

pANCA Positive

For *In Vitro* Diagnostic Use

REF 508291, 504086

Intended Use

This product is intended for use in conjunction with Inova's ANCA slides as a quality control of the IFA autoantibody procedure. The positive control serum assists in the detection of ANCA antibodies in patient serum by indirect immunofluorescence.

Summary and Explanation of the Test

Stabilized, prediluted and characterized autoantibody controls are derived from patients with various types of autoimmune disease. These controls are to be used as training or teaching aids or as additional reference reagents for those laboratories using NOVA Lite autoantibody immunofluorescence test kits. These controls can also be used as quality control sera (in addition to the positive and negative controls already provided with each NOVA Lite kit). The controls can be used either undiluted or in a serial dilution to confirm the antigenic activity of a given substrate.

Reagent

The product consists of human serum positive for ANCA antibodies. It is optimally diluted in buffer containing 0.09% azide as a preservative.

Warnings/Precautions

The serum used in this product has been tested at donor level and found negative for Hepatitis B surface antigen and antibodies to Hepatitis C virus and Human Immunodeficiency Virus (HIV 1 & 2). However, these tests cannot guarantee the absence of infective agents. Proper handling and disposal methods should be established as for all potentially infective materials and only personnel adequately trained in such methods should be permitted to perform the procedures.

This product should only be used by suitably trained persons for the purposes stated. Adherence to the given procedure is recommended.

This product contains sodium azide and must be handled with caution – do not ingest or allow contact with skin or mucous membranes. If contact does occur wash with a large volume of water and seek medical advice. Explosive metal azides may be formed with lead and copper plumbing; on disposal of reagent, flush with a large volume of water to prevent azide build up.

Storage Conditions

This product should be stored at 2-8°C. DO NOT FREEZE. It is stable until the expiry date given on the label.

Procedure

Materials provided

- 0.5mL pANCA Positive or
- 1 mL pANCA Positive Control

Additional Materials Required But Not Provided

1. Substrate slides
2. Phosphate buffered saline (PBS)
3. Humid chamber for incubation steps
4. Anti-human IgG FITC conjugate
5. Mounting media and coverslips
6. Fluorescence microscope

Test Procedure

(Refer to appropriate slide insert for full details.)

Use one/two drops of prediluted positive control.











Results

P-ANCA samples present as perinuclear staining with or without nuclear extension on ethanol fixed human neutrophil slides and coarse speckled cytoplasmic fluorescence on formalin fixed human neutrophil slides.

Limitations of the Procedure

The light source, filters and optics of different makes of fluorescence microscopes will influence the sensitivity of the assay.

Symbols Used

	In Vitro diagnostic medical device
	European Conformity
	European Authorized Representative
	Temperature Limitation
	Batch Code
	Catalogue or part number
	Manufacturer
	Use by
	Contains Sufficient Contenido suficiente para
	Consult instructions for use

Manufactured by:

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