Instruction for C-Reactive Protein (CRP) Detection Kit (Nephelometry)

【Product Name】

Generic name: C-Reactive Protein (CRP) Detection Kit (Nephelometry)
Trade name: CRP
English name: C-Reactive Protein (CRP) Detection Kit (Nephelometry)

【Package】

Specification 1: 25T/kit REF: 32026009
Specification 2: 2×25T/kit REF: 32080009
Specification 3: 50T/kit REF: 32027009
Specification 4: 100T/kit REF: 32028009
Specification 5: 150T/kit REF: 32029009
Specification 6: 200T/kit REF: 32030009
Specification 7: 250T/kit REF: 32031009
Specification 8: 300T/kit REF: 32032009

【Intended Use】

For in vitro quantitative determination of C-reactive protein (CRP) content in human serum or whole blood.

【Test Principle】

Couple the specific CRP antibody onto the latex particles to make a specific combination with the CRP in the sample and form an immune complex with latex – antibody - CRP antigen. The complex's production is in positive correlation with the CRP concentration of the sample. This immune complex can be detected by the specific protein analyzer. 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. Buffer solution: phosphate buffer 20mmol/L, sodium chloride 15.8g/L
2. Antiserum: 3-hydroxymethyl aminomethane - hydrochloric acid (Tris - HCl) 20mmol/L, rabbit anti human CRP antibody coupled latex particles 2g/L
3. Sample Diluent (optional)：NaCl, Proclin300
4. Magcard: polyvinyl chloride (PVC) plastic
5. 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 the C-reactive protein in the serum and whole blood.

【Sample Requirements】

The optimal sample is non-hemolyzed fresh serum or whole blood. The fresh serum will be released from the condensation of blood clots, The C-reactive protein in the sample stored at 2-8℃ is stable for 7 days.

【Test Methods】

Bring all reagents to room temperature (18-25℃) before the 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 600μl buffer solution, then add in 2μl 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 60μl 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: ≤ 10mg/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 CRP 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: CRP QC

3.2 Package Specification

0.2ml/bottle

3.3 Intended Use

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

3.4 Main Composition: CRP 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 (serum) 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.

When the test result is suspicious, need to re-test.

【Product Performance Indicators】

1. Analysis sensitivity: 3mg/L
2. Linearity range: 3-300mg/L
   (0-10mg/L absolute deviation ±0.5,
   10.1-30mg/L relative deviation ±8%,
   30.1-150mg/L relative deviation ±7%,
   >150.1mg/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.
- The waste solution after reaction contains both human and animal derived materials, should be treated as a potential source of infection.

【Labels】

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

【Reference】

Ultrarapid, Ultrasensitive One-Step kinetic Immunoassay for C-Reactive Protein (CRP) in Whole Blood Samples: Measurement of the Entire CRP Concentration Range With a Single Sample Dilution Clin, Chem, Feb 2002, 48:269-277.

【Manufacturer】

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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 2016.2401259 (**Approved**)

【Product Standard Code】

YZB/Guangdong --- *0052-2013*

【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.

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