

# ZENIT | PRIME

autoimmunity

High-speed random access chemiluminescence analyzer



**Robust automation,  
to new levels of efficiency  
in CLIA analysis**

Maximize throughput and efficiency to achieve maximum productivity with high analytical reliability

## Productivity meets reliability

**ZENIT PRIME** is the brand new A. Menarini Diagnostics **high-speed and high-throughput random-access immunoanalyzer** with advanced features and an expanding panel of tests.

**ZENIT PRIME** is designed to **optimize routine autoimmunity testing workloads** for medium to large laboratories.

This standalone system **automates all the steps of chemiluminescence (CLIA) analysis**, from primary sample tube to final results, with high accuracy, requiring minimum hands-on time.

Individual and asynchronous sample management makes it possible to **operate in different modes: random, batch or set priority** for urgent patient samples,

thus saving time and maximizing productivity.

**ZENIT PRIME** offers a **comprehensive menu of autoimmune disease tests**, including quantitative detection of the **most clinically relevant autoantibodies** and is designed to host other types of testing in the future (infectious diseases testing, diabetes, biologicals).

Our constant commitment to research and engineering development has made it possible to refine processes and achieve **unexpected levels of productivity**, while still retaining **high analytical reliability**.

Users can enjoy the **high performance** of this new generation immunoanalyzer thanks to an **intuitive user experience**.



## Value for the Lab



### Fully automated system

- Primary and secondary tube handling
- Ready-to-use reagent cartridges for 50/100 tests
- On-board dilution and pre-treatment of samples
- Calibration stable from 3 to up to 4 weeks



### Unparalleled efficiency

- Walk-away routine for up to 1000 tests in one working day (8 h)
- First result in 25 minutes
- Up to 126 on board samples
- Up to 25 different simultaneous immunoassays
- Random access to samples and reagents



### Accurate and reproducible results

- Coated microparticles (dispersed solid-phase) ensure uniform and extensive coating
- Clog detection to avoid sample alteration
- Disposable tips and cuvettes to avoid sample carry-over
- Pipetting needle washing with decontamination reagent
- Refrigerated compartment for stable on board reagents and samples (storage temperature of 4 °C when device is in sleep mode)
- PAC (Pre Analytical Cartridge) to verify all the steps of the analytical process



### Smart handling

- Flexible operating modes: random, batch and STAT priority function for urgent samples
- Easy-to-load and ready-to-use cartridges with all reagents included
- Touch screen workstation with intuitive GUI
- Auto re-run in case of out-of-range samples
- Automatic Reflex testing

True continuous loading capability for intelligent reagent, consumable and sample management

## Load and run

**ZENIT PRIME** carries out **all steps** of chemiluminescent immunoassay **on a single analytical platform** designed for continuous loading and random access with **minimum hands-on time**.



### MINIMUM HANDS-ON TIME

REAGENT  
CARTRIDGE  
LOADING



QC  
AND PATIENT  
SAMPLE  
LOADING



RESULT  
ANALYSIS AND  
VALIDATION



### ENHANCED AUTOMATION

Once the reagent cartridge is loaded in the carousel, the system performs **automatic magnetic particle suspension**. Assay-related information (composition, lot number, expiry date) and master calibration curve are **automatically transmitted** to system via RFID reading.

Assay cartridges can be **loaded and unloaded at any time during the working session** without risk of error.

Patient samples and Quality Controls (QC) are identified using a 1D barcode reader and **all information is transmitted automatically** to the software.

Each rack can be removed at any time during the working session and **a new position becomes available** to insert a new rack.

At the end of each session, the user can check results of the calibration curve and decide whether to validate the session or repeat the test.

In case of positive results outside the above-defined range, the system performs **auto re-run of out-of-range samples** after appropriate dilution.

