



**WHEN ACCURACY
CANNOT BE
COMPROMISED...**

Newborn Screening Systems

Infectious Diseases

Gastroenterology

Cardiac Markers

Clinical Chemistry


Haematology

Immunosuppressants, Vitamin D

RELIABLE QUALITY
FROM THE PIONEER

LABSYSTEMS
D I A G N O S T I C S
speaking your language

A TRIVITRON ENTERPRISE




About Trivitron and Labsystems Diagnostics

Trivitron Healthcare is a globally acclaimed medical technology solution company of Indian origin. Trivitron Healthcare has spread its wings across the globe to make healthcare affordable and accessible to all. With an enviable presence in 165 countries, Trivitron offers products for laboratory medicine, medical imaging, operating room, intensive care units and renal dialysis equipment. Since 2012, Labsystems Diagnostics is proud to be part of the Trivitron group of companies.

Labsystems Diagnostics Oy, Finland has been a forerunner in innovative diagnostic research and development for the last 30 years. The company develops, manufactures and markets high quality enzyme immunoassays (EIA, FEIA and MIFA), molecular assays (MDx) and Point-of-Care (POC) tests.

As an established European company, Labsystems Diagnostics has committed itself to developing high quality diagnostics products for use in clinical and research laboratories, for consumer use and as OEM products. The company strongly invests in research and development, in its highly qualified personnel and state of the art production. A highly rigorous quality system and CE-marked products ensure sustainable quality of the products. These assets combined with efficient customer support, long term customer satisfaction and a solid reputation ensure success.

Within 30 years of experience, throughout different ownerships, Labsystems Diagnostics has been a key pioneer to achieve many milestones. The company was one of the first in the world to develop EIA tests on microplate format, as well as to create a peptide based HIV assay. The first fluorometric PKU test for Newborn Screening on microplate was developed by the company. In the Point-of-Care field discipline, the company was the first to launch Troponin I test, patented Celiac test and Chlamydia IgM test. The fully automated high throughput system for Newborn Screening is the most recent milestone. And there are many more to come in LC MS/MS and genetic testing applications.





TRIVITRON GROUP OF COMPANIES
5 DEDICATED INNOVATION CENTERS / 8 MANUFACTURING FACILITIES
CLIENTS ACROSS 165 COUNTRIES / 50,000+ INSTALLATIONS



QUALITY CANNOT BE COMPROMISED

Continuous control of the product quality is the basis of LabSystems Diagnostics production and is naturally crucial for patient safety. A quality management system has been in place since 1994, now complying with the version ISO 13485:2003, and it also complies with the requirements of IVD directive (98/79/EC). The tests are CE marked for IVD use. External quality assurance rounds are regularly used, showing that our products are well in line with e.g. CDC samples.

Quality control in production means acceptance tests for every lot of the critical raw materials, testing of the kit composition with reference panels, and follow-up tests after production during the shelf-life.



NS2400-Neonatal Screening Automate



Biocard™ Quant Reader



Biocard™ Celiac Disease



NS Reader



NS Incubator/ Shaker



NS Washer



Automatic Neonatal DBS Puncher NS496

MODERN MANUFACTURING FACILITIES (FINLAND & INDIA)

Labsystems Diagnostics' state-of-the-art production facility in Vantaa, Finland.

For manufacturing
Newborn Screening
kits in microplate format

For manufacturing
diagnostics kits for
infectious diseases in
microplate format

For manufacturing
Point-of-Care rapid
tests for Cardiac markers,
Infection detection,
and Gastroenterology

For manufacturing
kits for Molecular
diagnostics (RT-PCR)

Labsystems Diagnostics has a modern office and factory in Vantaa, Finland, with total surface area of the building being 3700 m². Production is divided into unclassified laboratory area and clean area classified according to the USA class standard (FED-STD-209E), which restricts the amount of particles (particle size → 0.5µm)/m³ of air.

The production of many of the critical components is in our own hands, giving us good control of the component quality. We produce the microbe antigens in our P2 class safety laboratory. Protein chemistry department produces the enzyme labelled antibody/conjugates. Microtiter plates are coated with microbe antigens, antibodies and synthetic peptides depending on the product. For POC tests the colloidal gold is also produced in-house.

