Instruction for D-Dimer Detection Kit

【Product Name】

Generic name: D-Dimer Detection kit (Nephelometry)

Trade name: D-Dimer

English name: D-Dimer Detection kit (Nephelometry)

【Package】

Specification 1: 25T/kit REF:32026001

Specification 2: 2x25T/kit REF: 32080001

Specification 3: 50T/kit REF:32027001

Specification 4: 100T/kit REF:32028001

Specification 5: 150T/kit REF:32029001

Specification 6: 200T/kit REF:32030001

Specification 7: 250T/kit REF:32031001

Specification 8: 300T/kit REF:32032001

【Intended Use】

For in vitro quantitative determination of D-Dimer content in human plasma.

【Test Principle】

The mouse anti human D-Dimer monoclonal antibody coupled latex particles has an antigen-antibody reaction with D-Dimer in the sample and forms the agglutination and leads the turbidity increase. By detecting the reaction change at specific wavelengths and referring to the multi-point calibration curve, the D-Dimer content of 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.

【Main Compositions】

1. Buffer solution: phosphate buffer 20mmol/L, sodium chloride 15.8g/L

2. Antiserum: phosphate buffer 20mmol/L, mouse anti human D-Dimer monoclonal antibody coupled latex particles 1.2g/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 reagents stored at 2-8℃ are stable for 30 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 in vitro D-Dimer content in human plasma.

【Sample Requirements】

1. The optimal sample is non-hemolyzed fresh plasma.

2. Sample processing: take venous blood (9vol.) and 0.11mol/L (3.2%) sodium citrate (1vol.), mix carefully and avoid bubbles, then centrifuge it for 10 minutes at 3000r/min to obtain plasma.

3. Plasma stability: stable for 4 hours when stored at 15-25℃,stable for 24 hours when stored at 2-8℃, stable for 4 weeks under -20℃ storage condition (frozen within 4 hours after sampling).

4. Thaw frozen plasma in 37℃ water bath within 10 minutes, mix carefully and avoid bubbles, and test D-Dimer within 2 hours. Do not freeze the sample again.

5. Samples with clear interferent should eliminate the interferent and resample.

【Test Methods】

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

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 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 6μl sample plasma.

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 within 5 seconds.

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: 0-0.5mg/L

【Explanation for the Test Results】

The determination of D-Dimer is a good indicator for diagnosing active fibrinolysis, and has a significant diagnostic value for a variety of thrombosis diseases such as disseminated intravascular coagulation (DIC), cerebrovascular diseases, acute myocardial infarction (AMI), etc. Besides, the test of D-Dimer can also be regarded as a detection indicator for thrombolytic drugs treatment.

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.

When the test result is suspicious, need to re-test, if still suspicious, need to re-collected samples and re-test after 1~ 2 weeks, or switch to other test methodologies.

【Calibration and QC】

1. Calibration

Use the appropriate calibrator (recommended brand of SIEMENS or other approved brands) and the calibration period is 30 days. Recalibration is needed when replacing new batch number of reagents.

2. QC

It is recommended to use QC with normal value and pathological value 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: D-Dimer 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: D-Dimer 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.

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.

【Product Performance Indicators】

1. Analysis sensitivity: ≤ 0.1mg/L

2. Linearity range: 0-20mg/L, determination indicator: r ≥0.990

3. Measurement precision:

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

4. Accuracy: Bias% ≤ ±10%

5. Specificity:

When add in free bilirubin ≤ 18.4mg/dl, hemoglobin ≤ 460mg/dl, rheumatoid factors ≤ 500IU/ml, 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】

Tengwu, Yuan, etc.: Clinical Examination Guide 2003-2004, p699. 2003

【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 2014.2400443 (**Approved**)

【Product Standard Code】

YZB/Guangdong *---0603-2014*

【Instruction Approved and Revised Date】

Approved date: February, 23th, 2018

Revised date: October, 08th, 2018

【Guarantee and Technical Support】

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