



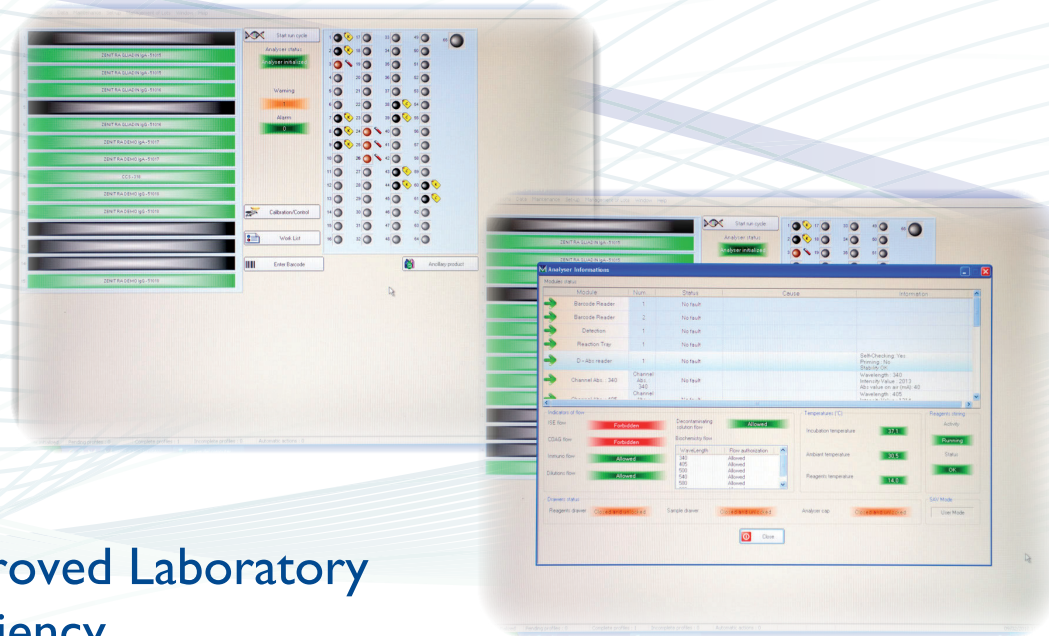
The Next Generation Analyser
for Autoimmunity



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for Autoimmunity

Improved Patient Care

- STAT function for urgent samples means critical patients are not kept waiting
- Barcoding means safety of result ensuring the right result goes to the right patient
- Full traceability of lot numbers of reagents linked to results
- High quality antigens and reagents giving accurate and reproducible results



Improved Laboratory Efficiency

- Random access and speed of throughput means turnaround times are reduced dramatically
- High capacity means the analyser is able to keep up with future laboratory requirements
- CPA is easier due to barcoding and QC storage
- QC samples stored automatically and printable on Levy Jennings plots
- Continuous access to samples means other analysers are not kept waiting

Analyser Features & Specifications



System

- Immunoassay analyser
- Continuous loading
- Bench top system

Analysers Physical Characteristics

- Analyser dimensions: L 105 cm x H 70 cm x W 75 cm
- Weight: 103 kg
- Computer System: L 60 cm x H 40 cm x W 50 cm

Throughput

- Up to 120 tests/hour (70 tests/hour for the immunoassays)

Number of tests online

- 15 different immunoassays

Immunoassay detection

- Chemiluminescence
- Luminometer

Samples

- Serum, plasma
- Primary tubes 5 mL (13 x 75 mm), 7 mL (13 x 100 mm), 10 mL (16 x 75 mm)
- Secondary tubes (13 x 75 mm)
- 500 µL cups and 1.5 mL cups
- 64/120 positions for samples, calibrators and controls
- Liquid level detection by capacitance
- Clot detection
- Dilutions and automatic pre-treatments

Barcode readers

- Reader on front for barcode identification of samples, cuvettes and ancillary reagents
- Integrated reader for reagents barcode

Reagent compartment

- 15 rails, each of which can hold 1 Immunoassay cartridge
- Storage at 12-15°C while operating
- Internal storage between 8-10°C in standby mode

Sample volume (µL)

- From 4 to 300 µL
- Programmable in steps of 0.5 µL

Reagent volume (µL)

- From 10 to 400 µL
- Programmable in units of 1 µL

Reaction volume (µL)

- From 180 to 550 µL

Pipetting system

- Pipetting reagents and samples by probe
- Liquid level detection by capacitance
- Preheating of reagents/samples
- Internal and external rinsing between sample pipettings

Spectrophotometer

- Spectrophotometer with interferential filters
- 6 wavelengths available: 340, 405, 500, 540, 580 and 620 nm
- Halogen lamp. Transmission by fibre optic
- Linearity: up to 3 OD
- Optic path of cuvettes: 0.7 cm

Luminometer

- Wavelengths: from 300 to 500 nm
- Linearity: up to 10 million RLU

Reaction carousel

- Thermo-regulated at 37°C
- 90 positions for disposable cuvettes
- Automatic cuvette supply by cuvette loader

