



Unmasking Autoimmune *Vasculitis*

Accurate diagnostics for
cutting-edge ANCA detection

sebia 

The new language of life

ANCA-associated vasculitis

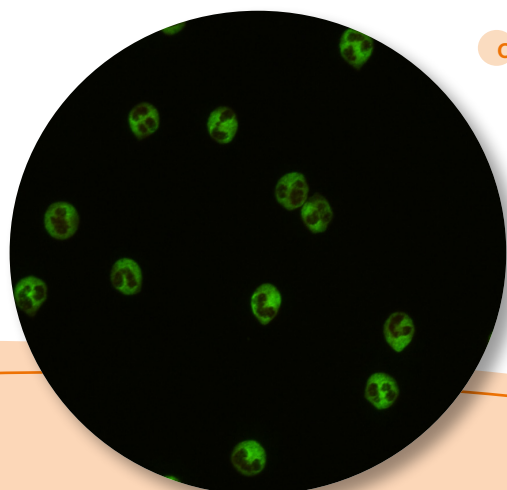
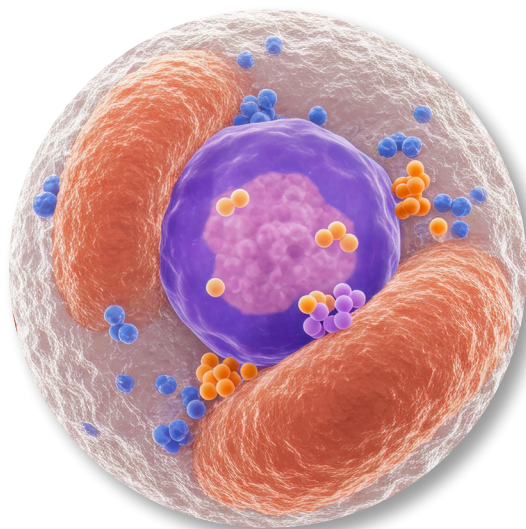
ANCA-associated vasculitis (AAVs) is a group of systemic autoimmune diseases characterized by inflammation and damage to small and medium-sized blood vessels. The term «ANCA-associated» refers to the presence of anti-neutrophil cytoplasmic antibodies (ANCA) in the patient's serum, which target proteins within neutrophils and monocytes. AAV encompasses several distinct clinical entities, including: **Granulomatosis with Polyangiitis (GPA)**, **Microscopic Polyangiitis (MPA)**, and **Eosinophilic Granulomatosis with Polyangiitis (EGPA)**.

ANCA are **autoantibodies** directed against neutrophil cytoplasmic antigens, mainly:

- **Proteinase 3 (PR3)** – often associated with **GPA**
- **Myeloperoxidase (MPO)** is commonly linked to **MPA and EGPA**

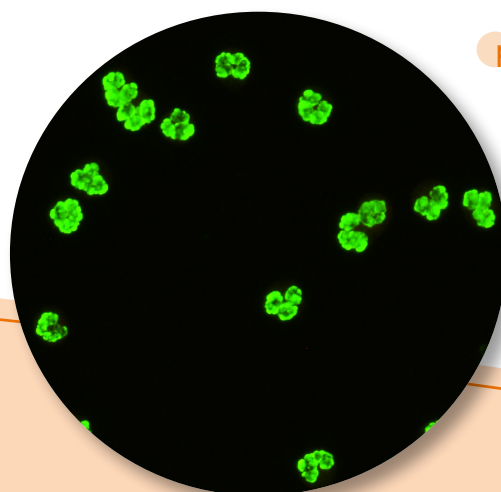
Detection of ANCA in the serum is a key diagnostic criterion for AAVs. The two main methods for ANCA detection are indirect immunofluorescence assay (IFA) and enzyme-linked immunosorbent assay (ELISA).

- **Indirect Immunofluorescence Assay** visualizes cytoplasmic (c-ANCA) or perinuclear (p-ANCA) patterns.
- **Enzyme-Linked Immunosorbent Assay** identifies specific antigens, like PR3 or MPO.