**Automatic Reflex testing** allows to streamline the routine.

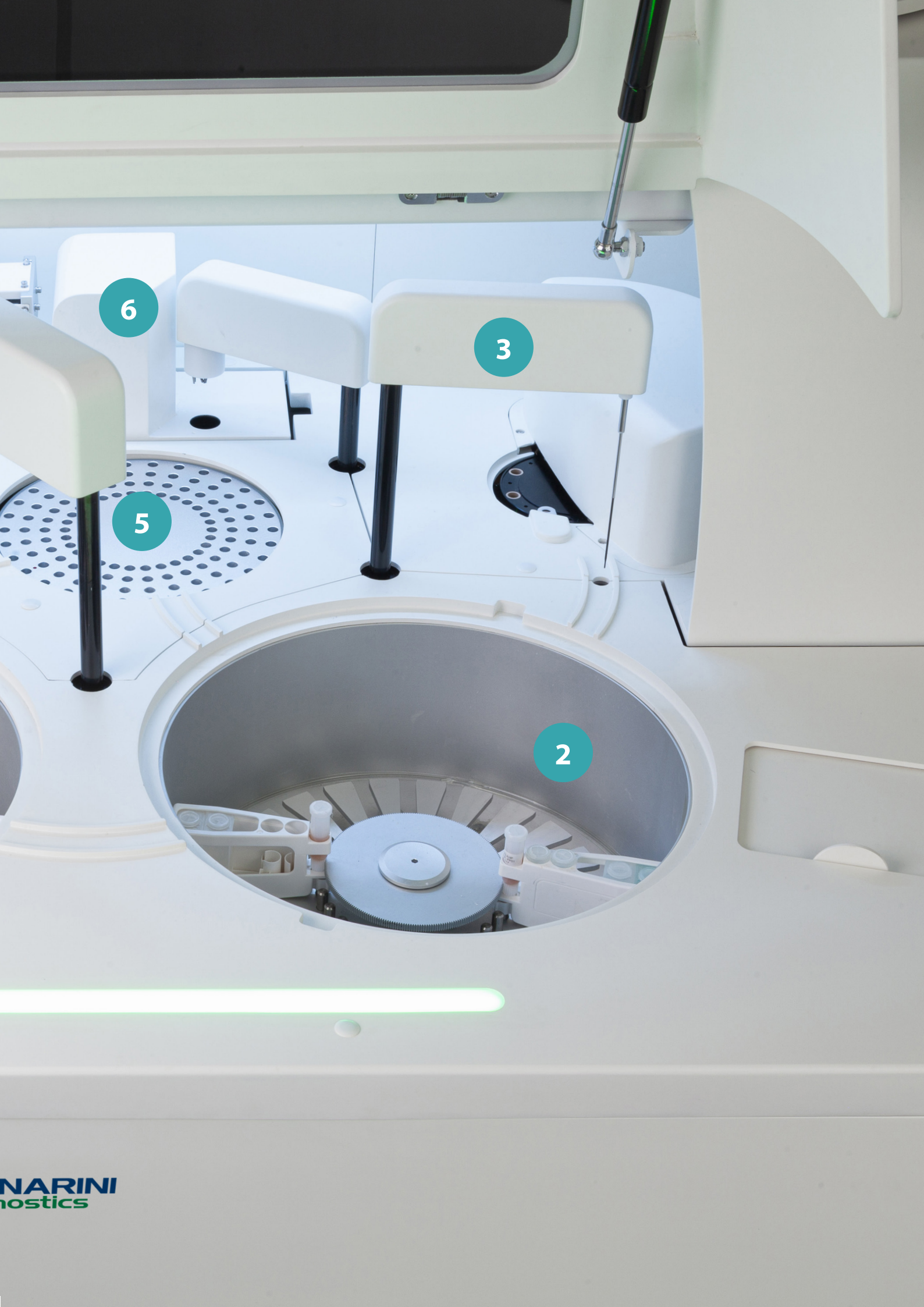


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autoimmunity

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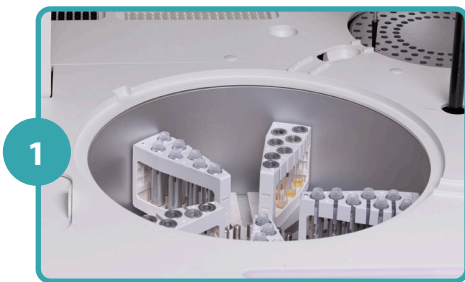


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3

5

2



1

**126 on-board samples**

The sample carousel can be loaded with up to 18 racks, each containing 7 sample tubes, and it is kept at stable and controlled temperature of <math><15\text{ }^\circ\text{C}</math>.



