

# ZENIT | PRO

autoimmunity

Fully automated IFA analyzer



## A different way to be unique

Total automation  
Unparalleled performance  
Enhanced standardization



## The Zenit brand: a leading presence with complete coverage in the autoimmunity field

Autoimmunity has been our focus since 1998.

Extensive research and a proven track record of accuracy and reliability have allowed us to expand our early experience into an international organization with a comprehensive offering including IFA, ELISA, CLIA, microarray, genetic testing, biomonitoring, with the smallest instrument range coupled with the widest possible array of antigens, both human recombinant and human purified, to cover all diagnostic needs. Our goal is to continue developing solutions for the clinic and laboratory that improve the diagnosis, prognosis, monitoring and treatment of autoimmune diseases.

## Evolving scenarios and innovative perspectives

### Autoimmune diseases and the role of IFA

The impact of autoimmune diseases has grown exponentially both from a clinical and a diagnostic point of view over the past few decades. The knowledge of the pathogenic mechanisms underlying autoimmune diseases contributed to identify new autoantibodies and new diagnostic/prognostic assays have been developed.

Antinuclear antibodies (ANA) are important elements in the diagnosis of a variety of autoimmune diseases, especially ANA-associated rheumatic diseases (AARD), and indirect immunofluorescence (IFA), although it has been in use for over 50 years, is still the recommended method to screen for ANAs.

Specifically, according to the recommendations of the American College of Rheumatology, ANA Task Force, the IFA assay on human epidermoid laryngeal carcinoma (HEp-2) cells represents the gold standard for ANA testing.

Nevertheless, performing ANA testing with IFA is time-consuming, labor intensive and burdened by some unfavorable features, such as the need for expert reading by skilled operators, a high rate of subjectivity and the low degree of standardization.

Laboratories that are testing on autoimmunity have made strides in automation over the past decade; technological solutions have been developed and automated reading systems have been made more and more reliable to achieve improved sensitivity and specificity, to obtain reproducible results and guarantee analytical precision.

**In order to further improve standardization** of the whole IFA procedure, **A.Menarini Diagnostics has developed Zenit PRO**, the brand new all-in-one system for the total automation of IFA: not only are reading and interpretation automatically performed but also the slide preparation, thus reducing the effects caused by less trained personnel and differences which might show up in different laboratories.

With Zenit PRO **you will achieve a new level of standardization, increase efficiency and productivity** with a remarkable impact on the overall laboratory management for improved health outcomes.

A generation ahead  
in IFA automation

## The evolution of standardization

Zenit PRO is the new high-performance A.Menarini Diagnostics **fully automated system** which streamlines the whole IFA protocol, **from slide processing to reading and interpretation of results.**

The system integrates an enhanced module that ensures the **complete slide preparation**, from serum dilution to coverslipping, with an **on-board reading** unit which provides unparalleled accuracy and allows automated whole well digitization for a better interpretation of Zenit IFA tests.

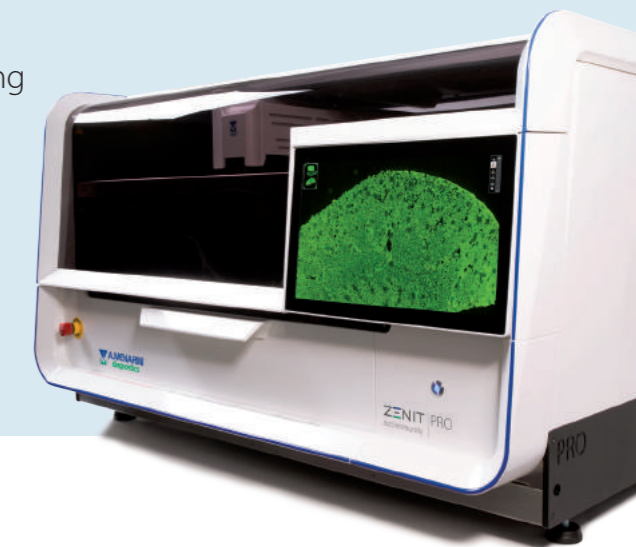
What makes Zenit PRO different are the image autofocusing technology, the software algorithms for IFA detection and pattern recognition, run-time, types of recognized ANA IFA patterns, and its ability to analyze different kinds of IFA substrate.