Cuvette loader

- Loader for cube of cuvettes
- Contains 960 disposable cuvettes
- Thermostatically controller

Common liquid consumables

- ZENIT RA System Liquid (5 litre containers)
- ZENIT RA VWash (10 litre containers)
- ZENIT RA D-Sorb (1 litre containers)
- ZENIT RA Triggers A & B (250 mL each)

Waste collection

- 10 litre container for liquid waste posing a biological risk
- Solid waste (cuvettes) disposal in re-usable container

Power supply

- Voltage: 110 - 240 V
- Frequency: 50 - 60 hertz
- Maximum power consumed: 1000 VA

Computer System: Minimum Configuration Required

Operating system

- Windows XP Pro Service Pack 2
- Windows Vista Service Pack 1
- English

Microprocessor

- Type Sempron 3100 or equivalent

Live memory

- 1 Gb

Hard disk

- 80 Gb

Ethernet

- 2 independent Ethernet network adaptors

Ports

- USB ports (min 2 one of which in front)
- Serial port for connection to centralized computer system

Input devices

- Keyboard (country specific)
- Mouse

Screen

- Monitor: Speakers integrated

Screen resolution

- 1024 x 768 pixels

Peripherals

- Reader – CD writer



Random Access



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The Next Generation Analyser for Autoimmunity



The new Menarini Diagnostics chemiluminescence analyser provides the high degree of precision and speed of analysis that your laboratory routine demands:

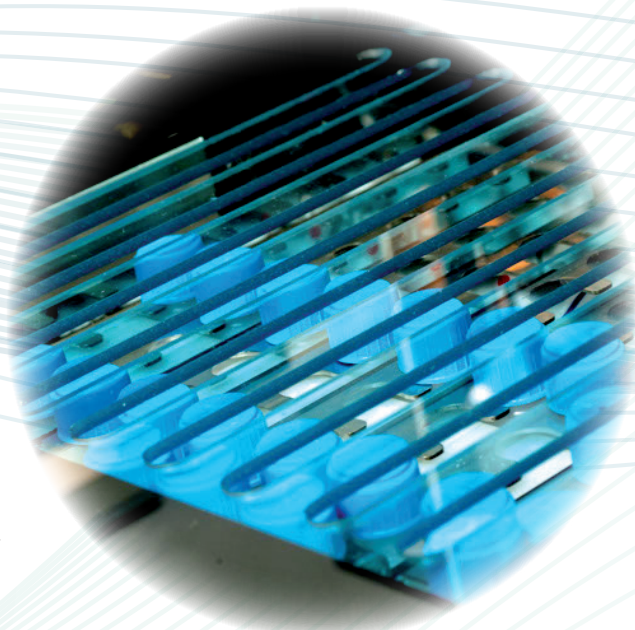
Time Saving

- First result after 25 mins means quick turnaround times
- Throughput rate of 70 tests per hour to keep up with modern laboratory expectations
- Continuous access to all reagents and samples
 - Samples can be used for other tests and placed back onto the **Zenit RA**
 - No need to shut down the instrument to load new reagents
- All reagents are stored on board and the instrument is ready to use as soon as the lab opens
- Host query on sample addition means less time sorting samples



Economical

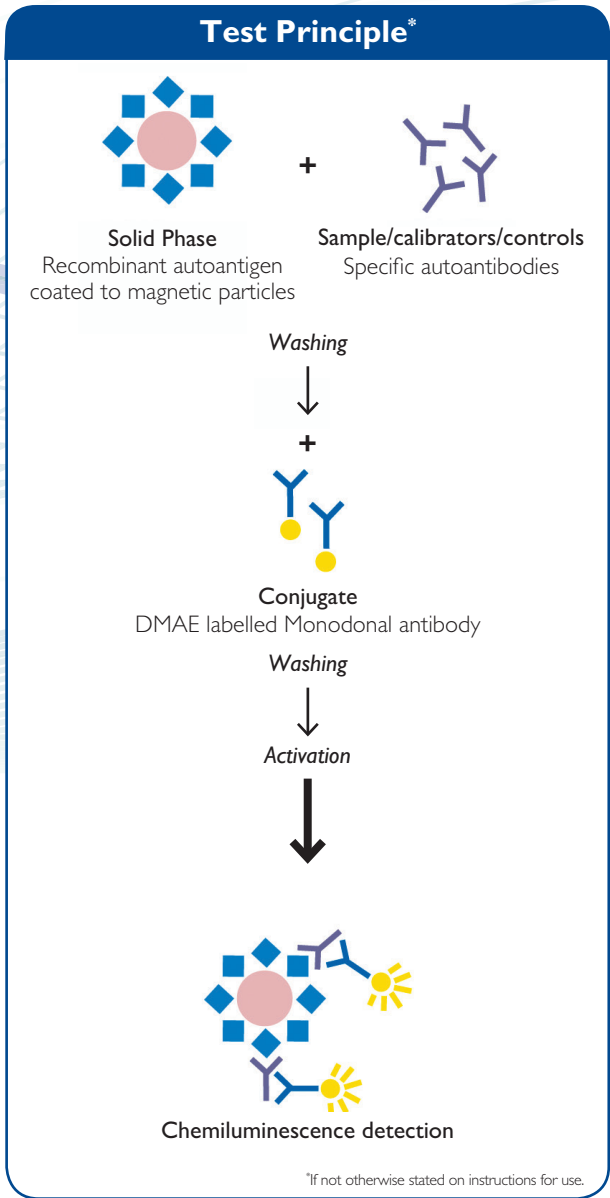
- Pre-determined calibration curve concept means only 2 controls are required to control each run
- The assay calibration is stable for up to 3 weeks
- Calibration concept requires only 2 tests to revalidate the curve every 3 weeks
- “Pack” format for reagents means transparent test costs and less room taken up in the refrigerator



