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- Diagnostik & molekulare Diagnostik
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Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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D-Dimer

HumaFIA SR

Fluorescence immunoassay for the quantitative determination of D-Dimer

Package Size 25 tests/kit

REF 16090/50

IVD

Intended Purpose

D-Dimer HumaFIA SR is a fluorescence immunoassay for the quantitative determination of D-Dimer in human whole blood/ plasma.

D-Dimer is the final product of the degradation of cross-linked fibrin by plasmin, and its generation or increase reflects the activation of the fibrinolytic system, which is the direct evidence of thrombus formation and dissolution.

D-Dimer mainly reflects fibrinolytic function. Increased or positive D-Dimer is seen in secondary hyperfibrinolysis, such as hypercoagulability, disseminated intravascular coagulation, kidney disease, organ transplant rejection, thrombolytic therapy, etc. As long as there is active thrombosis and fibrinolysis in blood vessels, D-Dimer will increase. Myocardial infarction, cerebral infarction, pulmonary embolism, venous thrombosis, surgery, diffuse intravascular coagulation, infection and tissue necrosis can all lead to the increase of D-Dimer. Especially for the elderly and hospitalized patients, it is easy to cause abnormal coagulation and lead to increased D-Dimer due to bacteremia and other diseases.

For professional in vitro diagnostic use only.

Test Principle

The kit uses a sandwich detection method to determine D-dimer in human whole blood/plasma. When an adequate volume of test sample is dispensed into the sample well of the test cartridge, the sample migrates by capillary action across the cartridge. D-dimer, if present in the sample, will bind to the D-dimer antibody conjugates, and flow downstream. The immunocomplex is then captured on the nitrocellulose membrane by the pre-coated another D-dimer antibody, forming an antibody-antigen-antibody complex. The more antigen in sample forms the more complex and leads to stronger intensity of fluorescence signal, which is processed by instrument for the test to show D-dimer concentration in sample.

Reagents and Contents

RGT	25 tests	Reagent cartridge, labelled as D-Dimer, individually sealed foil pouches
CAL	1 card	Calibration card, for upload of calibration curve into the analyzer
DIL	25 x 200 μL	Sample Diluent

Applicable instrument

REF	
16090	HumaFIA

Storage/Stability

Unopened at 4-30°C	Up to the stated expiration date. Do not use beyond the expiration date
Opened pouch at 18-28°C	Test should be completed within 1 hour

Reagent preparation

Specimens

1. Sample type: whole blood or plasma (using 3.2% sodium citrate as the anticoagulant). Other sample types have not been evaluated.
2. Venous blood should be collected in a sterile condition. Sodium citrate can be used for anticoagulation in plasma or whole blood. Anticoagulants other than sodium citrate are not recommended.
3. After clinical blood samples are collected, the test should be completed within 2 hours at room temperature of 18-28°C. If the test cannot be carried out in time, it is recommended that the whole blood sample be centrifuged and stored in cold storage. Plasma samples can be stored at 2-8°C for 8 hours. Stored at -20°C for 3 months. Avoid heating inactivated samples and hemolysis samples should be discarded.

Procedure

Follow the procedure exactly as described

Procedural Notes

1. Before sample testing, read the instruction and applicable Instrument User Manual carefully. Before using refrigerated test cartridge, allow it to reach the operating temperature (18-28°C). Place the test cartridge on a level, horizontal surface.
2. Check the lot number of the test cartridge matches that of the Calibration card.
3. Insert the Calibration card into the Calibration card port of the instrument for tests.
4. Refrigerated plasma specimens must be allowed to reach room temperature before testing. Frozen plasma should be vortex and centrifugated after thawing. The supernatant liquid should be obtained and reach room temperature before testing.
5. Pipette exactly 200 μL of plasma/whole blood to the vial of diluent. Reclose the cap of the vial and mix the sample mixture by inverting the vial 10 times.
6. Pipette exactly 80μL of diluted sample into the sample port of the test cartridge. Start the timer, 15 minutes is needed for the reaction.
7. Insert the test cartridge into the applicable analyzer after reaction time is elapsed, select the accurate sample type and press 'STAT sample'. The test cartridge can be detected automatically. The results will be displayed on the screen and printed when the analysis is complete.
8. After the assay completed, remove the cartridge from the analyzer.
9. Dispose of the used cartridge and pipette tips in accordance with any applicable regulations.

Calibration

Master curve calibration: Every HumaFIA SR reagent kit has a calibration card CAL, containing lot specific information for the calibration. After upload of calibration curve from the card, the calibration of this lot is stored at the instrument. All subsequent samples may be tested without further upload.

Calculation of results

The HumaFIA system automatically calculates the analyte concentration of each sample. The results are given in ng/mL FEU.

Quality Control

For quality control use the corresponding quality control products provided by HUMAN:

- Once every day, before using the test
- If you get unexpected results when using the test.
- After each upload of a calibration

Quality control results that do not fall within acceptable ranges may indicate invalid test results.

Reference Value

Reference value: < 550 ng/mL FEU.

It is recommended that each laboratory establish its own expected values for the population it serves.

Interpretation of Results

If the concentration in the sample exceeds the linear range, please dilute the sample with 5% BSA normal saline solution before testing, and report the result multiplied by dilution factor. The maximum dilution of the sample was 3 times.

The test results should not be used as the sole basis for diagnosis and should be combined with other clinical and laboratory data for clinical diagnosis. If the test results do not match the clinical assessment, further tests should be performed.

Limitations

Interference may be encountered with certain samples containing antibodies directed against reagent components. For this reason, assay results should be interpreted taking into consideration the patient's clinical history, and the results of any other tests performed.

When the sample contains high concentration of triglyceride, cholesterol, bilirubin or hemolysis, the test result will be affected. Do not use samples containing any of the following interfering substances for testing:

Severe lipemia: triglyceride concentration exceeds 15mg/mL;

High cholesterol: cholesterol concentration of more than 400mg/dL;

Jaundice: the concentration of bilirubin exceeds 40mg/L;
Severe hemolysis: the concentration of hemoglobin exceeds 6mg/mL;
As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample. The test has been formulated to minimize this interference; however, specimens from patients who have been routinely exposed to animal products may contain heterophile antibodies which may cause erroneous results.

Analytical Performance Characteristics

Appearance	The inner packaging is tightly sealed without leakage. The label content is complete, and the text is clear and easy to recognize. The surface of the test card should be smooth, without burrs, and uniform in color.
Film strip width	The width of the test strip in the display window should be ≥3.7mm.
Liquid migration speed	≥10 mm / min.
Samples that exceed the displayed range are marked as >higher or <lower than the measurement range	
Accuracy	Tested with accuracy reference material, the relative deviation between the average value of the test results and the marked value should be within ± 15%.
Within-run Precision	≤15%
Between-run Precision:	≤15%
Limit of detection	<20 ng/mL FEU
Linearity range	20-4400 ng/mL FEU

Notes

As with all diagnostic tests, the results should be interpreted with due consideration of other laboratory findings and of the clinical status of the patient.

Safety Notes

All patient specimens and controls should be handled as potentially infectious. All materials of animal origin avoid many risks associated with the use of human serum (e.g. Hepatitis B and C, HIV). Nevertheless, all material of human or animal origin should still be treated as potentially infectious material.

For users in the European Union only: Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

P234 Keep only in original container.

P260 Do not breathe dust/fume/gas/mist/vapors/spray.

P262 Do not get in eyes, on skin, or on clothing.

P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P401 Store in accordance with local/regional/national/ international regulations.

P501 Dispose of contents/container in accordance with local/regional/ national/international regulations.

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EC REP

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