Thus, Zenit PRO is able to overcome the drawbacks of manual ANA IFA analysis, and it efficiently contributes to the harmonization of the HEp-2 IFA analysis.

An advanced intelligent software orchestrates multiple processes into a seamless, fully automated continuous access system.

## Main features and benefits

- Automated IFA slide preparation and coverslip mounting
- Walkaway process with continuous access
- Whole well scanning
- Navigable well
- High throughput
- Reduction of intra- and inter-laboratory variability
- Full traceability
- Reduction of operating costs



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Driving standardization  
through automation

## Integrated slide processing that changes the way IFA is performed

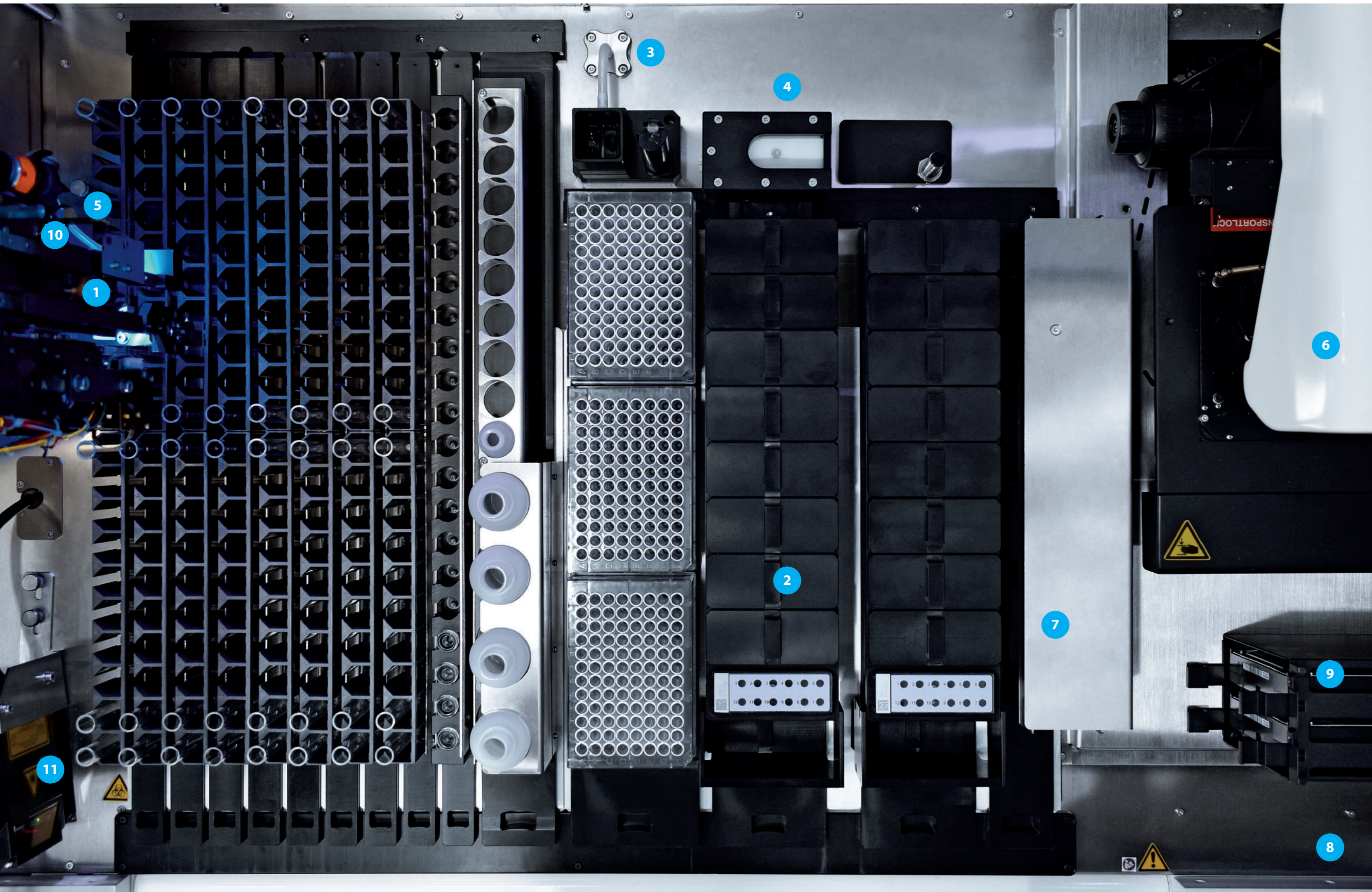
A. Menarini Diagnostics brought engineering and capability to the lab by simply developing the sole system that ensures **the complete preparation of the IFA slide**, from serum dilution to coverslipping, minimizing operator intervention all along a high-volume testing procedure.

