Instruction for Human Micro-albuminuria (mALB) Detection Kit (Nephelometry)

【Product Name】

Generic name: Human Micro-albuminuria (mALB)Detection Kit (Nephelometry)

Trade name: mALB

English name: Human Micro-albuminuria (mALB) Detection Kit (Nephelometry)

【Package】

Specification 1: 25T/kit REF:32026007

Specification 2: 2×25T/kit REF: 32080007

Specification 3: 50T/kit REF:32027007

Specification 4: 100T/kit REF:32028007

Specification 5: 150T/kit REF:32029007

Specification 6: 200T/kit REF:32030007

Specification 7: 250T/kit REF:32031007

Specification8: 300T/kit REF:32032007

【Intended Use】

For in vitro quantitative determination of micro-albuminuria (mALB) in human urine.

【Test Principle】

The soluble antigen and specific antibody react to form insoluble complex. When the light passes through the reaction suspension, it is scattered and detected by the specific protein analyzer. The scattered light value has a certain proportion to the sample's concentration. The reagents are pre-calibrated, each specific calibration curve has been recorded into the magcard, and each detection kit is allocated with one magcard.

【Main Compositions】

1. Antiserum: phosphate buffer 20mmol/L, rabbit anti human albumin antibody 2g/L
2. Buffer solution: phosphate buffer 20mmol/L, sodium chloride 1.5g/L
3. Magcard: polyvinyl chloride (PVC) plastic
4. Stirrer: stainless steel

【Accessories Required But Not Provided】

1. Pipettor
2. Pipettor tips
3. Reaction cup

【Storage and Validity Period】

The sealed detection kit can be stored at 2-8℃ for 12 months. Do not freeze. Once opened, the antiserum stored at 2-8℃ is stable for 30 days, the buffer stored at room temperature (18-25℃) is stable for 90 days.

【Applicable Instruments】

Applicable for PA50&PA54 Specific Protein Analyzer and PA120& PA200 Fully-auto Specific Protein Analyzer manufactured by Genrui Biotech Inc. to quantitatively test micro-albuminuria (mALB) in human urine.

【Sample Requirements】

The optimal sample is the middle section of fresh morning urine. The urine can be stored at 2-8℃ for no more than 72 hours, at-20℃ or lower temperature for a longer time. Urine should not be frozen or thawed repeatedly. For urine with normal appearance, centrifugation is not needed. But for urine with abnormal appearance, such as hematuresis, turbid urine, etc., centrifuge it with 3000r for 5 minutes before test.

【Test Methods】

Bring all reagents to room temperature (18-25℃) beforethe use.

1. Test methods for PA50&PA54 Specific Protein Analyzer

1) After startup, the instrument displays the main measurement interface, select the test item and sample type at the item column (After the confirmation, it will default to this item and sample type in the future.).
2) Click "LOT" at the batch No. column to enter the card-swiping interface. Put the corresponding magcard onto the magnetic induction area, when a "di" sound heard, the magcard was successfully swiped, and the interface returns to the main measurement interface. For the same batch of reagents, no need to swipe the card again.
3) The instrument interface prompts "Input Cup!"
4) Take out one cuvette, put one stirrer into it, then use the pipettor to accurately add in 400μl buffer solution, then add in 20μl sample.
5) Put the cuvette into the test channel, the instrument automatically stir for one time.
6) The instrument prompts "Please Add Antiserum", then use the pipettor to accurately add in 40μl mALB antiserum.
7) Immediately press the corresponding channel's start button, the instrument will stir automatically. When the test finished, the instrument will automatically display and print the test result.
8) After the test, take out the cuvette, the instrument prompts "Input Cup!", do the next test.

2. Fully-auto specific protein analyzer (PA120, PA200) detection methods are as follows

1) Login fully-auto specific protein analyzer PA120,PA200 PC software, put the magcard onto the magnetic induction area, the instrument will prompt the card is successfully swiped, for the same batch of reagents, only swipe the card once.
2) Login the main measurement interface, apply for testing according to the items and sample types to be tested.
3) Put the test sample in place, then put the corresponding reagents at the specified locations and start the test, the instrument will automatically aspirate all the test samples and complete the measurement process. After the test is completed, you can view the measurement results and print the test results.
4) Please refer to PA120, PA200 manual for detailed description of instrument operation method.

