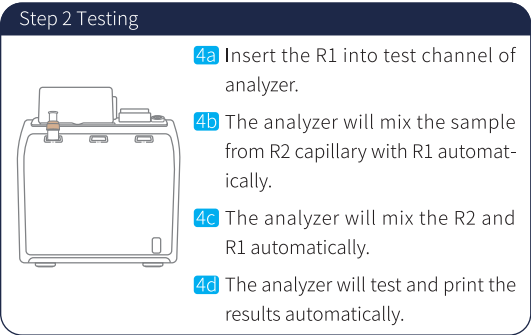


- Note:**
- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
  - The capillary of the R2 should be fully filled.



### 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  $\geq 25$  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.

### Limitations

Bilirubin >600 $\mu$ mol/L has effect on the test result.

### Performance Characteristics

1.Linearity range: 10 ~ 220mg/L

2. Detection limit:  $\leq 6$  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 mg/L	Within-Run		Between-Run	
		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 mg/L	Within-Run		Between-Run	
		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 mg/L	Within-Run		Between-Run	
		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 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
	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		
	In Vitro Diagnostic Medical device		
	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

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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