The Zenit PRO automated liquid handling system eliminates the inconsistency of human intervention, maximizing the accuracy of the overall IFA process and ensuring accurate sample dispensation, controlled incubation conditions and efficient washing.

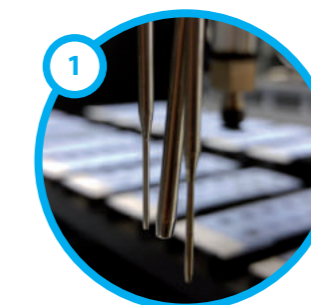


- Up to 160 tubes: 8 racks with 20 tubes each
- Up to 288 cuvettes: 3 x 96-well consumable plates, 1.2 ml volume
- Up to 20 slots for controls
- Up to 9 slots for conjugate and mounting medium
- Up to 4 slots for diluent

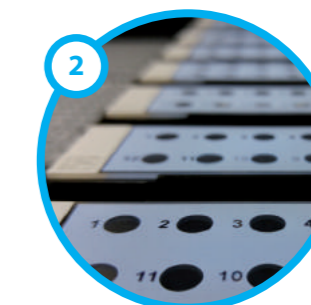




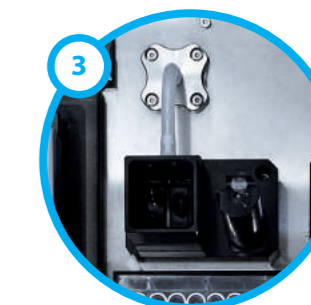
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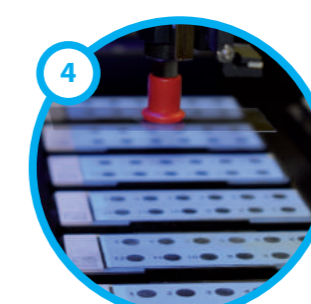
**More needles for higher speed**  
 Two dispensing needles and one aspiration needle increase preparation speed



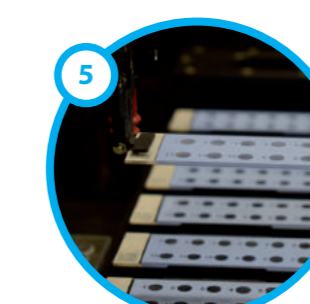
**Multiple run**  
 Up to 18 slides can be simultaneously loaded to be processed. Zenit PRO allows continuous access to add further tests while the system is operating



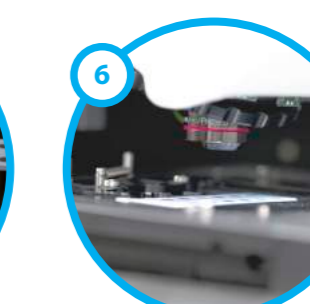
**Wash station**  
 A wash station ensures both internal and external cleaning of the three needles eliminating carryover



**Automated coverslipping and mounting**  
 The system automatically mounts each processed slide. A suction pad places the coverslip and seals the slide, avoiding the formation of air bubbles



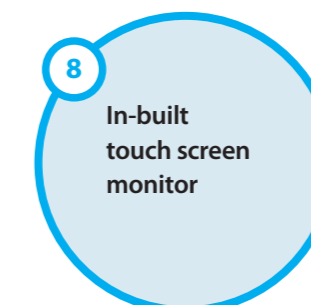
**Automated slide delivery**  
 A precision clamp delivers the mounted slide onto the microscope precision stage for automated scanning of each well