Sebia IFA
ANCA Ethanol
Fixed slide

cANCA



pANCA

Main benefits

1 Sebia ANCA IFA ensures a secure, non-invasive approach to aid in the diagnosis of autoimmune vasculitis

2 diFine® automated microscope and its AI algorithm offer the best-in-class image analysis and interpretation support validated in a clinical setting

Trusted IFA automation

Integrated, reliable and fully traceable workflow

Automated and standardized workflow with **dIFine® P30 processor**

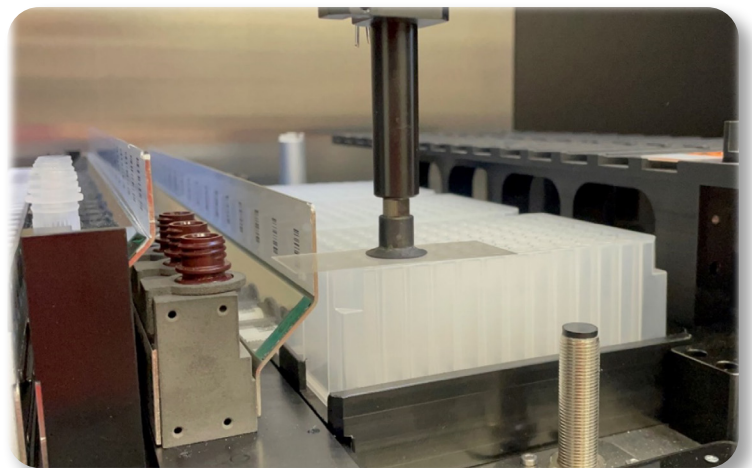
- ✓ Processes up to 240 samples and 30 IFA slides
- ✓ Seamless traceability and smart barcode scanning of samples, reagents and slides – streamlining workflows and minimizing errors
- ✓ Precise dispensation of mounting media and automated coverslipping, decreasing slide handling time and the risk of artifacts



Saving your time & effort!

The dIFine P30: a system so smart, it does the work, while you stay in control

- ✓ Dilution
- ✓ Incubation
- ✓ Washing
- ✓ Mounting
- ✓ Coverslipping



3

Anti-PR3 hs: anchor-ELISA-based random-access assay with an outstanding sensitivity (>95%)

4

High specificity: Highly purified human MPO, free of elastase and lactoferrin, avoiding antibody cross-linking

5

Uniquely comprehensive product portfolio offering a wide range of tests, IFA and ELISA-based, including atypical ANCA Monotests on Alegria 2

Alegria 2

Random Access Solution

Flexible, Reliable and Efficient

Cost-effective sample-to-result solution with Sebia's unique and comprehensive Autoimmune and Specialty Infectious panel utilizing the Alegria Monotest technology.

Customized, full patient profiles with up to 80 results in one run for fast and comprehensive diagnosis.



Anti-GBM

Highly purified collagen IV NC1 domain ensures exceptional reproducibility. Fully compatible with A2 STAT* functionality, it supports accurate and reliable diagnoses of anti-GBM disease.



Anti-PR3 hs

3rd generation assay, with optimum exposure of conformational PR3 epitopes, ensuring a higher sensitivity (96.1% vs 83.6%) compared to the previous generation for the diagnosis of GPA

Anti-MPO

A highly specific immunoassay to detect antibodies against MPO, for the diagnosis of MPA and EGPA. A special coating ensures high performance and stability

