

INSTRUCTIONS FOR USE

ANCA Negative Control

C025N / C025N-0.5

1ml/0.5ml

INTENDED USE

The Bio-Diagnostics ANCA negative control is intended for use in indirect immunofluorescent antibody (IFA) tests to detect autoantibodies in human serum.

SUMMARY AND EXPLANATION

This negative control has been found to be negative on all Bio-Diagnostics ANCA Antibody test systems. This control has been manufactured ready for use.

PRINCIPLE OF THE TEST

The positive control and human sera are incubated on ANCA 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 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 neutrophils appear apple-green when viewed under a fluorescent microscope, whilst a negative reaction appears black or greenish-black.

WARNINGS AND PRECAUTIONS

1. This negative control has been tested and found negative for HCV Ab, HBsAg, RPR and HIV 1/2 Ab by an FDA registered laboratory. However, these tests cannot guarantee the absence of infectious agents. All human components should be handled with appropriate care.
2. The control contains 0.05% ProClin 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 - ANCA negative control: C025N / C025N-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 **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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