

## INSTRUCTIONS FOR USE

### Hu Positive Control (strong)

**C038S - 0.5ml**

#### INTENDED USE

The Bio-Diagnostics Hu positive control is intended for use in indirect immunofluorescent antibody (IFA) tests to detect autoantibodies in human serum. This positive control material has been manufactured at a stronger dilution and should be diluted in PBS prior to use as a patient sample would be.

#### SUMMARY AND EXPLANATION

This Hu control has been found to be positive on Primate Cerebellum slides giving brilliant yellow-green fluorescence (between 1+ and 2+) of the Nuclei of both central and peripheral neurones when diluted 1/50 in PBS.

#### PRINCIPLE OF THE TEST

The positive control and human sera are diluted then incubated on Primate Cerebellum slides. The primary test reaction involves circulating antibodies present in the patient's serum, which attach to their homologous antigens. A rinsing period is followed by a secondary reaction using a primate specific FITC anti-human globulin conjugate. The antigen surface is then thoroughly rinsed free of unbound conjugate and viewed under an appropriate fluorescent microscope to visually identify various morphological patterns of fluorescence.

#### WARNINGS AND PRECAUTIONS

1. This positive control has been screened and found to be negative for HBsAg, HIV p24 Ag and HCV, and antibodies to HIV-1/2. However, these tests cannot guarantee the absence of infectious agents. All human components should be handled with appropriate care.
2. The control contains 0.01% thiomersal as a preservative. Although this is at a low concentration, these reagents should be considered toxic. They should not be ingested or allowed to come into contact with either the skin or the mucous membranes.
3. Do not use control beyond its expiry date.
4. For *in vitro* diagnostic use.

#### MATERIALS PROVIDED / STORAGE & STABILITY

**CONTROL +** Hu positive control: C038S (0.5ml)

The control must be stored at 2-8°C upon receipt. Check label for expiry date.

#### ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED

Substrate section slides as appropriate – Primate cerebellum (S5229)

FITC conjugate as appropriate (J502)

Mounting Medium (Bio-Diagnostics R005).

Phosphate Buffered Saline (PBS) (Bio-Diagnostics R002).

Test tubes and rack or microtitre system Disposable pipettes

Coverslips

Staining Dish and Slide Forceps

Moisture Chamber

Distilled Water

Volumetric Flask (500 ml)

Fluorescence Microscope

Paper Towels – lint free

All reagents required are available from Bio-Diagnostics Ltd - see website for details.

#### KEY FOR OTHER SYMBOLS

Used in this instruction leaflet and on accompanying product packaging:

 Manufacture **RFU** Ready for use

 Temperature limitation **IVD** *In vitro* diagnostic medical device

#### TEST INSTRUCTIONS

This control is supplied ready for use for testing on Bio-Diagnostics slides. Follow the recommended testing method for the particular slide type.

#### QUALITY CONTROL

Positive and negative serum controls must be included in each day's testing to confirm reproducibility, sensitivity and specificity of the test procedure.

#### TEST LIMITATIONS

No diagnosis should be based upon a single serologic test result since various host factors must be taken into consideration.

**EC REP**

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