Hipro™ mAlb Test (Nephelometry immunoassay Method)
Package Insert

【Product Name】

General Name： Microalbuminuric Test Kit （Nephelometry immunoassay Method）

Trade Name： mAlb Test

【Packing】

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.

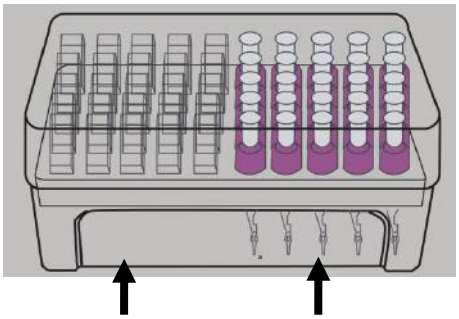
MALB are some protein who is difficult to detect by conventional qualitative or quantitative methods. The body protein does not normally excreted through the urinary excretion, is primary kidney disease and other diseases caused by kidney disease, is the most important one of the pathophysiology of symptoms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

【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.

The kits contains all the reactive reagents.（figure 1）.



Reagent 1 Reagent 2

【Components】

	Content	Quantity
Reagent 1	Phosphate buffer	10mmol/L
(Reaction cup)	Polyethylene glycol	< 4%
	sodium chloride	150mmol/L
Reagent 2 (R2)	anti MALB antiserum	Appropriate
IC Card	/	1

Do not mix different batches of reagents.

【Storage& Expire Date】

Store at: 2 ~ 8℃.

Validity Period: 1 year.

Do not keep the kits at room temperature for long time. Restore the kits at 2-8℃ after use.

【Applicable Instrument】

HP-083/4-I specific protein analyzer , HP-083/4-II specific protein analyzer, HP-AFS/3 specific protein analyzer, HP-AFS/1 specific protein analyzer.

【Specimen】

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

【Procedure】

Preparation

The operation of specific protein analyzer please refer to the instruction. Start up the analyzer **30 minutes** before the test.

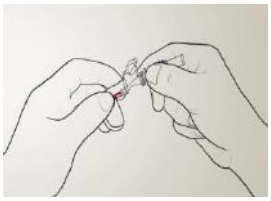
Attention：

HP-083/4-I 、 HP-083/4-II Specific protein analyzer: Insert the IC card into the slot, press the corresponding channel button to read the parameter information first.

Procedure

HP-083/4-I、HP-083/4-II Specific protein analyzer：

1、 Sample Preparation：



The test kit is equilibrated to room temperature, take samples by capillary in front of the sample collector, insert the sample collector into the cuvette.

Important: Due to the impact of evaporation, complete the test immediately once the capillary is full of samples. **Ensure the capillary full of samples**.

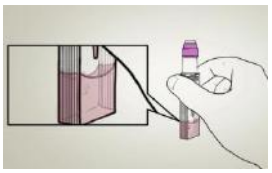
2. Sample Mixing：

Hold the middle of the cup on both sides, shake to mix

3. Reagent (R2) Injection：

Inject the reagent R2 into the cuvette.

4. Reagents Mixing：



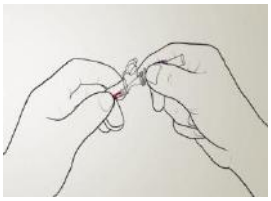
Attention：
Mixing Time:**3-5 seconds**

5. Test：

Insert into the corresponding test channel, The results will be displayed on the window and printed automatically

HP-AFS/1、HP-AFS/3 Specific protein analyzer:

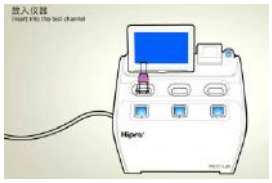
1. Sample Preparation:



The test kit is equilibrated to room temperature, take samples by capillary in front of the sample collector, insert the sample collector into the cuvette.

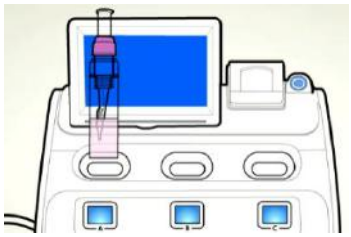
Important: Due to the impact of evaporation, complete the test immediately once the capillary is full of samples. **Ensure the capillary full of samples**.

2. Test：



Insert the R2 reagent into R1 cuvette, insert the R1 cuvette into the test channel, the test will be done automatically, The results will be displayed on the window and printed.

Attention:
In step 2, insert the cuvette into test channel directly and the two-dimensional code on the cuvette face to screen (As figure). **Do not mix the sample and press the piston.**



Calibration

This product can be traced back to ERM-DA471/IFCC .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 responses.

【Limitation】

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

【Performance】

1. Linearity range:10～220mg/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 Specific Protein Analyzer					
Sample	Mean	Within-Run		Between-Run	
	mg/L	S.D.	%C.V.	S.D.	%C.V.
Control 1	31.4	1.18	3.9	1.15	3.8
Control 3	154.7	6.56	4.3	6.61	4.2

b)

HP-AFS/3 Specific Protein Analyzer					
Sample	Mean	Within-Run		Between-Run	
	mg/L	S.D.	%C.V.	S.D.	%C.V.
Control 1	31.4	1.36	4.5	1.49	4.8
Control 3	154.7	6.77	4.3	6.31	4.0

4. Methodology comparison

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

Site No.	No.of Assays	Regression Line	Coefficient correlation
1	50	Y= 1.02X+0.05	0.97

The concentration of sample is about 5.0 mg/L-200mg/L

【Precaution】

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】

Symbol	Usage
	Use By
LOT	Batch Code
	Manufacturer
	Keep Away from Sunlight
2 °C 8 °C	Temperature Limitation
IVD	In Vitro Diagnostic Medical Device
EC REP	Authorized Representative in the European Community
CE	CE Mark
	Consult Instruction for use
	warning

【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

【Manufacturer】

Shijiazhuang Hipro Biotechnology Co.,ltd

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EC REP Lotus NL B.V.

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R&D CENTER: 3938 Trust Way, Hayward, CA94545 USA.

【Approval date and date of revision】

Approval date：Sept 9,2015

Date of Revision：May 6,2016

Date of Revision：May 1, 2017

Date of Revision：Jan 1, 2021

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