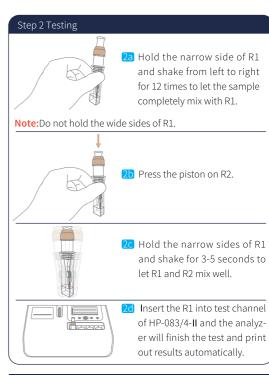
Note:

- 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 mAlb 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.



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.

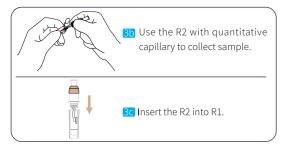


HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

Note:

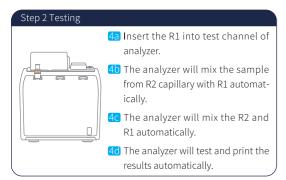
- Please read user manual of HP-AFS/1 and HP-AFS/3 before use.
- \bullet The analyzer will finish the self check after start-up.
- It is recommend to do analyzer calibration monthly and for each new lot of test kit.





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.



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: <25mg/L.

Recommended that each laboratory establish its own reference range

Interpretation

The results ≥ 25 mg / L suggested that kidney injury might

occur. 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 respons-

Limitations

Bilirubin > 600 µmol/L has effect on the test result.

Performance Characteristics

1.Linearity range: $10 \sim 220 \text{mg/L}$

2. Detection limit: ≤6 mg/L

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 Microalbuminuric 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	Within-Run		Between-Run	
Sample	mg/L	S.D.	%C.V.	S.D.	%C.V.
Control 1	31.4	1.18	3.8	1.15	3.7
Control 3	154.7	6.56	4.2	6.61	4.3

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean Within-Run Betweer		Within-Run		en-Run
Sample	mg/L	S.D.	%C.V.	S.D.	%C.V.
Control 1	31.4	1.36	4.3	1.49	4.7
Control 3	154.7	6.77	4.4	6.31	4.1

C.

HP-AFS/1 Automatic Immunoassay System						
Sample	Mean	Withi	Within-Run		Between-Run	
Sample	mg/L	S.D.	%C.V.	S.D.	%C.V.	
Control 1	31.4	1.39	4.4	1.49	4.7	
Control 3	154.7	6.85	4.4	6.95	4.5	

3. Methodology comparison

Compared to AA5500 mAlb (x) by test the same sample, the relative data as below:

HP-AFS/3 Automatic Immunoassay System					
Site No.	No.of Assays	Regression Line	Coefficient correlation		
1	50	Y= 1.02X+0.05	0.97		

The concentration of sample is about 10 mg/L-220mg/L.

Precautions

!\ Attention:

Only for in vitro diagnostic.

Only for professional use.

All samples and reactive wastes are treated as sources of infec-

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

Sy	mbol	Usage	Symbol	Usage		
	Ω	Use-By date	⊗	Do not freeze		
L	.от	Batch code	∞	Biological risks		
		Manufacturer	(2)	Do Not Reuse		
2'0	₹ 8°C	Temperature Limit				
7	Σ	Contains sufficient for <n> tests</n>				
(9	Do not use if package is damaged				
	<u>[i]</u>	Consult Instructions for use				
	*	Keep Away from Sunlight				
[VD	In Vitro Diagnostic Medical device				
EC	REP	Authorized Representative in the European Community				

References

1. Viberti GC, Wiseman MJ. The natural history of proteinuria in insulin-dependent diabetes mellitus. Diabetic Nephroparhy 1983;2:21-5.

2. Mogensen CE Microalbumin as a predictor of clinical diabetic nephropathy. Kidney Int, 1987;673-689.

3. Viberti GC. Early functional and morphological changes in diabetic nephropathy. Clin iNephrol 1979;12:47-53.

Approval Date&Revision Date

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

尺寸:24*25cm展开尺寸,横向三折页再垂直方向两次对折