

**IMMUTEX**

## TEST FOR INFECTIOUS MONONUCLEOSIS

### SUMMARY

Infectious Mononucleosis is a self-limited prolonged illness strongly associated with Epstein-Barr Virus. Though specific treatment is rarely required since the disease is usually asymptomatic, potential complications such as inflammation of the liver, enlargement of the spleen, pericarditis, myocarditis and encephalitis as well as hemolytic anemia associated with this disease requires physician's attention.

In individuals with suppressed or abnormal immunodeficiency disorders, cancer or those with recent organ transplant, Infectious mononucleosis occurs with severe complications.

Studies have cited the presence of heterophile antibodies during the course of infection with Infectious Mononucleosis.

### REAGENT

IMMUTEX is a ready to use, uniform suspension of stabilized, specially treated horse erythrocytes highly specific for heterophile antibodies associated with Infectious Mononucleosis. The reagent does not react with normal Forssman antibodies.

Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

### REAGENT STORAGE AND STABILITY

1. Store the reagents at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagents is as per the expiry date mentioned on the reagent vial labels. Once opened the shelf life of the reagent vial is as described on the reagent vial label provided it is not contaminated.

### PRESENTATION

REF	REF	10810020	10810050
IM REAGENT	▽	20 Tests	50 Tests
CONTROL	+	0.4 ml	0.4 ml
CONTROL	-	0.4 ml	0.4 ml
SIX CIRCLE GLASS SLIDE		1	1
SAMPLE DROPPERS		20	50
MIXING STICK LADDER		1	2
RUBBER TEAT		1	1
PACK INSERT		1	1

### ADDITIONAL MATERIAL REQUIRED

A high intensity direct light source, Stop watch.

### PRINCIPLE

IMMUTEX is a rapid slide haemagglutination test for the detection of heterophile antibodies. IM reagent will agglutinate when mixed with serum containing heterophile antibodies. No agglutination indicates absence of heterophile antibodies.

### PRECAUTIONS

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagents that are derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. The IM reagent contain 0.01% Thimerosal as preservative. Positive and negative controls contain 0.1% Sodium Azide as preservative. Avoid contact with skin or mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of reagents should be verified with known positive and negative controls provided with the kit.
5. Ensure re-suspension of the stabilized erythrocyte reagent before use to improve test readability by gently inverting the vial.
6. Do not interchange vial droppers.
7. Only a clean and dry glass slides must be used. Clean the slide with distilled water and wipe dry.
8. Accessories provided with the kit only must be used for optimum results.
9. Do not use damaged or leaking reagents.

### SAMPLE COLLECTION AND PREPARATION

1. No special preparation of the patient is necessary prior to specimen collection by approved techniques. Do not use haemolysed or contaminated samples. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.
2. Clean and dry glassware free from detergents must be used for sample collection.
3. Do not heat inactivate the serum.
4. Though fresh serum is preferable, serum specimens stored at 2-8°C for upto 24 hours, can also be used in case of delay in testing.

### TEST PROCEDURE

Bring all reagents and samples to room temperature before use.

#### Qualitative Method

1. Gently mix the IM reagent to re-suspend the stabilized horse erythrocyte reagent.
2. Place one drop of the sample to be tested onto one of the reaction circles of the glass slide using a sample dispensing pipette provided with the kit.
3. Place 40 µl of the positive and negative control onto separate reaction circles of the glass slide.
4. Add one drop of IM reagent to the test specimen on the slide. Do not let the dropper tip touch the liquid on the slide.
5. Add one drop of IM reagent to each of the controls.
6. Mix with separate mixing sticks, spreading the mixture uniformly over the entire reaction circle.
7. Immediately start the stopwatch. Rock the slide gently, back and forth, for 2 minutes.
8. Leave the slide undisturbed on the worktable for a further 1 minute.
9. Pick up the slide at the end of 1 minute and observe for agglutination by rocking the slide gently back and forth.

### INTERPRETATION OF RESULTS

Agglutination is a positive test result and indicates presence of heterophile antibodies in the test specimen.

No agglutination is a negative test result and indicates absence of heterophile antibodies in the test specimen.

### REMARKS

1. Markedly lipaemic, haemolysed and contaminated serum sample could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. Heterophile antibodies may be found in disease other than Infectious Mononucleosis. Low titres have been detected in cytomegalic inclusion disease and Toxoplasmosis.
4. Do not read the results beyond indicated testing time limit.
5. As with all diagnostic tests, the result of the test should be correlated with clinical findings to arrive at the final diagnosis.
6. The reagent performance should be validated by occasionally running the positive and negative controls provided with the kit.
7. Any deviation in test procedure could results in variable results.
8. Since techniques and standardization vary from lab to lab one tube difference in tube titres can be expected.
9. Use a separate disposable tip for each sample to prevent cross contamination.
10. Turbid and contaminated sera should not be used for testing.
11. After usage the IM reagent should be immediately recapped and replaced at 2-8°C.
12. Reagent vials that have leakage/ breakage problem should be discarded.
13. Only qualified and well trained staff should use the reagents.
14. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.

### PERFORMANCE CHARACTERISTICS

The performance characteristics of IMMUTEX was evaluated using known positive and negative samples. The known samples were validated using other commercial manufacturers stabilized horse erythrocytes reagent having similar performance characteristics.

	Total	IMMUTEX	
		+ ve	-ve
Infectious Mononucleosis +ve samples	15	15	0
Infectious Mononucleosis -ve samples	25	0	25
	40	15	25

● Sensitivity: 100% ● Specificity: 100%

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of Infectious Mononucleosis negative and Infectious Mononucleosis positive samples. No variations were found in the outcome of different tests.








**WARRANTY**

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

**BIBLIOGRAPHY**

1. Interpretation of Diagnostic Test, Wallach J., 5th Ed., 1992.
2. Zinsser, Microbiology, Edited by Joklik W. K., Willett H. P., 16th Edition.
3. Lee C. L., Davidsohn I., Slaby R., Am. J. Clin. Path., Vol 49, No. 1, 1968.
4. Clinical Diagnosis and Management, Henry J. B., 17th Ed., 1998.
5. Hoff G., Bauer S., JAMA, 1965: 194: 351-353.
6. Data on file: Tulip Diagnostics (P) Ltd..

### SYMBOL KEYS

	Temperature limitation		Manufacturer		Contains sufficient for <n> tests
	Use by		Consult Instructions for use	<b>CONTROL +</b>	Positive control
	Date of Manufacture	<b>REF</b>	Catalogue Number	<b>CONTROL -</b>	Negative control
<b>LOT</b>	Batch Number/ Lot Number	<b>IVD</b>	<i>In vitro</i> Diagnostic Medical Device	<b>REAGENT</b>	Description of reagent
	This side up	<b>PS</b>	Production Site	<b>EC REP</b>	Authorised Representative in the European Community

  
**T TULIP DIAGNOSTICS (P) LTD.**

**PS**

GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH,  
ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202,  
INDIA. Website: www.tulipgroup.com

PLOT NOS. 92/96, PHASE II C, VERNA IND. EST.,  
VERNA, GOA-403 722, INDIA.

**EC REP**

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

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