【Reference Value】

Reference range: ≤ 25mg/L

【Explanation for the Test Results】

If the sample's test result is beyond the linearity range, please use distilled water to dilute the sample with integral multiples and re-test. The result should multiply the dilution times.

Calculation method:Fitting the standard multi-point calibration curve by appropriate mathematical model (nonlinear) such as Logit / Log. Sample concentration value is obtained by calibration curve.

【Calibration and QC】

1. Calibration

It is recommended to use Randox or an internationally recognized mALB calibrator. The calibration period is 30 days. Recalibration is needed when replacing the batch number of reagents.

2. QC

It is recommended to use QC with normal and pathological values to do the indoor quality control, the tested control value should be within the definite limits, if the value is out of control, the laboratory should take appropriate corrective measures.

3. QC Solution (optional)

3.1 Product Name: mALB QC

3.2 Package Specification

0.3ml/bottle

3.3 Intended Use

Intended for in vitro diagnostic use in the quality control of diagnostic assays.

3.4 Main Composition: mALB antigen

3.5 Storage and Validity Period

The QC can be stored for 12 months at 2-8℃. It is stable for 30 days at 2~8℃ once opened.

3.6 Target and Limitation

Please refer to the label.

3.7 Test Method

The test procedure is same as sample test, please refer to the sample test method above.

【Limitations for the Test Results】

The diagnosis and treatment cannot only depend on this test result, please consider the clinical history and other laboratory test results at the same time. It is suggested that each laboratory builds up its own reference range based on its own patient group.

【Product Performance Indicators】

1. Analysis sensitivity: 10mg/L
2. Linearity range: 10-220mg/L
   (5-31mg/L absolute deviation ±2.5,
   31.5-83mg/L relative deviation ±8%
   83.1-157mg/L relative deviation ±7%
   >157.1mg/L relative deviation ±6%)
3. Measurement of precision:
   Repeatability: CV ≤ 4%, relative deviation of Detection Kit's inter-batches (R) ≤ 5%
4. Accuracy: Bias% ≤ ±10%
5. Specificity:

When add in 525IU/ml rheumatoid factors, 540IU/ml antistreptolysin O, 400μmol/L bilirubin, triglyceride < 10mmol/L, the test result Bias% ≤ ±10%

【 Precautions】

- Only used for in vitro diagnostic, please refer to the Operation Manual.
- Do not use the expired reagents. Shake the antiserum reagent well before use.
- Do not use reagents of different batches together.
- Reagent contains both human and animal derived materials, the laboratory procedures should be strictly enforced.

【Labels 】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Manufacturer
	Biological risks
	Batch code
	Temperature limit
	Use-by date
	Authorized representative in the European Community
	Volume
	Consult instructions for use
	Do not re-use
	Keep away from sunlight
	Contains sufficient for <n>tests
	Catalogue number
	CE Marking

【Reference】

[1] Multicenter study of Tina-quant Albumin in urine and /3-N-acetylglucosaminidase (ß-NAG) in urine. Workshop Munich November 29-30. 1990. Wien klin Wschr. 1991; 103, Supplement 189: 1-64.

[2] Passing H. Bablok W. A New Biometrical Procedure for Testing the Equality of Measurements from Two Different Analytical Methods. J Clin Chem Clin Biochem 1983; 21; 709-720.

[3] Hubbuch A. Results of a multicenter study of provisional reference ranges for albumin in urine of children and adults. Roche publication.

【Manufacturer】

Genrui Biotech Inc.

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【Medical Devices' Manufacturing Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046

【Medical Devices' Product Registration】

Certificate No.

Guangdong SFDA 2016.2401258 (**Approved**)

【Product Standard Code】

YZB/Guangdong --- *0053-2013*

【Instruction Approved and Revised Date】

Approved date: October 10th, 2016

Revised date: September, 30th, 2018

【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center.