

ZENIT
autoimmunity



The value of achievement
lies in the achieving
A. Einstein



What does it mean to observe?

To us it means putting passion
into what we do, it means caring,
it means having ideas.

It means observing the world
through talent and technology.

We help you see what otherwise would go unnoticed.

Look carefully;
there's something you did not notice before.
Now you can see it too, with us.

A. Menarini Diagnostics
The human touch of technology

What does it mean to observe?





To us it means putting passion into what we do,
it means caring, it means having ideas.



| An Italian story

The Menarini Group and A. Menarini Diagnostics



The Menarini Group is the leading Italian pharmaceutical company in the world, a guarantee of internationally recognized quality. The achieved results are proof of an efficient strategy based on Research, Innovation and Internationalization, along with the ability to recognize and meet the needs of physicians and patients alike.

One of the Menarini Group's strong points is its collaboration with international partners: our goal is to create synergies that give rise to cutting-edge solutions, pharmaceutical products, and services in the health sector.

At Menarini, quality is the basis of a shared Group strategy. All company structures are involved at different levels in the drug manufacturing process: an efficient system that has created a unique work standard for ensuring quality in every phase, from research to production, from distribution to providing scientific information. All for achieving a common goal: excellence.

"Health without borders", with this vision Menarini makes the difference, also in the field of diagnostics.

A. MENARINI DIAGNOSTICS IS SYNONYMOUS WITH QUALITY

Since 1976, our mission has been to improve the quality of people's lives and achieve maximum customer satisfaction by providing services and products for diagnostics and preventive medicine. All of our systems and products comply with strict regulations, fully satisfying the requirements of standards and Menarini quality controls. A. Menarini Diagnostics is certified by a third party in accordance with the requirements of the EN ISO 9001:2008 and EN ISO 13485:2012 standards.

A. MENARINI DIAGNOSTICS AT A GLANCE

With more than 1,000 employees and a network of 15 affiliates throughout Europe, A. Menarini Diagnostics is one of the major diagnostics companies in Europe.

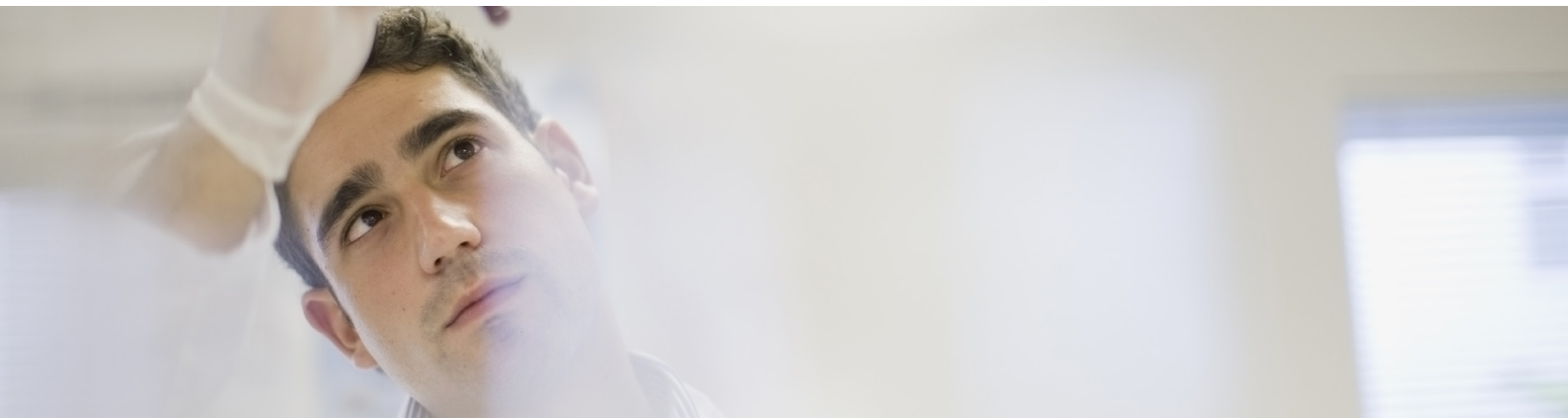
Specialized in self testing and laboratory testing, we currently provide approximately 500 million sensors for self testing per year and we have close to 10,000 laboratory instruments installed all over Europe.

The value of innovation















What does the future look like for **A. Menarini Diagnostics** in the field of autoimmunity?

A. Menarini Diagnostics and the Zenit brand: a galaxy of products for a leading presence in autoimmunity

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 offering high-quality diagnostic products and services for the detection and diagnosis of autoimmune diseases. Our goal is to continue developing solutions for the clinic and laboratory that improve the diagnosis, prognosis, monitoring and treatment of autoimmune diseases. Quality is our value, and continuous innovation our motto.



A leading presence with complete coverage in the autoimmunity field

| | | |
|---|--|---|
|   |  |  |
| |  |  |
| |  |  |
| |  |  |
| |  |  |
| |  |  |



**A. Menarini Diagnostics boasts a historical presence in the field of autoimmunity.
Our strengths include:**

- Quality and consistency
- State-of-the-art antigens
- The most advanced technologies
- A comprehensive offering: IFA, ELISA, CLIA, microarray, genetic testing, biomonitoring, with the smallest instrument range
- The widest possible array of antigens, both human recombinant and human purified, to cover all diagnostic needs
- Assays with excellent clinical sensitivity and specificity
- Accurate and standardized results
- International Symposia on current topics and a focus on scientific publishing

Our complete coverage of autoimmunity allows us to provide not only technical support, but also scientific and economic support.