Indian facilities also develop Special Chemistries, Clinical Chemistries, Haematology Reagents, Molecular Diagnostics Kits, Elisa Kits for emerging markets, at the state-of-the-art manufacturing plant inside the Triviron Medical Technology Park, Chennai. The medical technology park is a first of its kind in Chennai with multiple facilities.

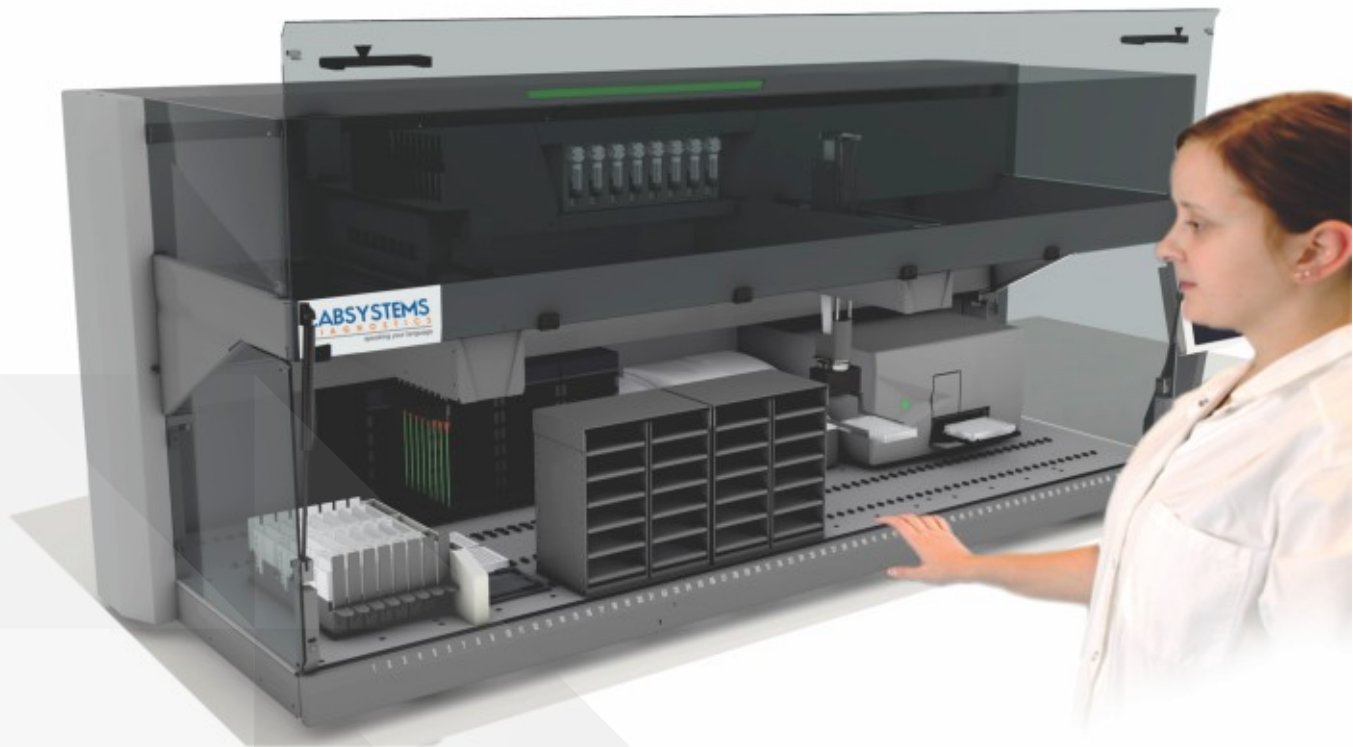
PRODUCT CLASSIFICATION

NEWBORN SCREENING	Made in Finland	8 - 11
INFECTIOUS DISEASES	Made in Finland	12
GASTROENTEROLOGY	Made in Finland	13
CARDIAC MARKERS	Made in Finland	14 - 15
CLINICAL CHEMISTRY	Made in India	16-17
HAEMATOLOGY	Made in India	18
IMMUNOSUPPRESSANTS, VITAMIN D		19

COMPREHENSIVE NEWBORN SCREENING SOLUTIONS AND PRODUCTS FROM THE PIONEER - CE CERTIFIED

Complete NS2400 Neonatal Screening Automate

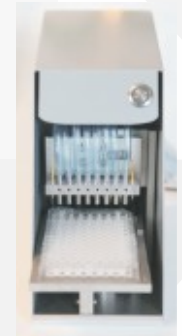
- Fully integrated robotic high throughput system
- Reduced running costs - no disposable tips
- Integrated disc remover
- High sensitive fluorometric detection