2

**25 different simultaneous immunoassays**

The reagent carousel has 25 refrigerated positions for immunoassay cartridges.



3

**Pipetting needle washing with decontamination reagent**

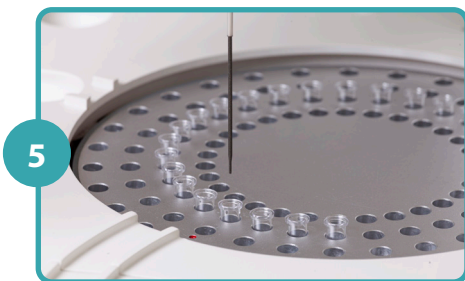
The system is equipped with a precision needle washed internally and externally every time reagents are distributed to minimize carry-over.



4

**Disposable tips and cuvettes to avoid sample carry-over**

The distribution arm pipettes and transfers samples using disposable tips to avoid carry-over.



5

**Reduced incubation steps**

The conjugate is dispensed at an optimal temperature of  $37\text{ }^\circ\text{C}$  to increase the reaction kinetics and reduce the incubation time to only 10 minutes. Thermoregulated incubator hosts 120 disposable cuvettes.



6

**Luminescence reading directly in the cuvette**

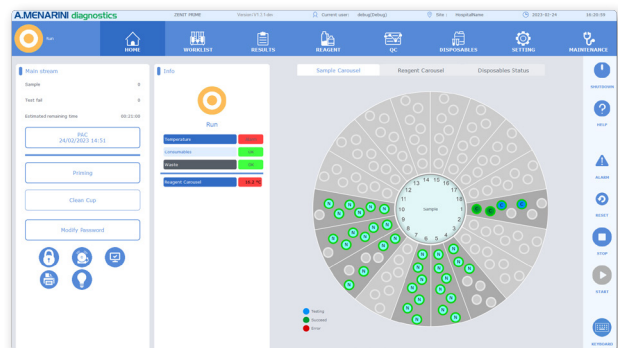
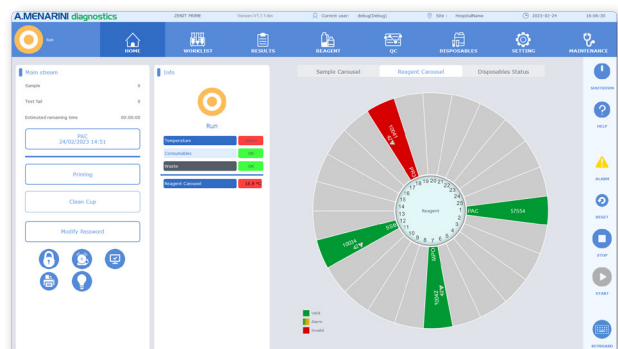
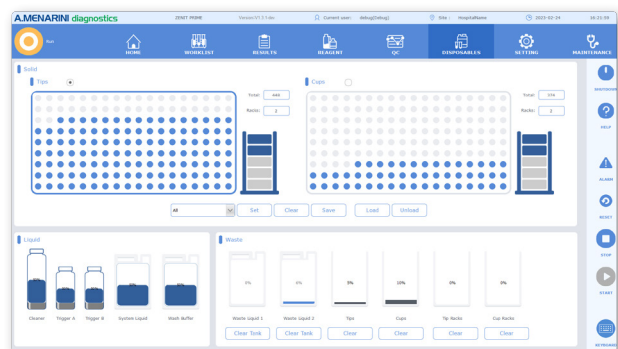
Reading station keeps cups in dark room during Trigger A and Trigger B distribution, followed by reaction reading.