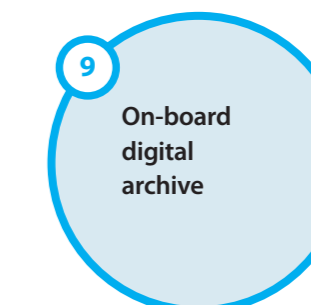
**Automated slide reader**  
 The motorized microscope drives to the substrate positions, autofocuses and scan each well



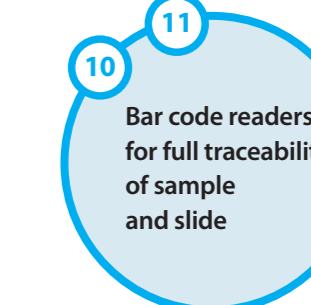
**Slide parking rack**  
 After termination of the reading procedure, a precision clamp delivers the slide into a parking rack to await removal by the operator. Up to 18 slides can be stacked in this area



**In-built touch screen monitor**



**On-board digital archive**



**Bar code readers for full traceability of sample and slide**

Advanced and powerful information management for results that matter

## As smart and simple as you want it to be

Zenit PRO offers **powerful analytics** and a **simple and intuitive user interface** that simplify workflows and enable meaningful analysis of results to efficiently achieve diagnostic goals even from the most challenging assays.

### Simply powerful

The system can process and scan a number of cellular substrates and provides **whole well digitization** of any IFA Zenit test: it performs the analysis on the whole well and not just on a limited number of

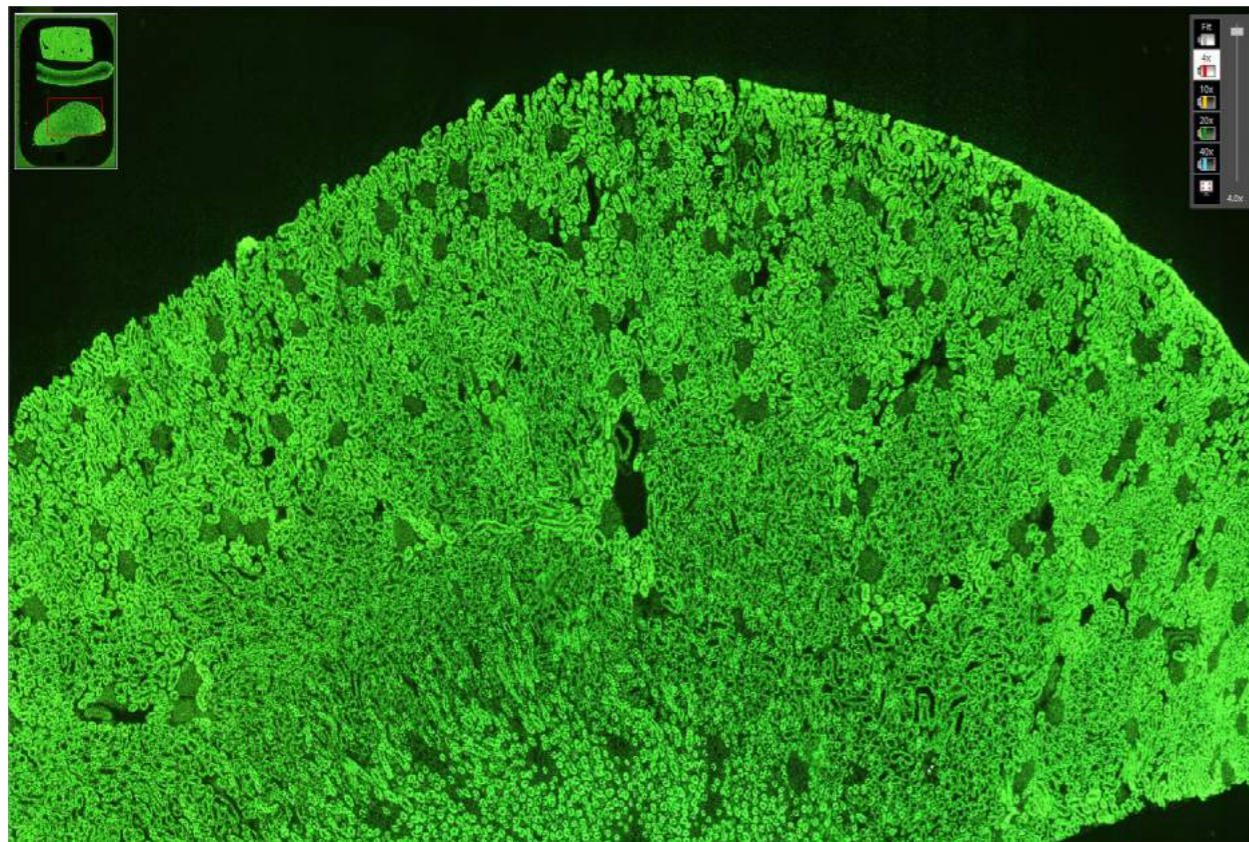
pre-defined images only partially covering the area of interest.