Newborn Screening System

Newborn Screening Modular Devices

- Automatic Neonatal DBS Puncher NS496
- NS Incubator/ Shaker
- Stand-alone NS96 Disc Remover
- NS200 Multimode reader
- NS Washer
- NS Reader
- Sample Cards

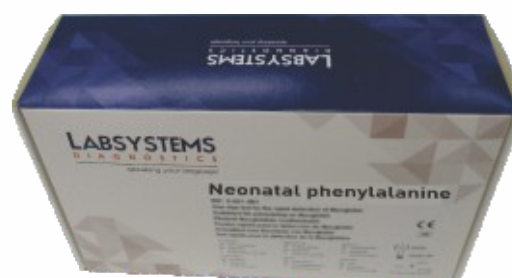


Newborn Screening Kits

Tests for dried blood spots (DBS). Reliable reagent kits with proven quality. All kits can be used manually, in modular systems or in fully automated, hands off systems.

- Neonatal Phenylalanine
- Neonatal hTSH FEIA Plus
- Neonatal 17-OH-Progesterone FEIA
- Neonatal IRT FEIA
- Neonatal Glucose-6-Phosphate dehydrogenase (Neonatal G6PD)
- Neonatal Galactose
- Neonatal Biotinidase
- Neonatal Toxoplasma gondii IgM FEIA

All kits are based on high sensitive fluorometric detection method.



* Biocard™ TSH POC Test (Coming soon)

NEWBORN SCREENING FOR DETECTION OF INHERITED METABOLIC DISORDERS - CE CERTIFIED

NeoMass AAAC is used with Tandem Mass Spectrometry to detect concentrations of amino acid, free carnitine, acylcarnitines, succinylacetone and argininosuccinic acid

- Ready-to-use kit for 960 tests
- 4 of steps: Punch, Extraction, Transfer, Injection into MS/MS
- Sample extraction without derivatization
- 4 sets of Isotope labelled internal Standards: 15 Amino Acids + 13 (Acyl) Carnitines + SUAC (Tyrosinemia type-1) + ASA (Argininosuccinic Acidemia)
- 3 Dried Blood Spot Controls framing the decisional cut-off area for each of the matching internal standards
- Turnaround time for 96 samples approximately 3 hours
- High specificity and sensitivity by MS/MS detection
- Validation for multiple instrument applications

Single method for screening > 50 disorders in only 3 hours

Amino Acid Disorders

- Argininemia (ARG1 Deficiency)
- Argininosuccinic Aciduria (ASL Deficiency)
- 5-Oxoprolinuria1
- **Carbamoylphosphate Synthetase Deficiency 1 (CPS1 Deficiency)**
- Citrullinemia I (ASS Deficiency)
- Citrullinemia II
- Homocystinuria
- Hypermethioninemia
- Hyperammonemia, Hyperornithinemia, Homocitrullinemia Syndrome1
- Hyperornithinemia with Gyral Atrophy 1
- Maple Syrup Urine Disease
- **N-acetyl Glutamate Synthetase Deficiency (NAGS Deficiency)**
- Phenylketonuria
- Classical/Hyperphenylalaninemia
- Defects of Biopterin Cofactor Biosynthesis
- Defects of Biopterin cofactor regeneration
- Tyrosinemia (detected by SUAC)
 - Transient Neonatal Tyrosinemia
 - Tyrosinemia Type I
 - Tyrosinemia Type II
 - Tyrosinemia Type III
- **Ornithine transcarbamoylase deficiency (OTC)**

Organic Acid Disorders

- 3-Hydroxy-3-Methylglutaryl-CoA Lyase Deficiency
- Glutaric Acidemia Type I
- Isobutyryl-CoA Dehydrogenase Deficiency
- Isovaleric Acidemia
- 2-Methylbutyryl-CoA Dehydrogenase Deficiency
- 3-Methylcrotonyl-CoA Carboxylase Deficiency
- 3-Methylglutaconyl-CoA Hydratase Deficiency
- Methylmalonic Acidemias
- Methylmalonyl-CoA Mutase Deficiency
- Some Adenosylcobalamin Synthesis Defects
- Maternal Vitamin B12 Deficiency
- Mitochondrial Acetoacetyl-CoA Thiolase Deficiency
- Propionic Acidemia
- Multiple-CoA Carboxylase Deficiency
- Malonic Aciduria

