AVITEX® ROSE WAALER Ref OD113

Slide haemagglutination test for the detection of Rheumatoid Factor

Store at 2°C to 8°C. DO NOT FREEZE

For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

AVITEX ROSE WAALER is a rapid slide haemagglutination test kit for the detection of Rheumatoid Factor (RF) in human serum. RF is found in sera of patients with Rheumatoid Arthritis and is believed to be IgM antibodies directed against the patients own immunoglobulin G. RF also has activity against animal IgG. Due to the variety of Rheumatoid Factors there is not a unique test capable of detecting them all.
For professional use only.

PRINCIPLE OF THE TEST

The **AVITEX ROSE WAALER** test reagent is a suspension of stabilised sheep red blood cells with rabbit anti-sheep IgG. When RF is present in the sample, clear agglutination is seen.

AVITEX ROSE WAALER has a detection limit of 8 IU/ml of RF in the patient serum and the reagent is calibrated against the World Health Organisation (WHO) International Reference Preparation.

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REAGENT

Sheep red blood cells (approximatly 5%) coated with anti-sheep IgG. Working Strength.

CONTROL + **0.5ml**
Positive Control. Serum containing Rheumatoid Arthritis Antibodies. Working Strength.

CONTROL - **0.5ml**
Negative Control. Serum free of Rheumatoid Arthritis Antibodies. Working Strength.

STIRRERS	**50**
PLASTIC SLIDE	**1**
INSTRUCTION LEAFLET	**1**

MATERIAL REQUIRED BUT NOT PROVIDED

Micropipettes capable of dispensing 50µl
Isotonic saline: 0.9% NaCl

PRECAUTIONS

AVITEX ROSE WAALER reagents contain materials of human origin which have been tested and confirmed negative for HCV, HIV I and HIV II antibodies, and HBsAg by FDA approved procedures. Because no test can offer complete assurance that products derived from human source will not transmit infectious agents it is recommended that the reagents within this kit be handled with due care and attention during use and disposal. All reagents should, however, be treated as potential biohazards in use and for disposal. Do not ingest.

AVITEX ROSE WAALER reagents do not contain dangerous substances as defined by current UK Chemicals (Hazardous Information and Packaging for Supply) regulations. All reagents should, however, be treated as potential biohazards in use and disposal. Final disposal must be in accordance with local legislation.

AVITEX ROSE WAALER reagents contain 0.095% sodium azide as a preservative which may be toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.

STORAGE

Reagents must be stored at temperatures between 2°C to 8°C.

The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on kit and components. Expiry date is the last day of the month on the bottle and the kit label. Do not use reagents after the expiry date.

Exposure of reagents to excessive temperatures should be avoided. Do not expose to direct sunlight.

DO NOT FREEZE ANY OF THE REAGENTS as this will cause irreversible damage.

SPECIMEN COLLECTION

Obtain a sample of venous blood from the patient and allow a clot to form and retract. Centrifuge clotted blood sample and collect clear serum. Fresh serum samples are required.

Do not use haemolysed, contaminated or lipaemic serum for testing as this will adversly affect the results.

Serum may be stored at 2°C to 8°C for up to 48 hours prior to testing. If longer storage is required, store at –20°C for up to 6 weeks. Thawed samples must be mixed prior to testing.

Do not repeatedly freeze-thaw the specimens as this will cause false results.

DO NOT DILUTE THE TEST SERA PRIOR TO USE IN THE QUALITATIVE TEST.

REAGENT PREPARATION

All reagents should be brought to room temperature (20°C to 25°C) and mixed gently prior to use. Do not induce foaming.

The test slide should be thoroughly cleaned before use as traces of detergent or prior specimen may affect the result.

Recommended Cleaning procedure:

1. Used cards must be immediately immersed in a disinfectant solution. Follow disinfectant manufactures guidelines.
2. The reaction circles must be physically rubbed with non-abrasive material to ensure removal of possible adhering particles.
3. Thoroughly rinse in purified water.
4. Allow reaction card to dry.
5. Spray cards with a 70% alcohol solution.
6. Allow the alcohol to evaporate prior to re-use.

LIMITATIONS OF USE

The use of samples other than serum has not been validated in this test.

There is no reuse protocol for this product.