Extensive connectivity and workflow support features for efficient lab processes

## Manage, collaborate, report

Collaborative and intuitive software ensuring complete traceability

- Friendly and interactive Graphic User Interface (GUI) with touch screen
- Complete traceability and dynamic acquisition/storage of information on reagent cartridges (composition, lot number, expiry date, master curve) via RFID (Radio Frequency Identification) tag
- Interactive stock management of specific and common reagents
- Real time monitoring of status and type of samples and reagents
- QC data management by Levey-Jennings charts and Westgard rules
- Remote troubleshooting and software updates
- Bi-directional LIS/middleware connection





## Expanding test menu

A. Menarini Diagnostics has been working with clinicians and researchers worldwide for several years to develop ZENIT products and provide a **constantly expanding auto-immunity portfolio** of highly specific next generation disease markers.

### Kit characteristics and advantages

- Bar-coded, ready-to-use cartridges
- On-board stability of reagents for 2 months
- Calibration stable for 4 weeks



The uniquely shaped ready-to-use cartridges are easy to load and contain all specific reagents needed for the test (diluent, conjugate, magnetic particles and calibrators)



### CONNECTIVE TISSUE DISEASES

- ANA Screen
- ENA Screen
- dsDNA IgG
- SS-A/Ro 52 KDA
- SS-A/Ro 60 KDA
- SS-A/Ro
- SS-B/La
- Sm
- U1-snRNP
- Scl-70
- Jo-1
- Centromere B



### THYROID

- Anti-TG
- Anti-TPO



### LIVER

- AMA M2 IgG
- LKM-1 IgG



### CELIAC DISEASE

- Deamidated Gliadin IgA
- Deamidated Gliadin IgG
- tTG IgA
- tTG IgG



### VASCULITIS

- MPO
- PR3
- GBM



### RHEUMATOID ARTHRITIS

- CCP



### ANTI-PHOSPHOLIPID SYNDROME

- Cardiolipin IgG
- Cardiolipin IgM
- $\beta$ 2-Glycoprotein I IgG
- $\beta$ 2-Glycoprotein I IgM



### INFLAMMATORY BOWEL DISEASE

- Calprotectin



## Technical specifications

SYSTEM	
Method	Chemiluminescence (CLIA) analysis
Throughput	Up to 120 tests/hour
Level of automation	Walk away, random access
Operating modes	Random, batch and STAT
First result	25 minutes
Sample capacity	126 samples loaded on board (18 sample racks)
Sample type	Serum, plasma, urine, saliva, cerebrospinal fluid (CSF)
Reagents capacity	25 on board positions
Reagent kit format	Ready-to-use reagent cartridge for 50/100 tests
User interface	Touch screen working station
PHYSICAL CHARACTERISTICS	
Dimensions	(W)148 cm x (D) 93 cm x (H) 140 cm
Weight	425 kg
CONNECTIVITY AND TRACEABILITY	
LIS connection	Bi-directional
Sample identification	Internal barcode reader
Reagent information	Dynamic RFID (Radio Frequency Identification) reading system
Common reagent	Barcode identification

## Materials and reagents

51994	ZENIT PRIME	Analyzer
52092	Zenit PRIME PAC	1 box
52093	Zenit PRIME CUVETTES	Pack of 972 cuvettes
52094	Zenit PRIME TRIGGER SET	1 flask of 250 mL of Trigger A (pre-activation solution) 1 flask of 250 mL of Trigger B (activation solution)
52095	Zenit PRIME SYSTEM LIQUID	2 bottles of 1L of 10X solution
52096	Zenit PRIME WASH SOLUTION	2 bottles of 1L of 10X solution
52097	Zenit PRIME CLEANER SET	2 bottles of 1L of solution
52098	Zenit PRIME TIPS	Pack of 972 tips
52100	Zenit PRIME TOP CAP SET	250 caps for closing control containers after first use

CE

IVD

ZENIT PRIME complies with IVD standard 2017/46

### HEADQUARTER

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