**extra prioritized samples (STAT)*

Proven medical value

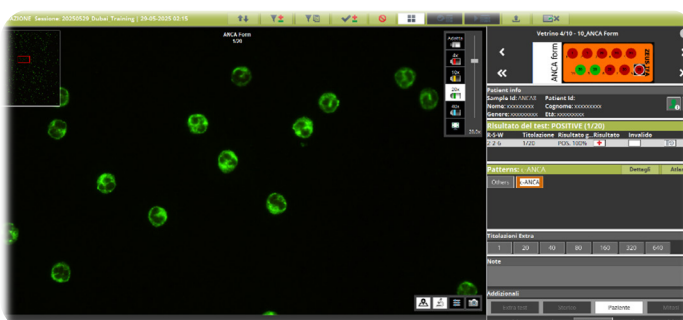
- Affordable screening approach
- Enables early diagnosis and treatment
- Prevents irreversible organ damage
- Helps guide confirmatory testing and biopsy decisions

A streamlined experience for the screening and differentiation of ANCA- associated vasculitis through IFA

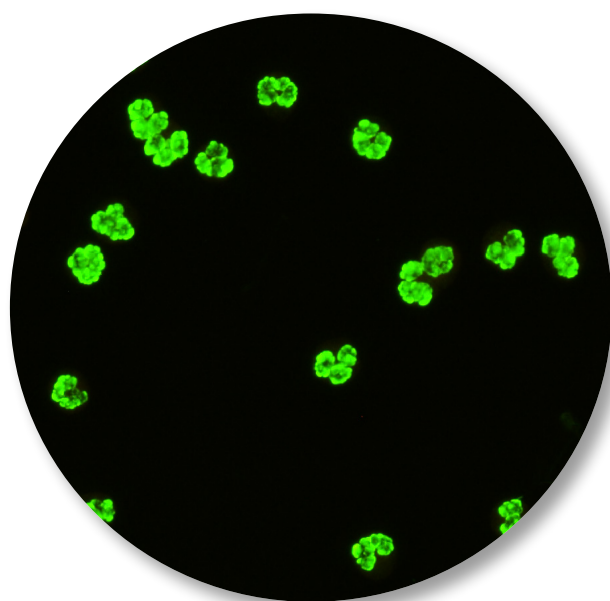


dIFine® automated IFA microscope and Sebia IFA ANCA Ethanol and Formalin fixed slides are optimized for reliable and user-friendly identification of positive and negative results.

- Easy handling due to automated acquisition, analysis, display, and storage of images
- Save time with batch releases of negative samples
- Result recommendations (cANCA, pANCA) through advanced artificial intelligence algorithm



- ✓ **Regular distribution**, virtually cluster-free
- ✓ **Uniform and well-preserved cell morphology** ensures consistent results
- ✓ **Controlled and standardized** neutrophil counts in each well





Ordering information

Instruments

- dIFine® Automated Microscope..... **FA08IMG**
- dIFine® MI Manual Microscope (w/o camera)..... **FA01NC**
(with camera)..... **FA01C**
- dIFine® P30 Processor..... **FA30SP**
- Alegria 2..... **ORG 320**

Reagents

Alegria Product Code

- Anti-PR3 hs (high sensitive)[#]..... **ORG 318**
- Anti-MPO[#]..... **ORG 219**
- ANCAscreen hs (high sensitive)[#]..... **ORG 389**
- Anti-GBM[#]..... **ORG 250**
- Anti-BPI¹..... **ORG 223**
- Anti-Cathepsin G¹..... **ORG 225**
- Anti-Lactoferrin¹..... **ORG 227**
- Alegria Check Vasculitis¹..... **ORG 167 - 2x05**

Open systems ELISA are also available

Reagents

IFA Product Code

- Anti-Neutrophil Cytoplasmic Antibodies (Ethanol-fixed)² **FA9601-1010**
- Anti-Neutrophil Cytoplasmic Antibodies (Formalin-fixed)² **FA9611-0510**
- Anti-Neutrophil Cytoplasmic Antibodies (Ethanol-fixed)¹ **A060L**
- Anti-Neutrophil Cytoplasmic Antibodies (Formalin-fixed)¹ **A060PL**

¹ CE-marked

² FDA-cleared



Scan here
for more information
about ANCA

For further information, please find your Sebia local representative to contact on our Website www.sebia.com/sebia/worldwide-presence/.