An innovative operating principle – CLIA (Chemiluminescence enzyme immunoassay) based technology

The assay is based on a two-step indirect chemiluminescent method that generates quantitative results. This particular technique uses autoantigen-coated magnetic particles as solid phase and an antibody labelled with a dimethyl acridinium ester (DMAE) as detection marker. The use of high quality antigens and large coated surfaces provides excellent sensitivity in Zenit RA immunoassays.

- In the first incubation phase specific autoantibodies, present either in the samples, calibrators or controls, bind to the immobilised antigen.
- Non-bound material is washed away after every incubation step.
- In the second incubation phase the DMAE conjugate reacts with the coated magnetic particle-autoantibody complexes.
- Chemiluminescence is activated by the addition of trigger solutions: A (hydrogen peroxide) and B (an alkaline solution), resulting in oxidation of the ester to an excited form. Return to a stable state is accompanied by the emission of light, which is measured and expressed in Relative Light Units (RLU).
- The signal is directly proportional to the concentration of specific autoantibodies in the samples, calibrators or controls.



The Materials and Reagents you need

■ ZENIT RA Analyser	Code 41400	■ ZENIT RA D-SORB Solution Pack of 2 bottles of 1 L ready to use solution	Code 41436
■ ZENIT RA Cuvette Cube Pack of 960 cuvettes	41402	■ ZENIT RA Cartridge Checking System	41401
■ ZENIT RA System Liquid 1 bottle of 0.5 L of 10X solution	41409	■ ZENIT RA Top Cap Set 300 caps for closing calibrators containers after first use	41566
■ ZENIT RA Wash Solution 1 bottle of 0.5 L of 20X solution	41407		
■ ZENIT RA Trigger Set 1 flask of 250 mL of Trigger A (pre-activation solution) 1 flask of 250 mL of Trigger B (activation solution)	41403		



A consolidated 22-test menu in Autoimmunity

Immunoassays currently available are listed below. Active collaborations between Menarini Diagnostics and clinicians and researchers world-wide provide a constantly expanding menu of highly specific next generation disease markers.

Connective tissue diseases	Code	Inflammatory bowel diseases	Code	Rheumatoid Arthritis	Code
■ ZENIT RA ANA Screen	41411	■ ZENIT RA anti-tTG IgG	41423	■ ZENIT RA anti-CCP	41430
■ ZENIT RA ENA Screen	41412	■ ZENIT RA anti-tTg IgA	41422	Vasculitis	
■ ZENIT RA anti-DsDNA	41413	■ ZENIT RA anti-Deamidated Gliadin IgG	41421	■ ZENIT RA anti-MPO	41428
■ ZENIT RA anti-SS-A	41414	■ ZENIT RA anti-Deamidated Gliadin IgA	41420	■ ZENIT RA anti-PR3	41429
■ ZENIT RA anti-SS-B	41415			■ ZENIT RA anti GBM**	
■ ZENIT RA anti-Sm	41416	Anti-phospholipid syndrome		Kit characteristics and advantages	
■ ZENIT RA anti-RNP	41417	■ ZENIT RA anti-Cardiolipin IgG	41424	■ Clinically validated quantitative assays	
■ ZENIT RA anti-Scl70	41418	■ ZENIT RA anti-Cardiolipin IgM	41425	■ Bar-coded, ready to use cartridges	
■ ZENIT RA anti-Jo1	41419	■ ZENIT RA anti-B2GPI IgG	41426	■ Magnetic particle-based principle	
■ ZENIT RA anti-Centromere B	41431	■ ZENIT RA anti-B2GPI IgM	41427	■ On-board stability of reagent cartridge: 8 weeks	
				■ Analytical performances evaluated according to the CLSI guidelines	
				■ Calibration stable for 2-3 weeks*	
				■ Pack of 50-100 tests	
				<small>*if not stated otherwise on instructions for use.</small>	
				<small>**available soon.</small>	