AVITEX® IM Ref OD103 OD053

Latex serology test for the detection of Infectious Mononucleosis (IM) Store at 2°C to 8°C. DO NOT FREEZE. For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

AVITEX IM is a rapid latex agglutination test for use with human serum or EDTA plasma in the detection and semi-quantitative measurement of the heterophile antibody associated with infectious mononucleosis (IM). Infectious mononucleosis involves the reticuloendothial tissue and is believed to be caused by the Epstein Barr (EB) virus. The antibody of IM was shown by Paul and Bunnell to agglutinate sheep and horse erythrocytes. Davidsohn used a modified procedure by introducing differential absorption steps to eliminate confusion by Forssman and serum sickness antibodies. The Davidsohn test procedure is accepted as the classic reference method in detecting IM. Absorption procedures have been eliminated in the **AVITEX IM** test.
For professional use only.

PRINCIPLE OF THE TEST

The **AVITEX IM** latex slide agglutination test is based upon the reaction between patient IM antibodies and a latex reagent sensitised with a bovine red cell Mononucleosis antigen. When the latex reagent is mixed with patient sera or EDTA plasma containing heterophile antibodies, a clear agglutination is seen within 2 minutes.

This test has been calibrated to MRC Research Standard A Infectious Mononucleosis Serum. 66/235

CONTENTS

	Ref OD103	Ref OD053
	50	100
LATEX	Suspension of polystyrene latex particles (approximatly 0.3%) coated with bovine red cell Mononucleosis antigen. Working Strength.	
CONTROL +	0.5ml	0.5ml
	Positive Control. Serm containing IM antibodies. Working Strength.	
CONTROL –	0.5ml	0.5ml
	Negative Control. Serum free of IM antibodies. Working Strength.	
STIRRERS	**50**	**100**
PLASTIC TEST SLIDE	**1**	**1**
INSTRUCTION LEAFLET	**1**	**1**

MATERIAL REQUIRED BUT NOT PROVIDED

Micro pipettes capable of dispensing 50µl.
Isotonic saline (0.9% NaCl)

PRECAUTIONS

AVITEX IM reagents contain materials of human origin which have been tested and confirmed negative for HCV, HIV I and HIV II antibodies, and HBsAg by approved procedures at single donor level. 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 IM 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 IM 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 AND PREPARATION

Serum:
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.

Plasma:
Obtain a sample of venous blood from the patient and add to an EDTA plasma collection vial. Centrifuge sample and collect clear plasma. Fresh EDTA plasma samples are required.

Do not use haemolysed, contaminated or lipaemic serum or plasma 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 1 year. 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 SAMPLE 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 or EDTA plasma have 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.

Due to possible prozone effect, the stength of agglutination in the screening test is not indicative of the IM heterophile antibody titre.
False negative results have been reported. Some of these represent cases of IM which persistently remain sero-negative for the IM heterophile antibody. However, some false negative results have been shown to be due to a delayed IM heterophile antibody response.

IM heterophile antibody titres have been shown to persist in some cases for months and years after clinical symptoms have subsided.

Conversely, IM heterophile antibodies have been detected prior to the onset of clinical symptoms. It is therefore necessary to exercise caution in the interpretation of test results. Patients with very high levels of the serum sickness heterophile antibody may react falsely positive for the IM heterophile.
These patients, however, are generally found only in countries where horse serum is used on a prophylactic basis.
IM heterophile antibody has been associated with several diseases other than IM. These include leukaemia, Burkitt's Lymphoma, pancreatic carcinoma, viral hepatitis, CMV infections and others. In these cases, it is difficult to disprove the possibility fo the concurrent disease states.

ASSAY PROCEDURE

Qualitative Method
1. Allow kit reagents and patient serum to come to room temperature.
2. Transfer one drop (50µl) of patient's serum to the test circle on the slide.
3. Shake the latex reagent, then using the dropper provided, 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. Gently and evenly, rock and rotate the test slide for 2 minutes whilst examining the test slide for agglutination.

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 one drop (50µl) of each serum dilution to the test circle on the slide.
3. Shake the latex reagent, then using the dropper provided, 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. Gently and evenly, rock and rotate the test slide for 2 minutes whilst examining the test slide for agglutination.

RESULTS AND INTERPRETATION

Examine the test slide under a strong light source after 2 minutes. Kit controls or known level value samples should be tested with each test run. The kit negative control should give a negative result after 2 minutes. The kit positive control should give a positive result at a titre of 1/4 +/- one double dilution after 2 minutes. 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 latex, in a clear solution. A negative result is indicated by no change in the latex suspension on the test slide.

The sensitivity of **AVITEX IM** is adjusted so that positive reactions will occur with samples that have guinea pig kidney absorbed Davidsohn sheep cell titres of 1/28. A guinea pig absorbed Davidsohn sheep cell titre can be approximated by multiplying the **AVITEX IM** titre by 28.

Detectable levels of the IM heterophile antibody are usually seen between the 6th and 10th day following onset of symptoms. The level usually increases through the second or third week of illness and, thereafter, can be expected to persist with gradual decline over a 12 month period. Positive results should be seen in approximately 98% of IM cases.

Semi Quantitative Method

The IM titre is the last dilution showing a positive result.
Titres of 1/512 have been detected with AVITEX IM with no prozone (Hook) effect.

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.

EVALUATION DATA

Reproducability of **AVITEX IM** is 100% (+/- one double dilution).

	Avitex IM		Totals
	+	-	
Heterophil +	133	7	140
Heterophil -	0	101	101
	133	108	241

Sensitivity 95%
Specificity 100%

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