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- Trockeneiszuschlag
- Gefahrgutzuschlag
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SZABO-SCANDIC HandelsgmbH

Quellenstraße 110, A-1100 Wien

T. +43(0)1 489 3961-0

F. +43(0)1 489 3961-7

mail@szabo-scandic.com

www.szabo-scandic.com

linkedin.com/company/szaboscandic

Anti-CCP

HumaFIA SR

Fluorescence immunoassay for the quantitative determination of Anti-cyclic citrullinated peptide (Anti-CCP)

Package Size 25 tests/kit

REF 16090/65

IVD

Intended Purpose

Anti-CCP HumaFIA SR is a fluorescence immunoassay for the semi-quantitative determination of Anti-CCP in human serum.

Anti-cyclic citrullinated peptide antibody (Anti-CCP), which is autoantibody against synthetic cyclic citrullinated peptide (CCP) as antigen, has high sensitivity and specificity for rheumatoid arthritis (RA), even in early RA patients, the sensitivity is 40%-60%. CCP antibody is not only an early diagnostic index of RA, but also a sensitive index to distinguish aggressive and non-aggressive RA. CCP antibody positive people usually appear or easily develop more severe joint bone destruction than antibody negative people. In addition to the early diagnosis of RA, anti-CCP antibodies are also important for the prognostic evaluation of the disease. The bone destruction of RA patients with positive anti-CCP antibodies is more serious than those with negative anti-CCP antibodies.

For professional in vitro diagnostic use only.

Test Principle

The test uses an indirect detection method to determine Anti-CCP in human serum. 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. Anti-CCP, if present in the sample, will bind to the mouse anti-human IgG antibody conjugates, and flow downstream. The immunocomplex is then captured on the nitrocellulose membrane by the CCP antigen, forming antibody-antibody-antigen complexes. The more Anti-CCP in sample forms the more complex and leads to stronger intensity of fluorescence signal, which is processed by instrument for the test to show Anti-CCP concentration in sample.

Reagents and Contents

RGT	25 tests	Reagent cartridge, labelled as Anti-CCP, 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: Serum. Other sample types have not been evaluated.
2. The serum should be separated by centrifugation within 2 hours from the time of blood collection.
3. After clinical blood samples are collected, the test should be completed within 2 hours at room temperature of 18-28 ℃. If the test cannot be carried out in time, it is recommended that the serum samples can be stored at 2-8℃ for 8 hours. Stored at -20℃ 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 specimens must be allowed to reach room temperature before testing. Frozen serum should be vortexed and centrifugated after thawing. The supernatant liquid should be obtained and reach room temperature before testing.
5. Pipette exactly 10 μL of serum 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 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.

Quality Control

For checking the correct functioning of the system, a suitable control material should be used, according to the legal requirements of the laboratory.

Reference Value

Reference value: ＜45 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

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 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	≥10mm / 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 >95%
Within-run Precision	≤15%
Between-run Precision:	≤15%
Limit of detection	< 20 U/mL
Measuring range	20-200 U/mL

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.

Beijing HumaDX Tech Co., Ltd.
Address: Room 1309, 3rd Floor, 1st Block, No. 55 Jiachuang 2nd Road, BDA 101111, Beijing, China
Email: service@humadx.com.cn Tel: +86-10-80828658

EC REP
HUMAN Gesellschaft für Biochemica und Diagnostica mbH
Address: Max-Planck-Ring 21, 65205, Wiesbaden, Germany
Tel: +49-6122-99880, E-Mail: human@human.de

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Effective Date: Jan 15, 2024
Version：HD/CE 65 202401 V001