------ SMC®-Technology

---- **> > >** Alegria – The Future of Life

The Random Access Analyser, which is based on SMC[®]-technology developed by ORGENTEC GmbH, represents a new dimension in the field of autoimmune diagnostics. It provides a fully automated process for detecting autoantibodies with a level of flexibility never before available.

With this system, users are now able to perform diagnostic tests in a way that is specially adapted to the individual needs of their own particular environment. Every patient sample can now be handled on an individual basis and at the lowest cost, thus liberating new resources for the benefit of the patient.

This current development, which has been created in close cooperation with specialists in Germany and abroad, is just another milestone in the long success story of ORGENTEC Diagnostika. Thanks to its compliance with high quality requirements, the device fits seamlessly into product lines already available on the market.

A new dimension in autoimmune diagnostics



An overview of the system's most significant advantages:

- Fully automated Random Access system with SMC[®]-Technology
- SMC[®]-Technology Sensotronic Memorized Calibration
- Robust and reproducible operating conditions thanks to temperaturecontrolled incubation units
- Maximum flexibility in diagnosis of autoimmune diseases
- Over 70 test systems available
- Up to 30 different results in just 90 minutes
- Free and flexible choice of up to 30 patients, with individual results in just one operation
- Every sample is validated through its own control.

All ORGENTEC Diagnostika GmbH test applications are evaluated in accordance with the European In Vitro Diagnostic (IVD) Directive and always meet the very latest in quality control requirements



SMC[®]-Technology test strips



SysTray



Incubation chamber

SMC®-Technology

- Each SMC[®]-Technology MPT strip has a complete set of reagents for determining individual samples
- Using SMC[®]-Technology, all test information is passed on directly to the system by means of specific barcodes
- The SMC[®]-Coding system contains information on product names, a batch-specific and complete standard curve,

Management of samples and reagents

- Each of the three carrier modules (SysTray A, B and C) can be loaded with ten patient/ sample strips
- Up to 30 different samples with individual parameters can be examined at the same time in one operational step
- Each strip has two cavities for handling samples, two incubation cavities for patient sample and a cut-off control, as well

Incubation units

- Inside the thermally regulated incubation unit, all processes run under strictly standardised conditions
- The system cycle is unable to start until predefined climatic conditions are reached, thus ensuring that the system's overall performance and the results it produces cannot be influenced by external climatic conditions
- Provisions for reloading other system trays (SysTray A, B and C)

Easy-to-use Software

threshold values for the internal calibrator control, a recalculation algorithm feature, as well as information on production and expiry dates of individual test strips

- By means of this information technology, it is guaranteed that only tests meeting quality requirements in accordance with the European IVD directive are used
- Expired test strips are not accepted by the system



External barcode identification

Barcode management

• The external barcode reader allocates individual patient samples to their own special location within the system. Together with the test information shown by SMC®-Technology, specific evaluations are created for each patient, thus making it impossible to confuse results

Integrated printer

• After a complete analyze all test data corresponding to the patients tested are printed out by the integrated printer

Software link-up and data management

- Overall performance and data management (OrgSys) are both supported by Windows®, thus enabling a guick and uncomplicated link-up to external computer systems via already installed standard protocols
- In addition, the analyser can be externally programmed and adapted at any time by system technicians via Windows[®] based maintenance and system software
- Via the integrated modem, external access to the entire system is possible at all times

Touchscreen

• Thanks to its easy-to-use software, all system functions can be easily operated and controlled via a large, user-friendly touchscreen

- as a complete set of reagents consisting of a sample buffer, a conjugate, a substrate and an internal calibrator control All reagents are packed under
- airtight conditions; they are not opened until immediately prior to the system being used, when they are directly inserted into the test. This eliminates any external influence or contamination





System liquid supply

System liquid supply

- There are four different symbolcoded reagent containers located in the device
- (2 x wash buffers both 1 litre;
- 1 x distilled water 2.5 litres;
- 1 x liquid waste container 5 litres)
- All containers are easy to use and are regulated by a system of strictly separate precision pumps

can be made in advance while another test procedure is still running, thus resulting in maximum capacity use in terms of flexibility and sample throughput

• When system requirements are reached inside the incubation unit, test-specific parameters for each reagent strip are selected by means of SMC[®]-Technology and assigned to the relevant sample

Rheumatology

ANA Detect ANAscreen ENAscreen Anti-C1q Anti-MCV Anti-SS-A Anti-SS-A 52 Anti-SS-A 60 Anti-SS-B Anti-Sm Anti-RNP / Sm Anti-RNP-70 Anti-Scl-70 Anti-Jo-1 Anti-Centromere B Anti-Nucleosome Anti-Histone Anti-Rib-P Anti-dsDNA Anti-dsDNA IgA Anti-dsDNA IgM Anti-dsDNA Screen Anti-ssDNA Anti-alpha-Fodrin IgA Anti-alpha-Fodrin IgG Rheumatoid Factor IgA Rheumatoid Factor IgG Rheumatoid Factor IgM Rheumatoid Factor Screen

ANCA Vasculitis Diagnostics

Anti-GBM ANCAscreen Anti-PR3 Anti-MPO Anti-BPI Anti-Elastase Anti-Cathepsin G Anti-Lysozyme Anti-Lactoferrin

Thrombosis Diagnostics

Anti-Cardiolipin IgG Anti-Cardiolipin IgM Anti-Cardiolipin IgA Anti-Cardiolipin Screen Anti-B2-Glycoprotein IgG Anti-B2-Glycoprotein IgM Anti-B2-Glycoprotein IgA Anti-B2-Glycoprotein Screen Anti-Prothrombin IgG Anti-Prothrombin IgM Anti-Prothrombin IgA Anti-Prothrombin Screen Anti-Phospholipid Screen IgG Anti-Phospholipid Screen IgM Anti-Phosphatidyl Serine IgG Anti-Phosphatidyl Serine IgM Anti-Phosphatidyl Inositol IgG Anti-Phosphatidyl Inositol IgM Anti-Phosphatidic Acid IgG Anti-Phosphatidic Acid IgM Anti-Annexin V IgG Anti-Annexin V IgM

Gastroenterology

Anti-Intrinsic Factor Anti-Tissue-Transglutaminase IgA Anti-Tissue-Transglutaminase IgG Anti-Tissue-Transglutaminase Screen Anti-Gliadin IgA Anti-Gliadin IgG Anti-Gliadin Screen Anti-Parietal Cell ASCA IgG ASCA IgA AMA-M2

Thyroid Diagnostics

Anti-TG Anti-TPO

Diabetes Diagnostics

Anti-Insulin





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Technical Data

Specifications:

350 W 10 inch, color LCD display 112 mm, thermo printer Universal range 90 -264 VAC 50 - 60 Hz 800 mm x 703 mm x 570 mm 50 kg LED technology, 650 nm

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