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Lieferung & Zahlungsart

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- Trockeneiszuschlag
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RF

HumaFIA SR

Fluorescence immunoassay for the quantitative determination of Rheumatoid Factor (RF)

Package Size 25 tests/kit

REF 16090/60

IVD

Intended Purpose

RF HumaFIA SR is a fluorescence immunoassay for the semi-quantitative determination of rheumatoid factor in human whole blood/serum/plasma. Rheumatoid factors (RF) are autoantibodies directed against the Fc region of altered IgG immunoglobulin. The common rheumatoid factors are IgM, IgG, IgA and IgE. RF detection is of great significance in the diagnosis, classification and curative effect observation of rheumatoid arthritis. Although the diagnosis of rheumatoid arthritis relies heavily on clinical examination, RF testing is useful in supporting clinical diagnosis and in assessing individual patient sensitivity and disease origin. Patients with positive RF test results account for 70% to 80% of patients with rheumatoid arthritis, and positive RF supports the tendentious diagnosis of early RA, and the diagnosis of non-active RA needs to refer to the medical history. In RA patients, the titer of RF is positively correlated with the clinical manifestations of patients, that is, the viral load increases with the aggravation of symptoms. The presence of high-potency RF accompanied by severe joint function limitation often indicates a poor prognosis.
For professional in vitro diagnostic use only.

Test Principle

The test uses an indirect detection method to determine rheumatoid factor in human whole blood/serum/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. Rheumatoid factor, if present in the sample, will bind to the rheumatoid factor antibody conjugates, and flow downstream. The immunocomplex is then captured on the nitrocellulose membrane by the pre-coated another rheumatoid factor antibodies, forming antibody-antigen-antibody complexes. 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 rheumatoid factor concentration in sample.

Reagents and Contents

RGT	25 tests	Reagent cartridge, labelled as rheumatoid factor (IgM), 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	Test should be completed within 1 hour

Reagent preparation

Specimens

1. Sample type: whole blood, serum or plasma (using EDTA as the anticoagulant). Other sample types have not been evaluated.
2. Venous blood should be collected in a sterile condition. EDTA can be used for anticoagulation in plasma or whole blood. Anticoagulants other than EDTA 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 being centrifuged and stored in cold storage. Serum and plasma samples can be stored at 2-8°C for 8 hours, or 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 RGT and of the diluent DIL matches that of the Calibration card CAL.
3. Insert the CAL into the CAL card port of the instrument for tests.
4. Refrigerated serum or plasma specimens must be allowed to reach room temperature before testing. Frozen plasma or serum should be vortex and centrifugated after thawing. The supernatant liquid should be obtained and reach room temperature before testing.
5. Pipette exactly 10 μL of serum/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, 10 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 completed.
8. After the assay is completed, remove the cartridge from the analyzer.
9. Do not re-use cartridge and diluent.
10. Dispose of the used cartridge, diluent 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 U/mL.

Reference Value

Reference value： < 20 U/mL
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

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 400 mg/dL;
Jaundice: the concentration of bilirubin exceeds 40mg/L;
Severe hemolysis: the concentration of hemoglobin exceeds 6 mg/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 animals or to animal serum 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 total agreement rate is >90%
Within-run Precision	≤15%
Between-run Precision:	≤15%
Limit of detection	< 10 U/m L
Linearity range	10-200 U/m L

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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