Instruction for β2-Microglobulin（β2-MG） Detection Kit (Nephelometry)

1. Product Name

Generic name: β2-Microglobulin（β2-MG） Detection Kit (Nephelometry)

Trade name: β2-MG

English name: β2-Microglobulin（β2-MG） Detection Kit (Nephelometry)

2. Package

Specification 1: 25T/kit REF: 32026048

Specification 2: 2X25T/kit REF: 32080048

Specification 3: 50T/kit REF: 32027048

Specification 4: 100T/kit REF: 32028048

Specification 5: 150T/kit REF: 32029048

Specification 6: 200T/kit REF: 32030048

Specification 7: 250T/kit REF: 32031048

Specification 8: 300T/kit REF: 32032048

3. Intended Use

The kit is used for the quantitative determination of β2-Microglobulin（β2-MG） in serum or urine. The β2-microglobulin is more sensitive than serum creatinine in the evaluation of renal function. If the Serum creatinine content is normal but the β2-microglobulin content increased, this is suggesting a potential kidney damage. The determination of β2-microglobulin in serum and urine is helpful in assessing renal function in patients after renal transplantation

4. Test Principle

Once the β2-Microglobulin in the sample meet with its corresponding antibody in the liquid phase, there will be formation of antigen - antibody complex, which have a certain degree of turbidity. The level of turbidity is proportional to the amount of antigen present in the sample. By detecting the reaction change at specific wavelengths and referring to the multi-point calibration curve, the β2-MG content can be calculated.

5. Main Compositions

5.1 Buffer solution: phosphate buffer 20mmol/L, sodium chloride 15.8g/L, Sodium azide （NaN_3）0.095%

5.2 Antiserum: phosphate buffer 20mmol/L, latex particles coupled with cyclic citrulline peptide antigen 1.2g/L

5.3 Quality control product (free choice): Anti-human β2-MG antibody latex particles.

5.4 Magcard: Load the calibration curve information for this batch

5.5 Stirrer: stainless steel

6.Accessories Required But Not Provided

6.1Pipettor

6.2Pipettor tips

6.3Reaction cup

7. Storage and Validity Period

The sealed detection kit can be stored at 2-8℃ for 12 months. Do not freeze. Once opened, the reagents stored at 2-8℃ are stable for 30 days.

8. Applicable Instruments

Applicable for PA50&PA54 Specific Protein Analyzer and PA120& PA200 Fully-auto Specific Protein Analyzer manufactured by Genrui Biotech Inc.

9. Sample Requirements

The serum should be timely separated after blood collection to avoid hemolysis, samples should be stored at 2-8 ° C for no more than 72 hours, Samples can be stored for longer periods of time if frozen at -20 ° C or lower temperature.

Centrifugate the Urine then take the supernatant, Need to use K_2HPO_4 to adjust the pH to 7-8 then detect since the β2-MG in the urine is unstable when the pH<5.5. Samples can't be stored for more than 48 hours if stored at 2-8 ° C.

10. Test Methods

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

10.1 Test methods for PA50&PA54 Specific Protein Analyzer

1) After start up, 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 4μl 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 100μl 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.

10.2 Fully-auto specific protein ananlyzer (PA120, PA200) detection methods are as follows

1) Login fully-auto specific protein ananlyzer PA120,PA200 PC software, put the magcard onto the magnetic induction area, the instrument will prompts the card is successfully swiped, The same batch of reagents, only need 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, 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.

11. Reference Value

Reference range: Serum 1-3mg/L ; Urine: 0.1-0.3mg/L

12. Explanation for the Test Results

Hemolysis interfere with the determination,try to avoid hemolysis during operation. The cuvette, light source, and needle may have an effect on the measurement results, If the test results do not match the clinical, the confirmation tests should be performed, Comprehensive judgment should be combined with the patient's history, symptoms and other results.

13. Calibration and QC

The calibration cycle is 30 days with a suitable calibrator, and a recalibration is required when changing the lot number. It is recommended to use normal and pathological values of biochemical quality control serum for indoor quality control, the measured control value should be within the limit, if the control value out of control, the laboratory should take appropriate corrective measures.

14. 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.

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.

Bilirubin≤30 mg/dL; ascorbic acid≤20 mg/dL; Triglycerides≤10 mmol/L; these value have no effect on the determination

15. Product Performance Indicators

15.1 Blank limit: ≤0.2mg/L

15.2 Linearity range: 0.2-18mg/L, determination indicator: r ≥0.990

15.3 Measurement precision:

Repeatability: CV ≤ 8%, relative deviation of detection kit's inter batches (R) ≤ 10%

15.4 Accuracy: Bias% ≤ ±10%

16. 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.

17. 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

18. Reference

1. Determination of β2-microglobulin in serum by a microparticle-enhanced nephelometric immunoassays; Clin. Chem,Dec(1992);38:2464-2468

2.Galvin,J.P.etal.,Partical Enhanced Photometric Immunoassay, Clin.Lab.Assays73(1983)

3.Schardi jn GHC and Status Van Eps LW(1987).Beta-2 microglobulin:its significance in the evaluation if renal function.Kidney Int1.32,635-641

4. National clinical testing procedures the fourth edition.

19. Manufacturer

Genrui Biotech Inc.

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20. Medical Devices'Manufacturing Permit No.

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

21. Instruction Approved and Revised Date

Approved date: June, 02nd, 2016

22.Guarantee and Technical Support

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

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