Scientific excellence and international commitment

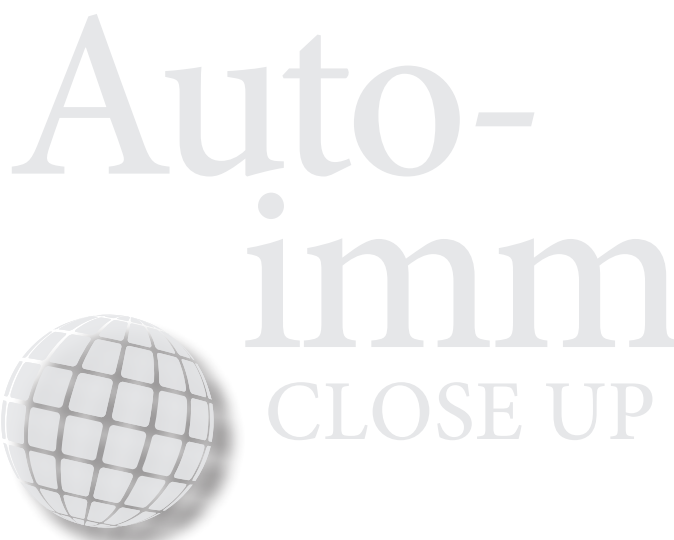
A. Menarini Diagnostics' competitive strengths include its diverse

We provide two publications in the field.

Autoimmunity Highlights, a peer-reviewed English-language journal published by Springer, was launched in 2010 with an unconditional grant from Menarini.

Autoimmunity Close Up builds on this by bringing autoimmunity-related news into the laboratory, and serving as a bridge between the clinic, the laboratory and specialists in the complex world of autoimmunity diagnosis.

It differs from *Autoimmunity Highlights* in being a house organ that includes also marketing and advertising material, but maintains a strong scientific focus on autoimmune disease testing. Moreover, *Autoimmunity Close Up* supports physicians by disseminating the latest scientific information on the autoimmune diseases themselves.



technological expertise and commitment to scientific innovation.

Throughout more than 35 years, A. Menarini Diagnostics has expanded beyond immediate geographical barriers to open up new frontiers in the world of diagnostics. We have always put our collective knowledge and expertise at the service of healthcare professionals and patients, seeking global dissemination of the benefits resulting from our decades of effort and experience. Autoimmunity has been a strategic area since the late 1990's.

Our scientific support includes literature support, organization of international symposia, attendance at important events, and opinion leader networking.

MAIN CONGRESS ACTIVITIES

- More than 10 mono-sponsored symposia from 2002
- Regular attendance at international congresses on autoimmunity, with workshops and other activities
- Local presence at most European congresses on autoimmunity
- Hundreds of posters and abstracts presented at congresses





It means observing



the world through talent and technology.

ZENIT | ra

autoimmunity

The fully automated immunoassay analyzer that best fits your needs in autoimmunity.



Zenit RA easily detects the most common autoantibodies in autoimmune diseases, providing clinically useful data in a short time. The flexibility of its work modalities makes it particularly well adapted to determining antigenic specificities in daily practice.

Autoimmune liver disease: can chemiluminescent, magnetic particle-based immunoassay (CMIA) increase sensitivity and specificity? Our opinion is yes, with Zenit RA LKM1, AMA M2.



Zenit RA is the exclusive new addition to A. Menarini Diagnostics Zenit series. It is magnetic micro-particle-based and uses chemiluminescent detection (acridinium) to provide the high degree of precision and rapidity of analysis that your autoimmunity laboratory routine demands:

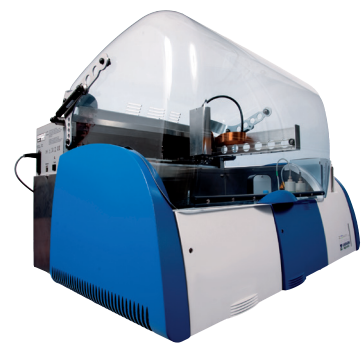
- Accurate, standardized and reproducible results
- First result within 25 minutes
- Throughput: 70 results/hour

Zenit RA provides maximum flexibility and operational readiness in autoimmunity testing:

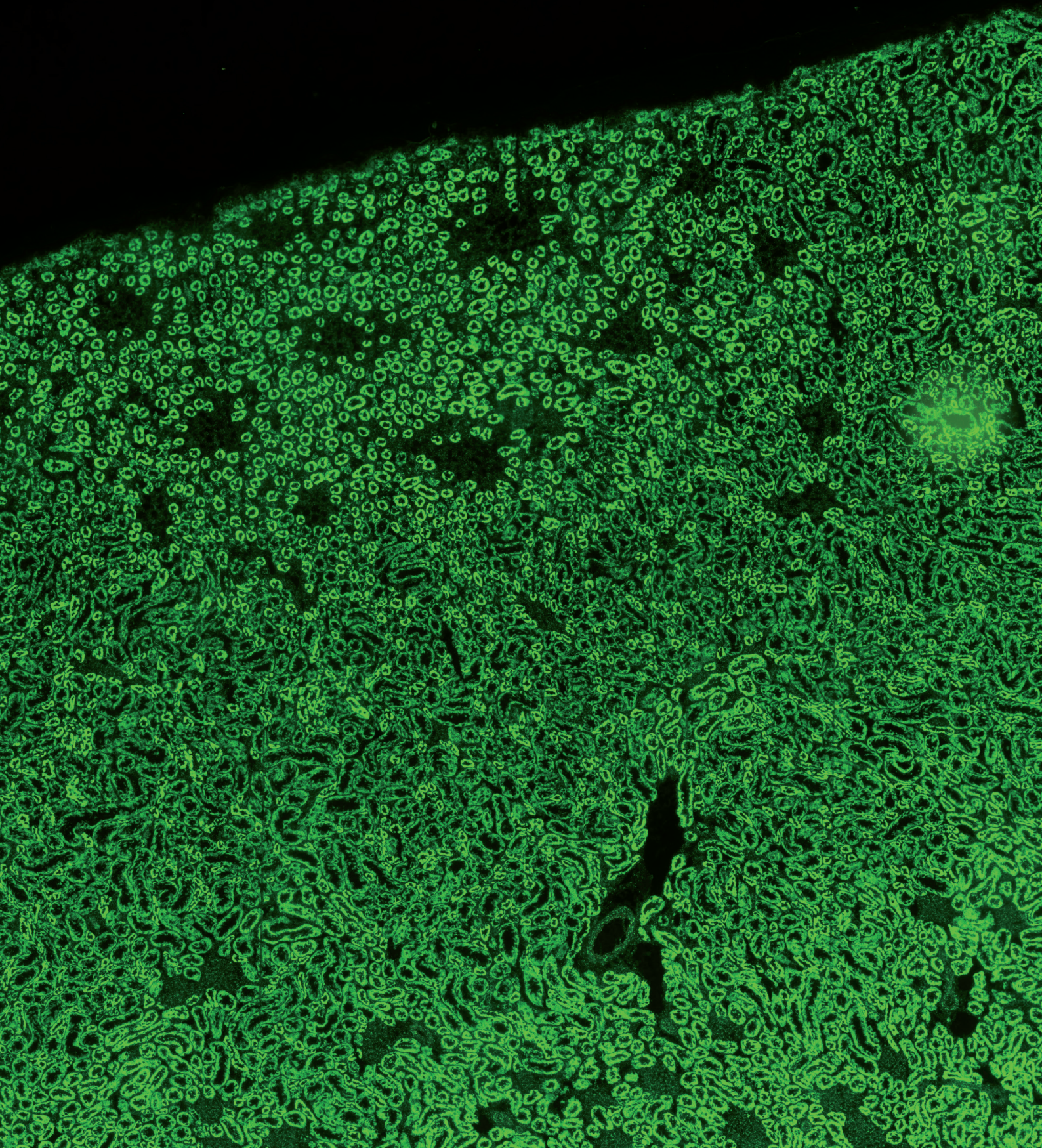
- Up to 15 different simultaneous immunoassays
- True walk-away operation
- Continuous access to samples, reagents, consumables and parts
- STAT priority function for urgent samples
- Continuous loading of bar-coded samples and reagents

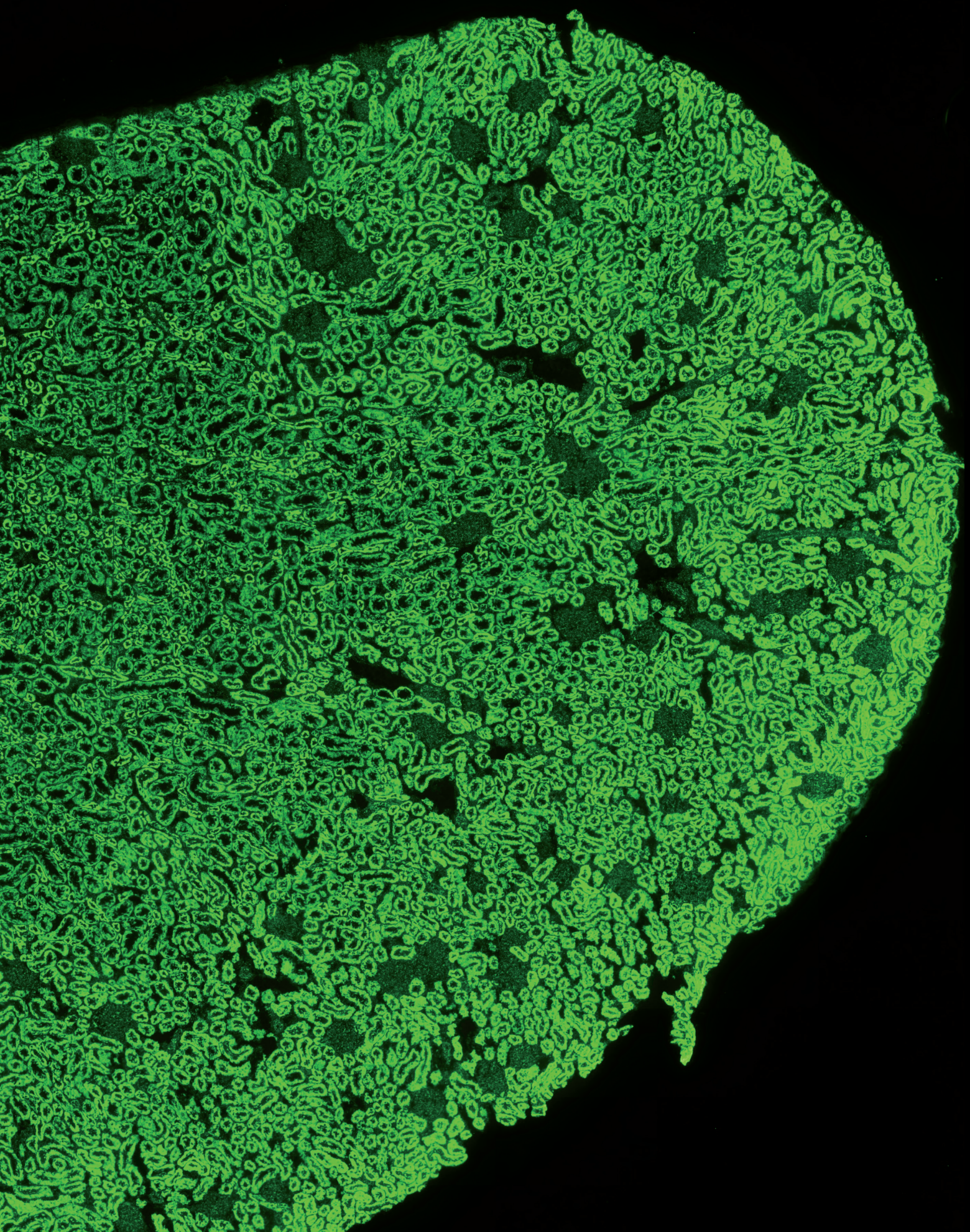
It brings a higher degree of versatility to autoimmune diagnostics:

- Consolidated 25-test autoimmunity menu
- Calibration stable for 3 weeks for all reagents
- Capacity and automation for medium to large laboratories



*Who launched the first method to detect tTG IgA antibodies
and semiquantitative detection of total IgA in a CMIA?*

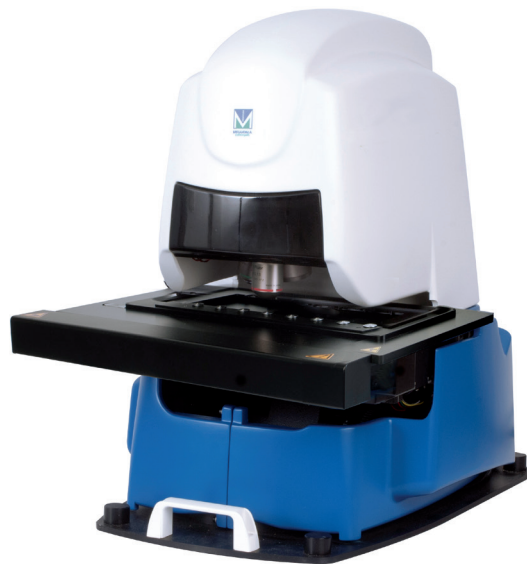




ZENIT | G-Sight

autoimmunity

Zenit G-Sight is a high-performance automated system for the scanning and interpretation of immunofluorescence slides in autoimmune diagnostics.



The Zenit G-Sight systems from A. Menarini Diagnostics for image acquisition and interpretation of cell- or tissue-based IIF tests are ideal for the automated serological diagnosis of autoimmune diseases.

Zenit G-Sight supports the decision-making process in the most accurate, specific and standardized way possible by providing tools such as negativity, positivity, and pattern interpretation in ANCA screening on IFA.



The G-Sight series offers a wide variety of analyzers, ranging from the entry-level version that loads two slides, up to the top of range, with eight IFA slides and the AMiDot microarray together.

Zenit G-Sight performs:

- fully automated image acquisition of cell- or tissue-based IIF tests with an autofocus process that avoids the need for additional counterstaining
- semi-quantitative analysis and intelligent pattern recognition for ANA HEp-2 assays, ANCA, performed on up to 13 digital tiles per well
- digitization for other IIF substrates