Fatty Acid Oxidation Disorders

- Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD)
- Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD)
- Medium/Short Chain Hydroxy Acyl-CoA Dehydrogenase Deficiency
- 3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency (LCHAD)
- Short Chain Acyl-CoA Dehydrogenase Deficiency
- Medium Chain Ketoacyl-CoA Thiolase deficiency
- Carnitine uptake deficiency
- Carnitine/Acylcarnitine Translocase Deficiency
- Carnitine Palmitoyl Transferase Deficiency Type II
- Carnitine Palmitoyl Transferase Ia deficiency
- Carnitine Palmitoyl Transferase Ib deficiency
- 2,4-Dienoyl-CoA Reductase Deficiency1
- Glutaric Acidemia type II
- Trifunctional Protein Deficiency



Patented innovation by Labsystems Diagnostics

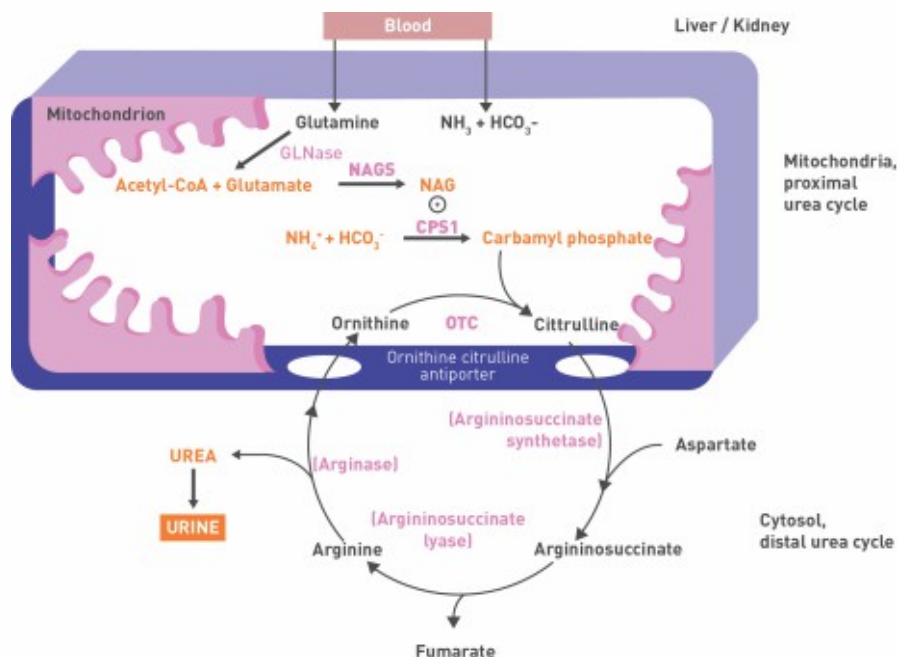
NeoMass AAAC innovation enables detection of all urea cycle deficiencies, including proximal abnormalities along with classical distal deficiencies measurements

The urea cycle is a metabolic pathway occurring in the liver and kidney. Ammonia, a product of protein metabolism, is removed from circulating blood through urea cycle by conversion into urea and its elimination in urine. Urea Cycle Disorders (UCD) occurs in some inborn errors of metabolism, resulting in accumulation of nitrogenous waste which leads to vomiting, increasing lethargy, seizures, hypotonia, respiratory distress, coma, and to death if untreated. Protein restriction is the mainstay of therapy for the management of urea cycle defects.

Unique Properties of NeoMass AAAC kit – detection of OTC, CPS1 and NAGS deficiencies

Deficiencies of enzymes in the proximal part of the urea cycle have been challenging to detect in the past but the patented innovation in the new NeoMass AAAC kit changes this. As a first in the world achievement, Labsystems Diagnostics has established a methodology to measure OTC, CPS1 and NAGS deficiencies on dried blood spots along with the traditional detection of ASS, ASL and ARG1 enzyme deficiencies. NeoMass AAAC for tandem MS will therefore enable detection of all urea cycle abnormalities.

