IFA DILUENT

AESKU.BION
AN AESKU.GROUP COMPANY

CE

NOTE: Changes highlighted

SYMBOL DEFINITIONS

= Consult Directions for Use
= Storage Temperature
= Expiration Date
e = Amount
IVD = *In Vitro* Diagnostic Reagent
REF = Code Number
LOT = Lot Number
= Contains biological material of animal origin

PRODUCT AVAILABILITY

The following is available from Bion Enterprises, Ltd. (Bion):

Description	Code No. REF
IFA Diluent, 60 ml bottle	DIL-9993
IFA Diluent, 125 ml bottle	DIL-9994
IFA Diluent, 250 ml bottle	DIL-9995

INTENDED USE

IFA DILUENT has been developed and optimized for use as a sample diluent with several test systems such as ANA, Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Herpes Simplex Virus type 1 (HS1), Herpes Simplex Virus type 2 (HS2), Measles Virus and Varicella Zoster Virus (VZV). The formulation of this product is intended to reduce the nonspecific fluorescence associated with some serum specimens, and thereby improve the readability of these specimens (qualitative interpretation), without effecting the endpoint titers of specific immunofluorescent reactions (semi-quantitative interpretation).

SUMMARY AND EXPLANATION

Nonspecific fluorescence results from the nonimmunological attachment of immunoglobulins to a substrate (fixed cells, microorganisms, tissue sections, etc.), followed by the binding of conjugate. The intensity and distribution (nuclear, cytoplasmic, etc.) of nonspecific staining may vary from sample to sample, the dilution of the sample used in the test procedure, and the composition of the substrate. Some serum specimens produce little or no nonspecific fluorescence. Other specimens produce so much nonspecific fluorescence that a specific staining pattern, if present, will be obscured. When this happens, the sample must be reported as “unable to interpret.” Alternatively, the sample may be titered to see if a specific pattern can be unmasked within the dilution series.

STORAGE AND STABILITY

Bion IFA DILUENT is stable at 2-8°C until labeled expiration date provided no gross contamination is seen. Do not use if the solution turns cloudy, or if a precipitate forms.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use. Thus, only staff trained in methods of in vitro diagnostics may perform the test.
2. Bion IFA DILUENT contains less than 0.1% thimerosal as a preservative which may be toxic if ingested.
3. Remove only the amount of Bion IFA DILUENT needed to perform each test run to reduce the possibility of product contamination.
4. Bion IFA DILUENT should be used only as a diluent for patient specimens. DO NOT use in any of the wash steps.
5. Bion IFA DILUENT should be used ONLY for IgG testing. IgM specimens should be treated with IgG Binding Reagent.

INSTRUCTIONS FOR USE

1. Bion IFA DILUENT is supplied "ready to use".
2. Refer to the procedural section of the product insert (TEST PROCEDURE Step 1).
3. Prepare the screening dilution of the patient sample using Bion IFA DILUENT instead of PBS.
4. For completion of the staining procedure, refer to the procedural section of the product insert.

NOTE: If the patient sample requires titering, **ONLY** the screening dilution should be prepared in the Bion IFA DILUENT. All subsequent dilutions must be prepared in PBS.

INTERPRETATION

Refer to the QUALITY CONTROL and INTERPRETATION OF RESULTS sections of the product insert.

SPECIFIC PERFORMANCE CHARACTERISTICS

The Bion IFA DILUENT was tested against PBS using serum samples with titers for ANA, EBV, CMV, HSV1, HSV2, Measles, and/or VZV. The Bion IFA DILUENT did not affect endpoint titers; titers and specimen result interpretation were within one twofold dilution (+/-) using Bion IFA DILUENT or PBS.[1]

BIBLIOGRAPHY

1. Data on file, Bion, Des Plaines, IL

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