INSTRUCTIONS FOR USE

ANA Nucleolar Positive Control (neat)

C003N/C003N-0.5

1ml/ 0.5ml

INTENDED USE

The Bio-Diagnostics ANA Nucleolar 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 ready for use.

SUMMARY AND EXPLANATION

This control has been found to be strongly positive on HEp-2 slides by giving brilliant yellow-green fluorescence (between 3+ and 4+) when used neat.

PRINCIPLE OF THE TEST

The positive control and human sera are incubated on HEp-2 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, fluorescent staining of the nucleoli of interphase cells is seen. Various sub-types of nucleolar can be identified by observing differences in nucleolar staining in the interphase and mitotic cells.

EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Bio-Diagnostics Ltd, Upton Industrial Estate, Rectory Road, Upton-upon-Severn, Worcestershire, WR8 0LX, United Kingdom. Tel: +44 (0) 1684 592262 email: enquiries@bio-diagnostics.co.uk

WARNINGS AND PRECAUTIONS

1. This positive control has been tested and found to be negative or non-reactive for STS, HBsAg, HBV by PCR (NAT), HIV 1/2 antibody, HIV by PCR (NAT), HCV antibody, and HCV PCR (NAT). 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 + ANA nucleolar positive control: C003N/C003N-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 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.

Issue Date: 11/09/2023

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