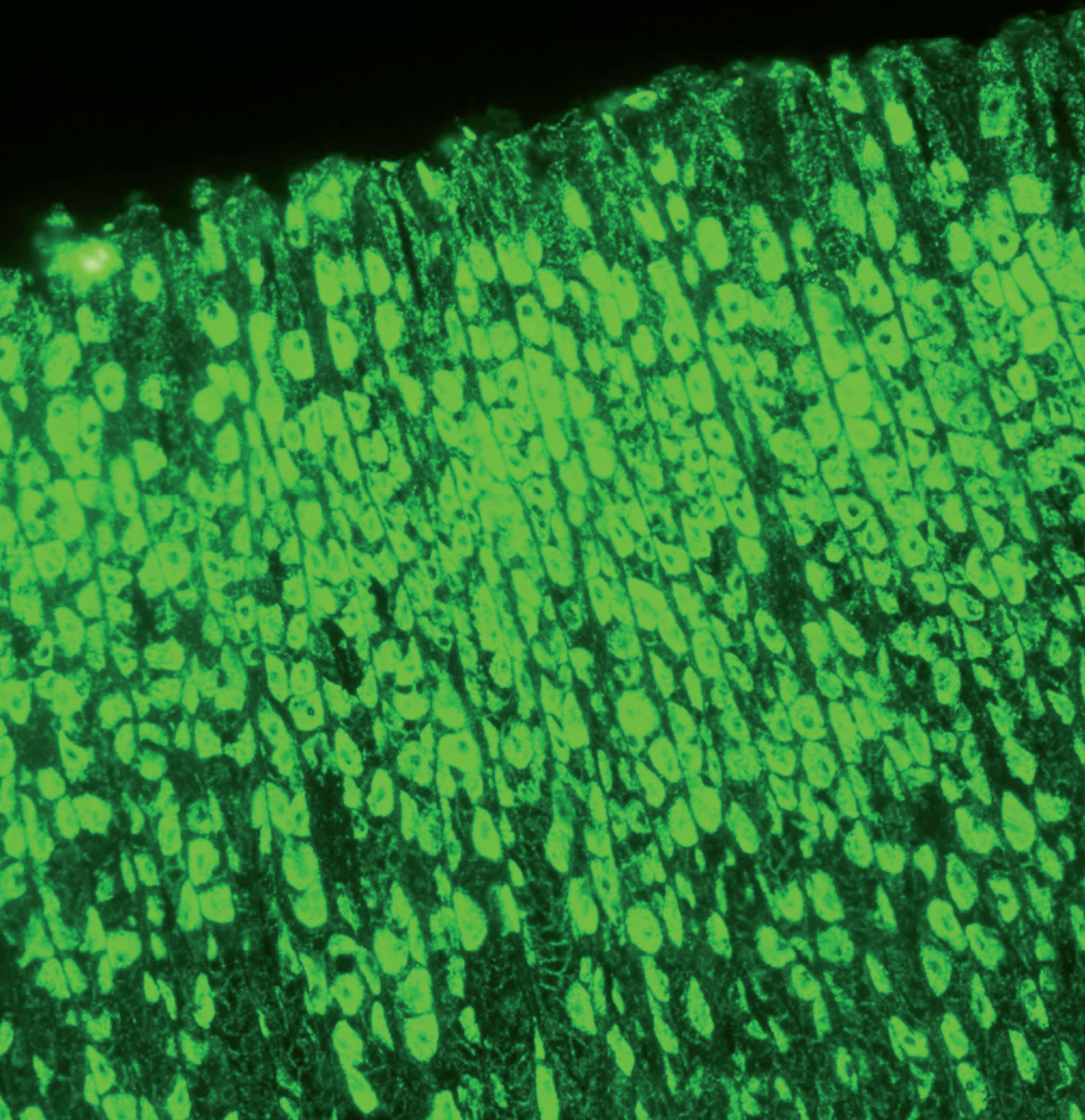
Moreover, Zenit G-Sight has a relative specificity of 98.9% and a reproducibility CV of 1.99%.

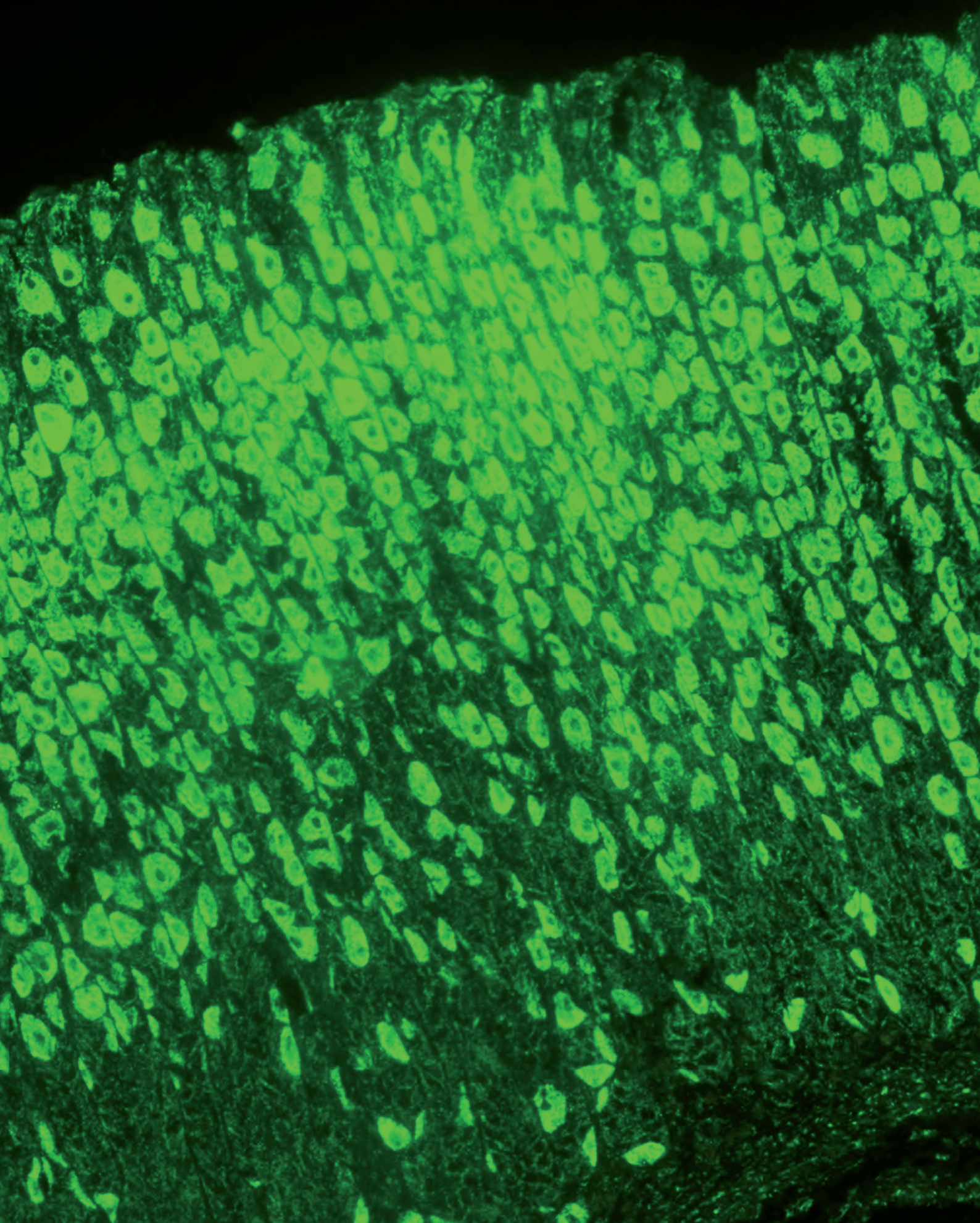
The system can detect positive/negative samples, measure fluorescence intensity, and evaluate and classify the main fluorescence patterns generated by ANA detection on HEp-2 and ANCA substrates.

