

ASSAY SYSTEM REAGENTS

For *In Vitro* Diagnostic Use

INTENDED USE

Please see the appropriate package insert.

REAGENTS

ImmunoFA slides consist of ten-well slides coated with fixed *T. gondii* strain RH, fixed HSV Type 1, or HSV Type 2, depending on the label.

Conjugate contains affinity purified goat antihuman antibodies conjugated with fluorescein isothiocyanate (FITC) in buffered diluent containing carrier protein and 0.1% sodium azide. Conjugate contains either anti-IgG (gamma) or anti-IgM (mu) and is supplied with or without Evans Blue counterstain.

Controls are diluted human sera containing preservatives.

PBS is a 10X concentrate of 0.01M phosphate buffered saline (pH 7.2 - 7.6) with 0.1% NaN₃.

Mounting fluid – 1,4-diazabicyclo[2.2.2]octane (DABCO), glycerol, in 0.2M Tris (pH 8.2 – 9.2) and <0.1% sodium azide preservative.

PRECAUTIONS

For *In Vitro* Diagnostic Use. Refer to the appropriate ImmunoFA package insert.

Warning - Potential Biohazardous Material

Sera used in the preparation of controls were tested by a FDA approved method for the presence of the antibody to human immunodeficiency virus (HIV) as well as for hepatitis B surface antigen and found to be negative (not repeatedly reactive). Because no test method can offer complete assurance that HIV, Hepatitis B virus, or other infectious agents are absent, specimens should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen (1).

Some reagents contain sodium azide which may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

RECONSTITUTION AND STORAGE

Store frozen slides (Products 1206 and 1207) below -20 °C. Store all other slides at 2-8 °C.

Conjugates are supplied in liquid form, ready for use, although each laboratory should confirm the most suitable working dilution in its own assay system. Store at 2-8 °C, and avoid repeated freezing and thawing.

Controls are supplied in liquid form, ready for use at the following working dilutions:

<u>Product No.</u>	<u>Working Dilution</u>
1203	1:16
1204	1:16
1205	1:16
1305	1:8
1341	1:8
1411	1:10
1412	1:10
1413	1:10
1511	1:10
1512	1:10
1541	1:10
1542	1:10

Controls are stable until the stated expiration date when stored at 2-8°C.

10X PBS is stored at room temperature. Dilute 1:10 with distilled water. Store 1X PBS at 2-8 °C.

Mounting fluid is supplied ready for use, and should be stored at room temperature.

PROCEDURE, QUALITY CONTROL, INTERPRETATION

See ImmunoFA Test System package inserts for information regarding procedures, quality control, and interpretation.

LIMITATIONS

Do not use with other manufacturers' reagents. Dilution or adulteration of these reagents may affect the performance of the test. Do not use reagent beyond the stated expiration date. Additional information is provided in the ImmunoFA Test System package inserts.

EXPECTED RESULTS

No specific performance claims are made for ImmunoFA components used singly. Performance claims are made only for ImmunoFA Test System kits used according to the kit package insert.

BIBLIOGRAPHY

1. Centers for Disease/National Institutes of Health Manual *Biosafety in Microbiological and Biomedical Laboratories*, 1984.

To place an order for ImmunoFA products, contact GenBio directly. For assistance, please call toll-free 800-288-4368.

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