Hipro™α1-MG Test (Rate Scattering Turbidimetric Method) Package Insert

【Product Name】

General Name：alpha-1-microglobulin Test Kit （Rate Scattering Turbidimetric Method)

Trade Name： α1-MG Test

【Packing】

25 Tests/ Kit.

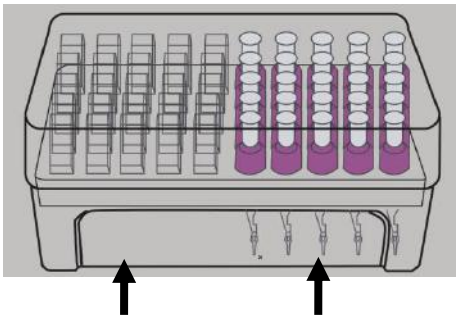
【Intended Use】

This product is used to determine the content of alpha-1-microglobulin (α1-MG) in human urine, it is mainly used for the auxiliary diagnosis of renal tubular injury.

【Principle】

The antibody of alpha-1-microglobulin is coated on the latex surface. The α1-MG in the sample and the antibody become to immune complexes by Latex agglutination reaction. The immune complexes will produce the phenomenon of light scattering which is proportional to the intensity of scattered light and samples of α1-MG levels. Using specific protein analyzer to measure the intensity of scattered light, the concentration of α1-MG 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 (R1)	Phosphate buffer	50mmol/L
	Polyethylene glycol 6000	5.8%
Reagent 2 (R2)	Anti human alpha 1-microglobulin antibody latex particles	5g/L
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】

Fresh urine, random urine samples, The sample store at 2-8 ℃ for 7 days. Each urine sample must be centrifuged before the test (15,000 x g for 10 minutes).

【Procedure】

Preparation

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

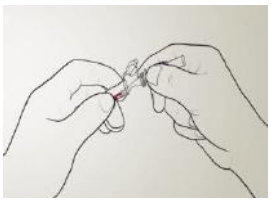
Attention：

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**.

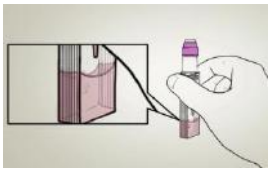
2. Sample Mixing：

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

3. Reagent (R2) Injection：

Inject the reagent R2 into the cuvette.

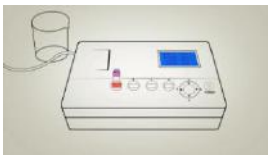
4. Reagents Mixing：



Attention：

Mixing Time**:3-5 seconds**

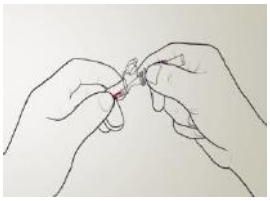
5. Test：



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:

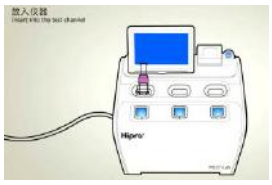
1. Sample Preparation:



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**.

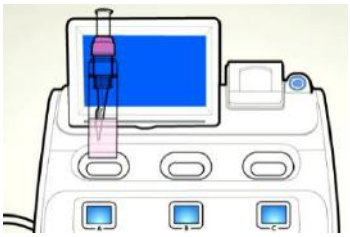
2. Test：



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 α1-MG TIA diagnosis. 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】

< 12mg/L

Recommended that each laboratory establish its own reference range

【Interpretation】

The test results≥12mg/L indicate that there may be renal tubule injury, it is recommended to conduct further examination to find out the cause of the increase and take corresponding treatment measures.

The result only for clinical reference, comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other

laboratory tests and treatment response.

All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

【Limitation】

Hemoglobin>10g/L, triglyceride>6.5mmol/L, bilirubin > 310μmol/L will affect the test result.

【Performance】

1. Linearity range: 5 mg/L ~ 90mg/L.

2. Detection limit: ≤3 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=21).

3. Precision

Test the control material by alpha-1-microglobulin 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	7.35	0.48	6.6	0.50	6.8
Control 2	21.24	1.11	5.2	1.14	5.4
Control 3	61.97	2.72	4.4	2.72	4.4

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	7.38	0.48	6.5	0.50	6.8
Control 2	21.30	1.04	4.9	1.10	5.2
Control 3	62.35	2.65	4.3	2.78	4.5

4. Methodology comparison

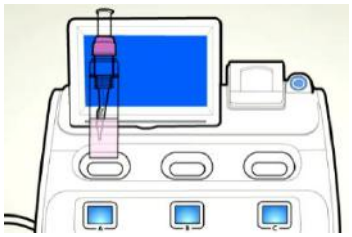
Compared to α1-MG TIA(x) by test the same serum sample, the relative data as below:

HP-AFS/3 Specific Protein Analyzer				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	urine	50	Y= 1.01X+0.17	0.96

The concentration of sample is about 5 mg/L -70 mg/L.

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.**



【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.Qin Ruixiang. Significance of detection of urinary α_1-MG, β_2-MG, and Alb in SLE and early renal impairment in patients[J].Journal of Radioimmunology,2005,18(3):214-215.

2.Ji Fengke, Xiong Peihua, Zhang Ling, et al. The clinical significance of determination of urine α1-MG and β2-MG in patients with systemic lupus erythematosus and lupus nephritis [J], Chinese Journal of Misdiagnosis, 2009,9 (6): 1319-1320.

3.Wei Yanhong, Yang Guangmin. Research progress in the biological characteristics and clinical application of α 1-microglobulin[J] International Journal of Laboratory Medicine, 2012, 33(17):2111-2113.

【Manufacturer】

Shijiazhuang Hipro Biotechnology Co.,ltd
No.3 Building,Block C,Fangyi Tech. Park, No. 313Zhujiangdadao Street,Shijiazhuang, 050000 China.

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Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
R&D CENTER: 3938 Trust Way, Hayward, CA94545 USA.

【Approval date and date of revision】

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