Zenit G-Sight (with an 8-slide capacity) is perfect for daily routines with large sample numbers, maximizing efficiency and optimizing human resources.



Can you browse your IFA images? Only if you have G-Sight.





ZENIT | UP

autoimmunity

Zenit UP is a new, accurate and reliable, all-in-one, microplate and slide processor for automating ELISA, IFA and microarray methods.



Zenit UP is the new “all-in-one” automated ELISA microplate, IFA slide and AMiDot microarray processor available exclusively in the Zenit series. Zenit UP is the complete solution for processing ELISA, IFA and microarray assays in the same session, on the same platform.

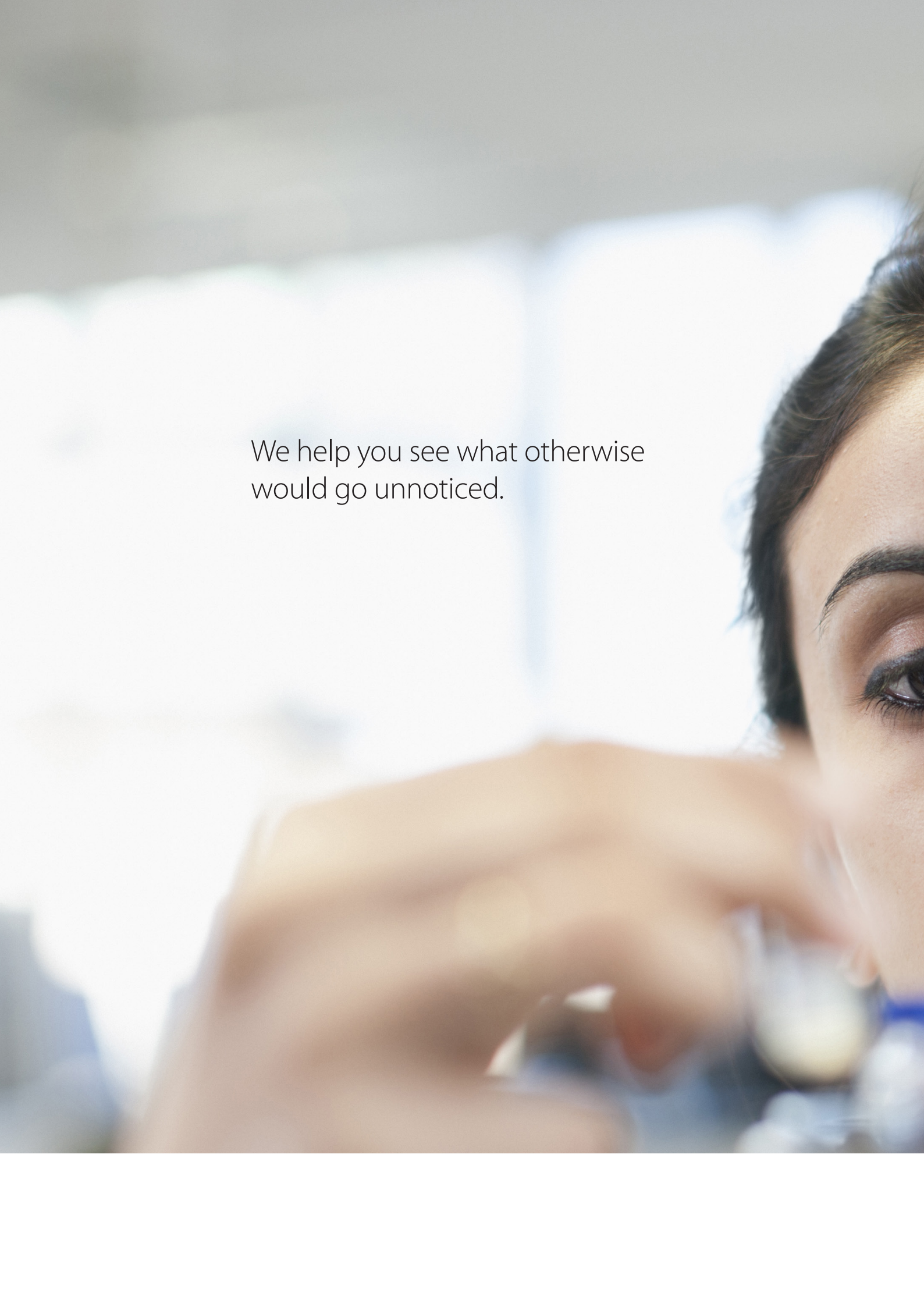
Designed for performance, Zenit UP provides unparalleled versatility and precision, with proven high-accuracy pipetting and flexible configurations.

Zenit IT is the **A. Menarini Diagnostics** solution for managing your workflow with comprehensive middleware specifically for the autoimmunity laboratory.



Middleware has historically been the province of Information Technology solutions, a kind of "IT plumbing" that connects system components. Zenit IT is much more. This state-of-the-art software provides the IT infrastructure that autoimmunity experts need.

