Instruction for Cystatin C Detection Kit (Nephelometry)

1. Product Name

Generic name: Cystatin C Detection Kit (Nephelometry)
Trade name: CYS-C
English name: Cystatin C Detection Kit (Nephelometry)

2. Package

Specification 1: 25T/kit REF:32026003
Specification 2: 2×25T/kit REF: 32080003
Specification 3: 50T/kit REF:32027003
Specification 4: 100T/kit REF:32028003
Specification 5: 150T/kit REF:32029003
Specification 6: 200T/kit REF:32030003
Specification 7: 250T/kit REF32031003
Specification 8:300T/kit REF:32032003

3. Intended Use

For in vitro quantitative determination of Cystatin C (CYS-C) content in human serum or plasma.

4. Test Principle

CYS-C of the sample has an agglutination reaction with the rabbit anti human CYS-C antibody latex particles suspension of the reagent. The reaction formed antigen-antibody complex, which has turbidity. With a certain amount of antibody, its turbidity is in direct proportion to the CYS-C of the sample. By detecting the reaction change at specific wavelengths and referring to the multi-point calibration curve, the CYS-C content in the sample can be calculated. The reagents are pre-calibrated, each specific calibration curve has been recorded into the magcard and each detection kit is allocated with one magcard.

5. Main compositions

5.1 Buffer solution: phosphate buffer 20mmol/L, sodium chloride 15.8g/L
5.2 Antiserum: 3-hydroxymethyl aminomethane - hydrochloric acid (Tris - HCl) 20mmol/L, rabbit anti human CYS-C antibody coupled latex particles 2g/L
5.3 Magcard: polyvinyl chloride (PVC) plastic
5.4 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. to quantitatively test t Cystatin C (CYS-C) in human serum or plasma.

9. Sample Requirements

The optimal sample is non-hemolyzed fresh serum or heparin anticoagulant plasma. The fresh serum will be released from the condensation of blood clots, plasma is obtained by centrifugation. CYS-C in the sample can be stored at 2-8℃ for two days.

Samples with clear interferent should eliminate the interferent and resample.

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 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 300μl buffer solution, then add in 10μl 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 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 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: 0-1.16mg/L
Male: 3 ~ 59 years old: 0.49-1.14mg/L;
60 ~ 88 years old: 0.71-1.63mg/L
Female: 3 ~ 59 years old: 0.51-0.97mg/L;
60 ~ 88 years old: 0.62-1.54mg/L

12. Explanation for the Test Results

The determination of CYS-C is used for evaluating the early renal damage and judging the recovery situation of renal transplantation patient.

13. Calibration and QC

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.

It is recommended to use Randox or an internationally recognized CYS-C calibrator. The calibration period is 30 days. Recalibration is needed when replacing new batch number of reagents. It is recommended to use QC serum 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.

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.

15. Product Performance Indicators

15.1 Analysis sensitivity: ≤ 0.1mg/L

15.2 Linearity range: 0-8mg/L, determination indicator: r ≥0.990

15.3 Measurement precision:

Repeatability: CV ≤ 5%, relative deviation of detection kit's inter batches (R) ≤ 5%

15.4 Accuracy: Bias% ≤ ±10%

15.5 Specificity:

When add in free bilirubin ≤ 311μmol/L, hemoglobin ≤ 460mg/dl, ascorbic acid 2.8mmol/L, rheumatoid factors ≤ 240IU/ml, the test result 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

Serum cystatin C, determined by a rapid, automated particle-enhanced turbidimetric method, is a better marker than serum creatinine for glomerular filtration rate Clin. Chem.,Oct 1994, 40: 1921-1926.

19. Manufacturer

Genrui Biotech Inc.

Address: 6F, Shanshui Building B, Nanshan Yungu Innovation Industrial Park, 1183 Liuxian Blvd, Nanshan District, 518055, Shenzhen, P. R. China.

20. Medical Devices' Manufacturing Permit No.

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

21. Medical Devices' Product Registration Certificate No.

Guangdong SFDA 2014.2400442 (**Approved**)

22. Product Standard Code

YZB/Guangdong *---0602-2014*

23. Instruction Approved and Revised Date

Approved date: April, 24th, 2014

Revised date: July, 14th,2016

24. Guarantee and Technical Support

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