Now featured with NeoMass AAAC – detection of Urea Cycle Disorders (UCDs)



New Proximal urea cycle deficiencies

- N-Acetylglutamate Synthase (**NAGS**) Deficiency
- Carbamyl Phosphate Synthetase (**CPS1**) Deficiency
- Ornithine Transcarbamylase (**OTC**) Deficiency
- Ornithine Translocase Deficiency (**HHH**) Syndrome

Traditional – distal urea cycle deficiencies

- Argininosuccinate Synthetase (**ASS**) Deficiency (Citrullinemia I)
- Citrullin Deficiency (Citrullinemia II)
- Argininosuccinate Lyase (**ASL**) Deficiency (Argininosuccinic Aciduria)
- Arginase Deficiency (**ARG1**) (Hyperargininemia)

EIA Kits - CE Certified

Established 96 well enzyme immunoassay kits

- Chlamydia pneumoniae IgG, IgA, IgM EIA
- Mycoplasma pneumoniae IgG, IgA, IgM EIA
- Bordetella pertussis PT IgG, IgA EIA (PT antigen)
- Chlamydia trachomatis IgG, IgA EIA
- Toxoplasma gondii IgG, IgM IgG Avidity EIA



MIFA Tests - CE Certified

Easy-to-read, species specific microimmunofluorescence kits

- Chlamydia pneumoniae IgG/IgM MIFA
- Chlamydia pneumoniae IgA MIFA



Real Time PCR Kits - CE Certified

Easy reaction set-up, short run time, internal control included

- Chlamydia pneumoniae and Mycoplasma pneumoniae Duplex Real-Time PCR Test
- Bordetella pertussis and Bordetella parapertussis Duplex Real-Time PCR Test



Reliable POC Tests - CE Certified

Reliable POC tests with all accessories included

- Biocard™ M. pneumoniae IgM Test
- Biocard™ C. pneumoniae IgM Test



Biocard™ - CE Certified Celiac Disease Test

Biocard™ Celiac Disease Test is a patented rapid test for the detection of IgA antibodies associated with celiac disease from fingertip blood samples.

- Both home and professional tests available
- Simple and quick test procedure
- Reliable results in less than 10 minutes
- Sensitivity 95,8% and specificity 96,6 %
- Shelf life 24 months



Biocard™ - CE Certified Helicobacter pylori IgG Test

Biocard™ Helicobacter pylori IgG Test is a one-step immunochromatographic test for the rapid and convenient detection of H. pylori antibodies from serum or whole blood samples.

- Both home and professional tests available
- Easy-to-use
- Reliable results in 5 minutes
- Sensitivity 93.2 % and specificity 97.7 %
- Shelf life 24 months

Biocard™ - CE Certified Helicobacter pylori Urease Test

Biocard™ Helicobacter pylori Urease Test is a tablet test for the qualitative detection of urease activity from biopsy or culture samples.

- The test result within 30 minutes
- Sensitivity 95 % and specificity 98.3 %
- Shelf life 24 months

ACUTE CARE TESTS - CE CERTIFIED

Biocard™

Troponin I Test

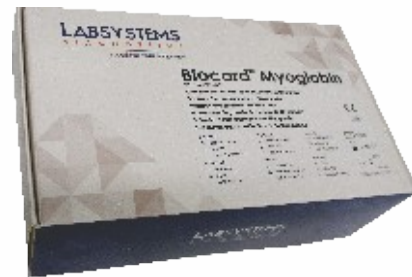
Biocard™ Troponin I Test is a one-step immunochromatographic test which utilizes two highly specific monoclonal antibodies against cardiac troponin I. Detectable level is reached approx. 4-6 hours after an Acute Myocardial Infarction (AMI).



Biocard™

Myoglobin Test

The Biocard™ Myoglobin Test is a rapid POC test for the detection of Myoglobin from plasma or serum samples. Myoglobin appears in serum approx. 1-4 hours after the onset of an AMI, well before most of the other markers.



Biocard™

CRP Test

C-reactive protein (CRP) is an acute phase protein. The concentration of CRP rapidly increases in whole blood after onset of an infection or tissue damage.