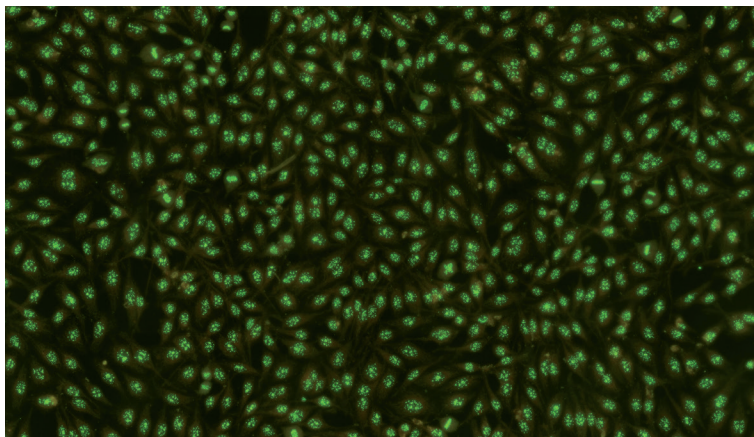
The clinical picture at a click.



We help you see what otherwise
would go unnoticed.



A. Menarini Diagnostics works closely with industry experts to develop our proprietary products, resulting in continuous expansion and updating of our product offering.



Enzyme-linked Immunosorbent Assay (ELISA) is a widely used method for monitoring and diagnosing diseases. Zenit Reagents is the brand name of the A. Menarini Diagnostics ELISA kits for researchers and in vitro diagnostics clinicians. Most kits utilize the latest target antigens for detection with high sensitivity and specificity. Ready-to-use reagents (substrate, assay diluent, and stop solution) are included for easy operation. Flexible break-away microwells provide convenience and cost savings.

A useful diagnostic tool to increase sensitivity and specificity for the diagnosis of celiac disease through the Zenit ELISA Celiac Fusion tTG/DGP.

With over 20 years of leadership in ELISA technology, A. Menarini Diagnostics offers an impressive array of more than 50 different ELISA assays that feature accurate qualitative and quantitative detection of antibodies for the diagnosis of autoimmune diseases.

- Antigens selected and presented in a highly purified form for the highest accuracy
- Standardized component sets and methods for greater reproducibility
- Optimal detection systems for enhanced sensitivity and specificity
- Optimal design for performance on our automated ELISA platforms, such as Zenit UP
- Choice of single or multiple point calibration for greater flexibility

ELISA Zenit Reagents include kit for the diagnosis of:

| | | |
|---------------------------|--------------------------------|------------------------------------|
| Antiphospholipid Syndrome | Glomerulonephritis | Rheumatoid Arthritis |
| Autoimmune Gastritis | Goodpasture Syndrome | Scleroderma |
| Autoimmune Hepatitis | Graves Disease | Sjögren’s Syndrome |
| Cardiovascular Disease | Hashimoto’s Disease | Systemic Lupus Erythematosus (SLE) |
| Celiac Disease | Neuropsychiatric Lupus | Ulcerative Colitis |
| Churg-Strauss Syndrome | Pernicious Anemia | Wegener’s Granulomatosis |
| Crohn’s Disease | Primary Biliary Cirrhosis | Autoimmune Diabetes |
| Dermato/Polymyositis | Primary Sclerosing Cholangitis | Skin Blistering Disease |

Immunofluorescence microscopy is the cornerstone of autoimmune diagnostics.

Zenit IFA reagents offer a complete line of products for semi-quantitative detection of autoantibodies against various subcellular components including nucleic acids, nuclear proteins, and cytoplasmic proteins.

A. Menarini Diagnostics is recognized as a leader in innovating assays with the IFA technology. The use of digital scanners leverages the advantages of standardization in the reading and interpretation of such important substrates as HEp-2.

Our IFA products are formulated to work with modern digital scanners in the Zenit G-Sight series.

Zenit IFA reagents range: more than 20 complete IFA kits, and 50 different types of single slides.

Each component is rigorously optimized and provided in easy to use dropper vials. Our conjugates contain ideal F/P ratios to produce clear specific fluorescence. Counterstains are formulated to provide the best contrast and reduce background. Serum diluents stabilize antigen/antibody complexes and preserve ideal morphology to provide clear reactions. Our mounting medium is specifically formulated to preserve staining with minimal fading.

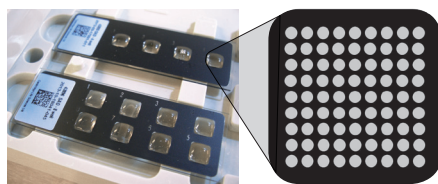
Quality is the hallmark of our IFA product range.

Need to find multiple antibodies in a single well? You need Zenit IFA COMVI HEp-2 and triple tissue.

ZENIT | AMiDot

autoimmunity

The innovative new tool for large-scale second-line autoantibody screening.



Zenit AMiDot employs pre-designed microdot arrays for a panel of autoimmune diseases, such as systemic autoimmune disease, autoimmune vasculitis, idiopathic inflammatory myopathies, gastrointestinal autoimmune disease, autoimmune liver disease.

The immunoassay-based Zenit AMiDot test consists of two components: **Zenit AMiDot Reagent Kit** containing conjugate, sample diluent and wash buffer, and a **Zenit AMiDot Slide Pack** containing glass microscope slides with 4 or 8 wells delineated by a hydrophobic mask. These wells are coated with an array of autoimmune antigens, calibrators and controls.

