

INSTRUCTIONS FOR USE

Universal Negative Control

C000N/C000N-0.5

1ml/0.5ml

INTENDED USE

The Bio-Diagnostics Universal negative control is intended for use in indirect immunofluorescent antibody (IFA) tests to detect autoantibodies in human serum. This negative control material has been manufactured so that it is ready for use.

SUMMARY AND EXPLANATION

This negative control has been found to be negative in all Bio-Diagnostics Antibody test systems and may also be used as a negative control on Bio-Diagnostics rodent and monkey tissue slides.

PRINCIPLE OF THE TEST

The controls and human sera are incubated on tissue sections. 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 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 nuclear fluorescence. With a positive reaction, the nuclear pattern appears apple-green when viewed under a fluorescent microscope, whilst a negative reaction appears black or greenish-black.

WARNINGS AND PRECAUTIONS

1. The negative control has been tested and found negative for HCV Ab, HBsAg, RPR and HIV 1/2 Ab by an FDA registered laboratory. 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 - Universal negative control: C000N/C000N-0.5

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

FITC conjugate as appropriate

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 catalogue for details.

KEY FOR OTHER SYMBOLS

Used in this instruction leaflet and on accompanying product packaging:

 Manufacture  Ready for use

 Temperature limitation  In vitro diagnostic medical device

TEST INSTRUCTIONS

This control is supplied ready to 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.



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