This feature offers several advantages:

- As the number of counted and analyzed cells is fairly large (greater than 3.000 for each well), the results are more reliable and consistent
- Results are robust even in the presence of micro-bubbles or damaged areas in the well
- High sensitivity thanks to the possibility to adjust cell count and cell identification to detect rare patterns or a pattern displayed by a few cells only.

### Full screen view of the IFA test:

The digitized image is displayed and can be navigated with the virtual microscope tool that allows the user to have a broad view of the substrate at multiple magnifications.



### From assay to answer

Results are **interpreted and validated by the operator**, using the **touch screen monitor**, or remotely at another station within the laboratory using a powerful yet intuitive software interface. Customizable views facilitate navigation.

**Multiview**  
for visualization and analysis of multiple wells of the same patient's sample on the same slide (different dilutions)

**Send to LIS**  
Sends results directly to LIS as soon as each well is validated and before the session is archived

**Extra tests**  
To select additional IFA/non IFA tests

**History/Patient**  
To evaluate on the screen multiple tests (digital wells) of the same patient (different dilutions, different tests, both of the same session or from the archive)

**Mitoses**  
Mitotic images of recognized patterns are detected and shown in a dedicated gallery. Each image can be easily identified in the digital well, automatically relocated at the center of the screen

**Atlas**  
Atlas with reference images and user-defined pattern guide with ICAP nomenclature

Smart analysis software  
for meaningful data

## Add confidence to your results

The system includes the **automatic classification of positive/negative results for Zenit ANA HEp-2 tests** and the identification of a number of cellular patterns even in mixed cases. The software measures

the intensity of fluorescence for each positive test and provides a pattern suggestion based on a wide database of reference images used to train a state of the art classifier.

### Additional recognition software modules

#### Zenit ANA HEp-2 pattern recognition

Homogeneous, Fine speckled, Coarse speckled, Nucleola, Centromere, Few nucleolar dots, Multiple nuclear dots, Ribosomal-like, Mitochondrial-like, Mitoses recognition on identified pattern

#### Smart ANCA analysis software

ANCA positive/negative classification and pattern recognition (c-ANCA, p-ANCA, Other ANCA)

