rheumachec®
RAPID TEST

Instructions for use

1 × / 10 × immunochromatographic rapid test for detecting rheumatoid factors and autoantibodies against mutated citrullinated vimentin (Anti-MCV®) in whole blood.

For in-vitro diagnostics only.
For professional use by skilled persons only.

ORG 170-01
ORG 170-10

Contents

Special feature: duration of the test approx. 15 minutes

1. Test description – Test principle

The **rheumachec®** rapid test is a membrane-based two-stage assay for the rapid combined detection of rheumatoid factors (RF) and autoantibodies against MCV (Anti-MCV®) in whole blood in case of suspected rheumatoid arthritis. The test is not suitable for the use of other body fluids.

The test consists of

› a special autoantibody-binding protein coupled to colloidal gold particles (detector),

› a membrane on which a unique combination of RF- and Anti-MCV®-specific antigens is immobilised.

The test is based on immunochromatography: First of all, the sample flows through a blood separator that retains cellular blood components. Pathological autoantibodies contained in the resulting blood plasma bind to the antigens on the test membrane (human immunoglobulins and recombinant MCV) and are visualised through the gold-labelled detector. One or two red-violet lines appear on the positions RF and/or MCV. The remaining antibody-detector complex migrates to control zone C. The red-violet line created here indicates a correct test procedure.

2. Kit components

1 × / 10 × **rheumachec®** test cassette
1 × / 10 × automatic lancet
(company: Vitrex Medical AS[1)])
1 × / 12 × plastic pipette 10 µl
(company: Savetec Clinical Products, Inc[1)])
1 × dropping bottle with 3 ml buffer solution
(containing 0.09 % sodium azide)
1 × cleansing swab
(only ORG 170-01) (company: H&W cv[1)])
1 × instructions for use

No other material is required.

[1)] Proof of delivery and address available on request from ocd group.

2.1. Storage and stability

The closed **rheumachec®** rapid test remains stable at temperatures between +4 °C and +28 °C. Do not expose to light, protect from sunlight.

The **rheumachec®** rapid test can be used until the expiry date printed on the packing.

3. General notes and safety precautions

› Non-compliance with these instructions for use may give incorrect measuring results.

› The test or individual test components must not be reused.

› Usual laboratory procedures and safety precautions for the dealing with and disposal of samples and used material have to be complied with.

Warning: Special care is required when performing the **rheumachec®** rapid test on persons who take blood thinners or suffer from a disorder of blood coagulation (e. g. haemophilia).

4. Sampling and preparation

The **rheumachec®** rapid test is intended for the use of capillary whole blood. It is possible to perform the test using 10 µl i.v. whole blood.

Use fresh samples only. Blood samples have to be collected according to the applicable guidelines and procedures.

5. Test procedure

Duration of the test approx. 15 minutes

I. Execute the test at room temperature.

II. Massage the patient's fingertip a bit in order to increase blood flow at the puncture site. Clean the puncture site thoroughly with an alcohol swab.

III. Remove protective cap from automatic lancet. Place the open side of the lancet onto the puncture site. Trigger the automatic lancet by pressing it against the fingertip. After this procedure, the lancet has to be discarded!

IV. If required, squeeze a small amount of blood out of the fingertip by applying mild pressure. Absorb the drop of blood using the plastic pipette. To this effect, hold the pipette horizontally or at a slight angle and dip the tip into the drop of blood; the required volume (10 µl, mark) is pulled into the pipette by capillary forces. The air vent of the plastic tube at the level of the mark has to be unobstructed during this procedure (Fig. 1). Please note: do not press the pipette bulb during this procedure, the pipette fills up automatically!

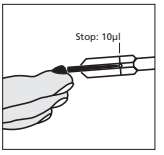

Fig. 1

V. Now hold the plastic pipette vertically and place it over the square sample field. Press the pipette bulb gently and place the blood drop onto the fleece in the square sample field (Fig. 2). Do not damage the fleece in the sample field.

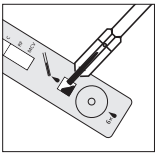
Fig. 2


Fig. 3

Please note: If the blood cannot be blown out by simply pressing the pipette bulb, you will have to cover the air vent of the plastic tube (mark) with a finger (Fig. 3).

VI. Put 6 drops of buffer solution (💧) onto the round buffer field immediately after having applied the sample

VII. Put the test cassette in a horizontal position during the execution of the test. – Evaluation of the test after 15 minutes.

6. Evaluation and result interpretation

6.1. Reading and evaluation of the results

Negative: A red-violet line appears in control zone C only.

Positive: In addition to the red-violet line in control zone C, one or two other lines appear for MCV and/or for RF.

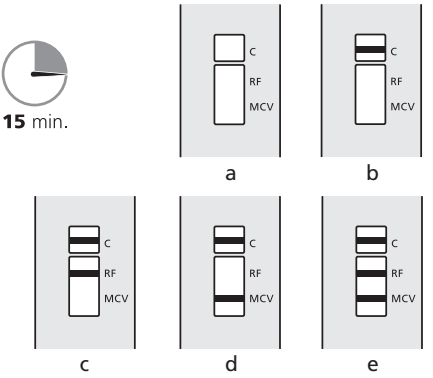

Fig. 4: Evaluation of the **rheumachec®** rapid test:
a: invalid; **b:** negative; **c:** RF-positive; **d:** Anti-MCV®-positive; **e:** Anti-MCV®-positive *and* RF-positive.

› **Please note:** Changes in the test results 30 minutes after the end of the test and later should not be taken into account for evaluation. Within this period of time, any line appearing for RF or MCV – irrespective of colour intensity – is interpreted as positive.

6.2. Unclear results

The test result cannot be determined if no red-violet line appears in control zone C. In this case, it is recommended to use a new test cassette and to repeat the test.

7. Features of the test and performance data

› The **rheumachec®** rapid test has been evaluated using a leading rheumatoid factor ELISA and Anti-MCV® ELISA using clinical samples.

› For Anti-MCV® as marker for rheumatoid arthritis, clinical specificity is 98 %, sensitivity amounts to 72 %.

› Compared to RF ELISA and Anti-MCV® ELISA, the **rheumachec®** rapid test achieves a positive correspondence of 93 % and a negative correspondence of 98 %. No matrix effects and anticoagulant effects occur.

› Intra-assay and inter-assay coefficient of variation for precision < 10 %

› Cut-off value*: 50 units/ml (according to corresponding ELISAs)

› RF and Anti-MCV® concentrations below 50 units/ml do not produce any visible result lines at the corresponding positions (RF or MCV). The control line (C) as an indicator of functionality of the **rheumachec®** rapid test will turn red-violet in any case.

**threshold of detectability*

8. Restrictions and limitations of the test

› The detection of rheumatoid factors alone does not constitute an evidence of rheumatoid arthritis. Rheumatoid factors can be detected in case of other diseases as well and in approx. 5 % of healthy population. At higher age, up to 25 % of the test persons are RF-positive.

› In persons with renal insufficiency, the **rheumachec®** rapid test may give false-positive results, since the Anti-MCV® and rheumatoid factor titre may be increased by the affected renal elimination.

› A false-positive result may occur in competitive athletes when the concentrations of rheumatoid factors and Anti-MCV® increase over the normal level for a short period on account of the high strain on the muscles.

› A positive detection of Anti-MCV® is a significant indication of rheumatoid arthritis or early arthritis and requires a visit to a specialist. The result of the **rheumachec®** rapid test alone does not establish a final diagnosis.

Literature:
Literature is available on request from ocd group.

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