Internal controls built into the Zenit AMiDot array ensure that each patient sample has been diluted correctly and that the test procedure has been followed.

The Zenit AMiDot fluorometer will interpret the microdot array and produce a report listing concentration and positive, borderline or ne-

gative status for each antigen if the calibration and controls meet required specifications.

The Zenit AMiDot range is compatible with the Zenit UP system, and the Zenit G-Sight series as well.

Zenit AMiDot system, an aid to diagnosis

- For Ag typing after IF screening
- For Ag typing after ELISA or CLIA screening
- To complete ELISA and IFA
- To complete CLIA and IFA

Zenit AMiDot at a glance

- 20 quantitative results per patient
- Up to 38 different antibodies or antigens measured in duplicate per patient
- Integral controls in each well
- Calibration in each well
- Fully automatable using existing IFA instrumentation
- Read time less than 40 seconds per slide
- Printout by patient or by slide

Need to automate slide microarrays?

Look to Zenit AMiDot prepared with Zenit UP and read with Zenit G-Sight for AMiDot.

Biomonitoring

The Zenit product range includes all of the most innovative technologies for detecting everything relevant to the diagnosis and monitoring of autoimmune diseases.

The development of biological drugs (i.e., antibodies with unique characteristics and specificities) is an important advance in the treatment of inflammatory conditions such as rheumatoid diseases and inflammatory bowel diseases. However, efficacy can be hampered by the development of anti-drug antibodies (ADAs). It is important to monitor the levels of these so-called biologicals during treatment. Most biologicals are relatively expensive, and drug dose, response and efficacy should be monitored on an individual basis.

Awareness of these issues has led to the development of drug monitoring regimens to optimize therapy both clinically and economically.

A. Menarini Diagnostics offers several monitoring tools, reagents and services developed to measure drug activity and ADAs.

... and so much more

Celiac disease and type 1 diabetes are autoimmune disorders affecting the lining of the small intestine in celiac disease and pancreatic beta-cells in type 1 diabetes.

Celiac disease is far more common in people with type 1 diabetes than in the general population – as many as 10% of children with type 1 diabetes test positive for the antibodies that indicate celiac disease, compared with only one 1% of children in

the general population. Moreover, a growing body of research suggests type 1 diabetes is triggered by exposure to gluten, the protein linked to celiac disease, supporting the theory that the two disorders share common genetic causes.

We are proud to offer an easy range of PCR endpoint kits, to detect the alleles associated to celiac, ankylosing spondylitis and type 1 diabetes.

Optimizing treatments with biologicals? A. Menarini Diagnostics has the best solution for you.

AUSTRIA

A. Menarini GmbH
Pottendorfer Strasse 25-27
A-1120 Wien, Austria
Tel. +43-1-80415760
Fax +43-1-8043194
www.menarinidiagnostics.at

BELGIUM

A. Menarini Diagnostics Benelux S.A/N.V.
Belgicastraat 4
1930 Zaventem, Belgium
Tel. +32-2-7214545
Fax +32-2-7209292
www.menarinidiagnostics.be

FRANCE

A. Menarini Diagnostics France S.A.R.L.
3-5, rue du Jura - BP 70511
94633 Rungis Cedex, France
Tel. +33-1-56346910
Fax +33-1-56346911
www.menarinidiagnostics.fr

GERMANY

A. Menarini Diagnostics Deutschland
Eine Division der Berlin Chemie AG
Glienicke Weg 125 - 12489 Berlin, Germany
Tel. +49-30-67073000
Fax +49-30-67073020
www.menarinidiagnostics.de

GREECE

A. Menarini Diagnostics s.a.
575, Vouliagmenis Ave.
164 51 Argyroupolis - Athens, Greece
Tel. +30-210-99 44 952
Fax +30-210-99 45 029
www.menarinidiagnostics.gr

ITALY

A. Menarini Diagnostics Srl
Via Lungo l'Enza, 7
50012 Bagno a Ripoli - Firenze, Italy
Tel. +39-055-5680422
Fax +39-055-5680905
www.menarinidiagnostics.it

PORTUGAL

A. Menarini Diagnósticos
Quinta da Fonte - Edifício D. Manuel I, 2º B
2770-203 Paço de Arcos, Portugal
Tel. +351-210-930-000
Fax +351-210-930-001
www.menarinidiag.pt

SLOVENIA

A. Menarini Diagnostics s.r.l.
Podružnica Ljubljana
Dolenjska cesta 242c
1000 Ljubljana - Slovenija
www.menarinidiagnostics.si

SPAIN

A. Menarini Diagnosticos S.A.
Avenida del Maresme 120
08918 Badalona, Barcelona, Spain
Tel. +34-93-50-71000
Fax +34-93-27-80215
www.menarinidiag.es

SWITZERLAND

A. Menarini Diagnostics s.r.l.
Eggbühlstrasse 14
8050 Zürich, Switzerland
www.menarinidiagnostics.ch

THE NETHERLANDS

A. Menarini Diagnostics Benelux N.V.
De Haak 8,
5555 XK Valkenswaard, The Netherlands
Tel. +31-40-20-82000
Fax +31-40-20-42184
www.menarinidiagnostics.nl

UNITED KINGDOM

A. Menarini Diagnostics Ltd
405 Wharfedale Road, Winnersh-
Workingham, Berkshire RG415RA, UK
Tel. +44-118-944 4100
Fax. +44-118-944 4111
www.menarinidiag.co.uk

Look carefully; there's something
you did not notice before.
Now you can see it too, with us.





menarindiagnosics.com