- Quantitative detection of CRP from fingertip blood samples
- 10 tests with all accessories



Biocard™

D-DIMER Test

Coming Soon

Rapid POC test for the detection of Deep Vein Thrombosis or Pulmonary Embolism

PREDICTIVE CARE TESTS - CE CERTIFIED

Biocard™

MPO Test

Biocard™ MPO (Myeloperoxidase) test is designed for the quantitative detection of elevated levels of MPO for predicting risk for coronary events.

- Quantitative detection of MPO from fingertip blood samples
- 10 tests with all accessories

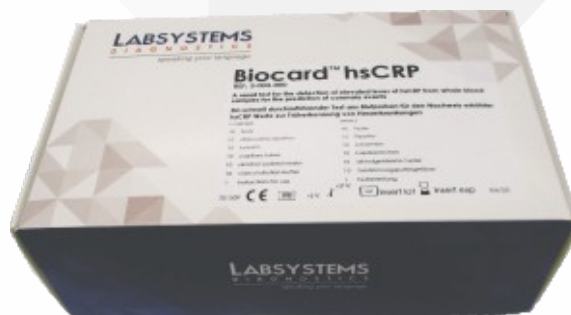


Biocard™

hsCRP Test

High-sensitive C-reactive protein (hsCRP) can be used as a predictive marker for the risk detection of Coronary Artery Disease alone or in combination with Biocard MPO Test

- Quantitative detection of hsCRP from fingertip blood samples
- 10 tests with all accessories



Biocard™ Quant Reader

- Operating system : Windows CE
- Power supply : 100V-240V AC
- Keyboard : Touch Screen
- Display : 5.7" Color Display
- Built -In printer
- Records up to 1000 patients
- Connectivity via USB and Serial port



CARDIAC MARKERS

ELECTROLYTE ANALYSERS

Elite

- Wider menu due to dual configuration in single model: Na, K & Cl or Na, K & Li.
- Saves money due to long life maintenance-free electrode.
- Accurate, precise results & error-free analysis ensured by unique air detector.
- Fast turnaround time by reporting results in 49 Seconds.
- Operational ease due to adjustable sampling arm provides access to tube or cup.
- Easy & fast operation with help of direct function Keys on full Scale Keyboard.



SEMI-AUTOMATED CLINICAL CHEMISTRY ANALYZER

Labmate

- Most versatile analyzer having Clinical Chemistry, Turbidimetry, and Coagulation mode with multipurpose Incubator
- 3 Reading modes for Flow Cell, Cuvette & Tube
- Easy-to-use with touch screen, mouse, keyboard and barcode reader
- 7" colour display with touch screen operations
- Accurate & precise results with long-life 8 IAD Filters (340nm – 670nm)



CLINICAL CHEMISTRY REAGENTS KITS

Clinreact™

- Comprehensive test menus for enzymes, substrates & specific protein parameters.
- Customized & pre-measured pack size configuration.
- Parameter reagents available in ready-to-use liquid, stable & lyophilised powder format.
- Specially designed mono vial [1 ml] reagent range provides ease of convenience in analysis.
- Parameter available with different selection of methods (IFCC or DGKC).
- Reagent provides precise sensitivity, wide measurement range & long shelf life stability.
- Long working reagent & on board stability for precise automated analysis.
- Each parameter offer low Interference & ATCS ensure minimize turbidity cause by Lipemia.
- Suitable for semi & fully automated analyzer application with high sensitivity of detection.
- Special chemistry / turbidimetry range [available upon request].
- Power reagent format [available upon request].
- CE marked reagents ensure best quality Reagents to suit your laboratory requirements & QC



FULLY AUTOMATED CLINICAL CHEMISTRY ANALYZER

Nanolab 220 / 240 *

- Designed to suit workload & workflow requirement of small & medium laboratory.
- High performance delivered through speed, versatility & efficiency.
- Cutting-edge technology & user-friendly operation.

Nanolab 220

- Ideal throughput upto 220 Test/Hr (385 Test/Hr with ISE (Na, K, Cl))
- User convenient Flexible configuration for Sample / Reagent positions.
- Accurate & precise result with Rear Spectrophotometry filter 340-670nm.
- Error free estimation due to 40 disposable ultraviolet transmitting cuvettes.
- Easy & flexible operation through user intuitive software & real time running status
- Precise pipetting ensured by multifunctional sample/reagent probe & independent mixer.