#### Smart nDNA analysis software

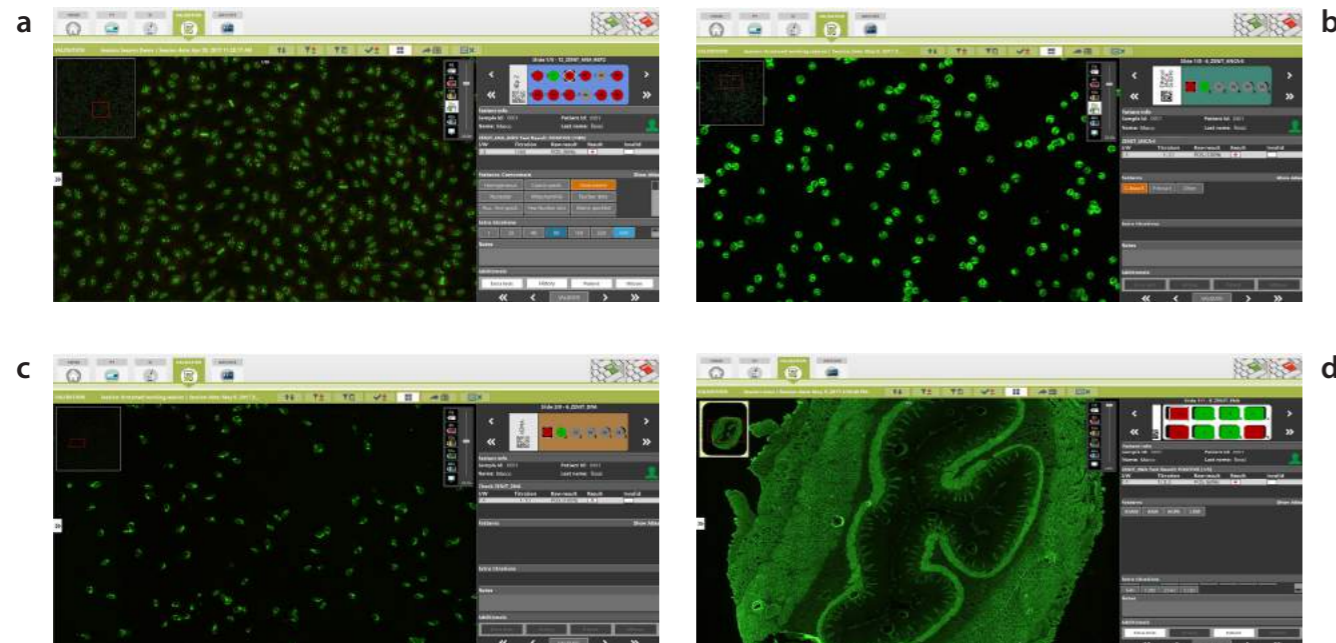
nDNA positive/negative classification

#### Smart EMA analysis software

EMA positive/negative classification

Further information available online at [www.menarindiagnostics.com/Products/Autoimmunity](http://www.menarindiagnostics.com/Products/Autoimmunity)

The Smart analysis software includes the automatic identification of a) Zenit ANA HEp-2 patterns, b) ANCA positive/negative classification and pattern recognition, c) positive/negative classification of nDNA and d) positive/negative classification of EMA.



## Technical Specifications

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<b>Slide processing</b>	
Pumps	1 peristaltic pump and 2x1,25 ml syringe pumps
Traceability	Samples: Linear barcode reader with focal adjustment Slides: Data matrix 2D barcode reader
Slide capacity	18
Sample capacity	160
Dilution cuvettes	288 (3x96-well consumable plates, 1.2 ml volume)
Probes	3 (2 dispensing needles + 1 aspiration needle)
Slide washing	Continuous flow or multi drop
External tanks	2x2l Buffers; 1x5l Wash; 1x5l Waste with level sensor
<b>Slide reading</b>	
Microscope	Epi-fluorescent microscope. Excitation 450-490 nm; Fluorescence 520 nm
Objectives	4x for pre-focus, 20x for acquisition (10x, 40x optional). Resolution 0.50 micron per pixel at 20x
Optical source	Blue high power LED 480 nm
Image compression	JPEG-2000
Scanning speed (at 20x)	ANA, nDNA, ANCA: < 30 sec per well Tissues: < 2,5 min per well
<b>Image and data processing</b>	
Integrated visual display unit on board	15" touch screen full HD monitor
Integrated elaboration unit	On board, 2 hard disks 1TB RAID 10 (1 TB to store data). Operating system: Windows 10
Bidirectional communication	HL7, XML
<b>Environmental setting - Working session</b>	
Temperature	20-35 °C
Humidity	10% - 60% non condensing
Power supply, Entry level	AC 110-120V or 220-240V 50-50 Hz
<b>Transport/Storage</b>	
Size	WHD 120x70x90 cm
Weight	Approx 150 kg
Temperature	From -20 to 60 °C
Humidity	90% RH max. (non condensing)
<b>Optional Modules</b>	
Remote station	Client access to archive and validation modules
ANA HEp-2 pattern recognition	Homogeneous, Fine speckled, Coarse speckled, Nucleolar, Centromere, Few nucleolar dots, Multiple nuclear dots, Ribosomal-like, Mitochondrial-like, Mitoses recognition on identified patterns.
Smart ANCA analysis software	ANCA positive/negative classification and pattern recognition (c-ANCA, p-ANCA, other-ANCA)
Smart nDNA analysis software	nDNA positive/negative classification
Smart EMA analysis software	EMA positive/negative classification

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