A low or suspected positive result should be re-assessed. Diagnosis should not be made solely on the findings of one clinical assay. When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

RF tests are important in distinguishing between Rheumatoid Arthritis, Autoimmune and other inflammatory disease states. It should be noted that positive tests for RF are not given by every test with every case of clinically diagnosed Rheumatoid Arthritis.

Healthy individuals can give positive reactions in RF tests and the incidence is between 3-5% of the population. Positive reactions do occur in conditions such as infectious mononucleosis, syphilis, hepatitis and various other clinical conditions. These false positives normally give very low titres in the Quantitative test.

ASSAY PROCEDURE

Qualitative Method

1. Allow test reagents and patient serum to reach room temperature.
2. Transfer 50µl of patient's serum to a test circle on the slide.
3. Shake the Rose Waaler Reagent, then add one drop of suspension to the test circle.
4. Mix the drops using a disposable stirrer ensuring coverage of the test circle with the mixture.
5. Place the test slide on the bench and leave for 2 minutes.
6. Gently and evenly, rock and rotate the test slide once and place the test slide on the bench once more.
7. One minute later, read the test slide for the presence of haemagglutination.

Semi Quantitative Method

1. Using isotonic saline prepare serial dilutions of the patients serum (1/2, 1/4, 1/8, 1/16, 1/32, 1/64 and so on)
2. Transfer 50µl of each serum dilution to a test circle on the slide.
3. Shake the Rose Waaler, then add one drop of suspension to the test circle.
4. Mix the drops using a disposable stirrer ensuring coverage of the test circle with the mixture.
5. Place the test slide on the bench and leave for 2 minutes.
6. Gently and evenly, rock and rotate the test slide once and place the test slide on the bench once more.
7. One minute later, read the test slide for the presence of haemagglutination.

RESULTS AND INTERPRETATION

Kit controls or known level value samples should be tested with each test run. The kit negative control should give a negative result. The kit positive control should give a positive result at a titre of 1/4 +/- one double dilution. If levels of controls or users known samples do not give expected results, test results must be considered invalid.

QUALITATIVE METHOD
A positive result is indicated by the obvious agglutination pattern of the red cell reagent, in a clear solution. A negative result is indicated by no change in the red cell suspension on the test slide.
AVITEX ROSE WAALER has a detection limit of 8 IU/ml. Positive results will be obtained at a RF serum concentration of 8 IU/ml or more and negative results will be obtained at a RF concentration below 8 IU/ml.

SEMI-QUANTITATIVE METHOD
The serum RF concentration can then be calculated approximately by multiplying the dilution factor (i.e 2, 4, 8 or 16) by the detection limit, i.e. 8, to give the number of IU/ml concentration e.g. if the agglutination titre appears at 1/8 the approximate serum RF concentration is 8 x 8 = 64 IU/ml. Titres of 1074 IU/ml have been detected with AVITEX ROSE WAALER with no prozone (Hook) effect.

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TROUBLESHOOTING

Use a separate disposable tip for each sample to prevent cross contamination.

Replace caps on all reagents immediately after use.

Prior to the start of the assay bring all reagents to room temperature (20°C to 25°C). Gently mix all reagents by gentle inversion or swirling.

For use by operatives with at least a minimum of basic laboratory training.

Do not use damaged or contaminated kit components.

EVALUATON DATA

Reproducability of **AVITEX ROSE WAALER** is 100% (+/- one double dilution).
Calibrated to major competitors and in house standards.
In an evaluation 50 positive samples and 50 negative samples were tested in parallel with a major competitor.
Comparative overall sensitivity: 100%
Comparative specificity: 100%

REFERENCES

1. **Adams, L.E., Hesa, E.** J-Amer Technol 48, 1978.
2. **Normanusell, D**. Immunochemistry 9, 1972.
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4. **Asslmeh, S.N., Johnson, P.M,** J. Immunol. Methods 34, 1980.

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OMEGA DIAGNOSTICS LTD.
Omega House, Hillfoots Business Village
Alva FK12 5DQ, Scotland, United Kingdom
odl@omegadiagnostics.co.uk
www.omegadiagnostics.com
AN ISO 9001 AND ISO 13485 CERTIFIED COMPANY