Nanolab 240

- Real performance through constant 240 test/ hour throughput with on board laundry.
- Complete consolidation for wide range of assays suited to variety of laboratory types.
- Accurate detection through versatile optics design (Holographic Grating Photometer).
- Accurate result precision ensured by positive displacement ceramic piston syringe.
- Long on board stability ensured by 66 shared refrigerated reagent carousels.



COMPREHENSIVE SOLUTION FOR QC MANAGEMENT, WITH CE CERTIFIED HEMATOLOGY REAGENTS

Dilucel / Rincel / Lycel

- Precise & accurate with high linearity
- Product stability with long shelf life
- Customized packing
- Excellent lot-to-lot consistency

COMPLETE RANGE OF ADVANCED, FULLY-AUTOMATED HEMATOLOGY ANALYZERS

Cellenium[®] Jr/19/21/21Jr *

Cellenium Junior

3 part diff with 19 Parameters

- Ease-of-operation with keyboard and simple access keys
- RDW-CV and RDW-SD to differentiate various types of anemia
- Liquid valves with volumetric counting ensure sturdiness and reliability
- Separate modes for WBC/HB or RBC/PLT or all 19 parameters - cost-effective



Cellenium 19

3 part diff with 20 Parameters

- 20 customized flagging system to classify abnormal samples
- Enhanced PLT measurement by P-LCR to avoid spurious reporting
- Easy and fast operation through large LCD touch screen, keyboard and mouse
- Precise and accurate measurement by dual / triplicate counting of WBC, RBC and PLT without additional cost



Cellenium 21 & 21Jr

3 Part Diff with 21 Parameters

- Selection of choice suitable for workload & workload Through
 - Cellenium 21: 60 Sample/Hr
 - Cellenium 21 Jr: 30 Sample/Hr
- Highly reliable Volume Vs Counting Technology improve precision of result & calibration requirements.
- Advance technology to minimise coincidence error through PHM (Particle Pulse Height) + PWM (Pulse Width Monitoring)
- 10.4" Colour Touch Screen operation for both model with option of connectivity for Mouse & Keyboard for user friendly operation.
- High resolution Disk Aperture for accurate counting of Blood Cells WBC: 100µm & RBC/PLT: 68µm.



HAEMATOTOLOGY

Immunosuppressants

Coming Soon

Immunosuppressants are mainly used in the organ transplant cases. There are four immunosuppressants which are proven to be clinically relevant in organ transplantation. These are Tacrolimus, Everolimus, Sirolimus and Cyclosporin A. In organ transplantation cases, it is essential to monitor the therapeutic range of these immunosuppressants to protect the patient from toxic effects. The previous methods of quantification for these drugs are proven to provide false positive and false negative results. LCMS/MS technology truly maximizes accuracy, sensitivity and specificity. It is clearly superior to alternative methods for detecting the immunosuppressants but there have not been low cost and easy to use LC MS/MS kits available in the market until today. With considerable increase in organ transplantation, the need for this testing method and a low cost kit has been arising.

Trivitron has undertaken an R&D project to develop ready to use, affordable, high quality and high throughput LC MS/MS kits. We are aiming to provide our customers with these new products soon.

- 4 times higher sensitivity
- 4 step extraction procedure
- 4 Immunosuppressant in one analysis
- 3 minutes run time
- 4 variants
- Unit mass resolution for MASS
- Extended column life
- Cost effective



Vitamin D2 / D3

Coming Soon

Vitamin D2 (Ergocalciferol) and D3 (Cholecalciferol) are the two forms of Vitamin D. Vitamin D is mainly required for the intestinal absorption of Calcium, Iron, Magnesium, Phosphate and Zinc. Human body synthesizes Vitamin D in presence of sunlight.

Recent studies have shown that Vitamin D3 is a more natural form of Vitamin D than Vitamin D2. Also Vitamin D3 is more stable, having less toxic effects and is a more potent form than Vitamin D2. Therefore, whenever there is a need for dietary supplementation of Vitamin D, the clinician should find out which Vitamin D deficiency, the patient is suffering from. The classical techniques are not able to distinguish and quantify the Vitamin D2 and Vitamin D3.

LC MS/MS technology can distinguish between Vitamin D2 and Vitamin D3 and also can quantify their concentrations accurately.

- Ready-to-use LC-MS/MS kit
- User-friendly
- Affordable Reagents

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