

INSTRUCTIONS FOR USE

Endomysial Positive Control (strong)

C026S - 0.5ml

INTENDED USE

The Bio-Diagnostics Endomysial 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.

SUMMARY AND EXPLANATION

This control has been found to be strongly IgA and IgG positive on monkey Oesophagus/endomysial slides by giving brilliant yellow-green fluorescence (between 3+ and 4+) when diluted at 1/5 in PBS. The suggested endpoint titre is 1/40. Due to variations within each laboratory, the endpoint titre may vary by a 1+ score.

PRINCIPLE OF THE TEST

The positive control and human sera are diluted then incubated on monkey oesophagus 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, a chicken wire pattern surrounding the smooth muscle fibres is observed.

WARNINGS AND PRECAUTIONS

1. This positive control has been tested and found negative for HIV 1/2, HCV, HBsAg, HIV1 RNA, HBV DNA and HCV RNA and Syphilis by FDA approved tests. 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 + Endomysial positive control: C026S

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

TEST INSTRUCTIONS

Dilute at 1/5 in PBS. The suggested endpoint titre is 1/40. Due to variations within each laboratory, the endpoint titre may vary by a 1+ score. 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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