

## ORDIN DE PLATĂ

Nr.

809

DATA EMITERII

18 februarie 2026

TIP.DOC.1

PLĂTIȚI:

10 550-00

LEI

Zece mii cinci sute cincizeci lei 00 bani

PLĂTITOR: (R) BIOSISTEM MLD SRL

CODUL IBAN

MD95ML00000002251429243

CODUL FISCAL

1010600028048

PRESTATORUL PLĂTITOR: BC'Moldindconbank'S.A.

BENEFICIAR: (R) IMSP"Spitalul Clinic al Ministerului Sanatatii"

CODUL IBAN

MD05ML00000002251512149

CODUL FISCAL

1003600150716

PRESTATORUL BENEFICIAR: BC'Moldindconbank'S.A.

DESTINAȚIA PLĂȚII: Pentru garantia pentru oferta la procedura de achiziție publică nr. ocds-b3wdp1-MD-1770129543067 din 19.02.2026

TIPUL TRANSFERULUI  
NORMAL/URGENT

N

L.Ș.

CODUL TRANZACȚIEI

001

DATA PRIMIRII

18 februarie 2026 17:23:07

DATA EXECUTĂRII

SARIVAN GABRIEL

SARIVAN GABRIEL

Document transmis prin instrument de plată electronic cu acces la  
la distanță de tip internet-banking

SEMNĂTURA PRESTATORULUI

SEMNĂTURILE EMITENTULUI

L.Ș.

MOTIVUL REFUZULUI

Nota: Responsabilitatea privind veridicitatea și corectitudinea informației indicate în ordinul de plată îi revine emitentului\*

\*Regulamentul cu privire la transferul de credit, debitarea directă și atribuirea codurilor IBAN, aprobat prin HCE al BNM nr. 108 din 08.06.2023

REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

**Societatea cu Răspundere Limitată "BIOSISTEM MLD"**  
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

*Numărul de identificare de stat - codul fiscal*  
**1010600028048**

*Data înregistrării*

**12.08.2010**

*Data eliberării*

**12.08.2010**

**Svirepova Ludmila, registrator**

*Funcția, numele, prenumele persoanei  
care a eliberat certificatul*

*L. Svirepova*  
semnătura

MD 0101250





## AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

### EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei.**

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **15.09.2023.**

**Registrator în domeniul  
înregistrării de stat**

Digitally signed by Rusu Diana  
Date: 2023.09.15 16:44:17 EEST  
Reason: MoldSign Signature  
Location: Moldova



**Rusu Diana**



**EB 0461494**



# BC "MOLDINDCONBANK" S.A.

## Filiala "Invest"

Republica Moldova, MD-2068  
mun. Chişinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDM2X329

Data 14. IAN. 2016  
Nr. 03/2 - 19/23

Республика Молдова, MD-2068  
мун. Кишинэу, бул. Московской, 14/1  
Тел. : (373-22) 43-44-81, 43-46-24  
Факс : (373-22) 43-44-22  
код: MOLDM2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243.**

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

Ex. Diana Brinza  
Tel. 43-45-96

## **Lista fondatorilor Biosistem-mld SRL**

<b>Nr.</b>	<b>Nume, Prenume</b>	<b>IDNP</b>
<b>1.</b>	<b>Vitalie Poiata</b>	<b>0983103892591</b>
<b>2.</b>	<b>Alexandr Nasedchin</b>	<b>2002001070747</b>
<b>3.</b>	<b>Dmitrii Kojevnikov</b>	<b>0972305012362</b>

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 0.04.24065

Certificate Holder: **BIOSYSTEMS S.A.**  
Costa Brava 30  
08030 Barcelona  
Spain

including the branch offices according to annex

Scope: Design, development, manufacture, distribution, installation and service of instruments and reagents for:  
\* Clinical diagnostics.  
\* Agri-food analysis.  
\* Veterinary diagnostics.  
Reagent labelling and assembly.  
Storage of raw materials for instruments, instruments and reagents for:  
\* Clinical diagnostics.  
\* Agri-food analysis.  
\* Veterinary diagnostics.  
\* Dispatched or stored product.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2025-12-19 until 2028-12-18.  
First certification 1996

2025-12-17

  
TUV Rheinland Ibérica Inspection,  
Certification & Testing S.A.  
Garrotxa, 10-12 – E-08820 El Prat de  
Llobregat



www.tuv.com

# Certificate

**Quality Management System**  
**EN ISO 13485:2016**  
**EN ISO 13485:2016/AC:2018**  
**EN ISO 13485:2016/A11:2021**

Registration No.: SX 1695779-1  
Certificate Holder: BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

Scope: The design and development, manufacture, distribution and servicing of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry.  
The design and development, manufacture and distribution of in vitro diagnostic tests kits, related calibrators and controls for professional use used in clinical chemistry and immunochemistry for the detection of tumor markers, rheumatoid-inflammatory diseases markers, cardiac markers and used for diagnosis and management of auto-immune diseases and infectious diseases

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92837241-30  
Effective date: 2025-12-13  
Expiry date: 2028-12-12  
Issue date: 2025-11-14  
Replaces certificate SX 1695779-1 issued 2022-12-12

This certificate can be validated on <https://www.certipedia.com>

  
Daniel Świątko  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 1695779-1  
Certificate Holder: BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain	The design and development, manufacture, distribution and servicing of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry. The design and development, manufacture and distribution of in vitro diagnostic tests kits, related calibrators and controls for professional use used in clinical chemistry and immunochemistry for the detection of tumor markers, rheumatoid-inflammatory diseases markers, cardiac markers and used for diagnosis and management of auto-immune diseases and infectious diseases.
/02	BIOSYSTEMS S.A. Polígono Industrial Can Tapioles Naves 12, 13, 21, 22 08010 Montcada i Reixac - Barcelona	Labelling, assembling, warehousing and shipment of in vitro diagnostic tests kits for clinical chemistry and immunochemistry. Warehousing and shipment of in vitro diagnostic medical device instruments used in clinical chemistry and immunochemistry.

This certificate can be validated on <https://www.certipedia.com>

## EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

### **Hereby DECLARES**

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

### **Directive on in Vitro Diagnostic Medical Devices (98/79/EC)**

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6<sup>th</sup>, 2012



Dr. Antonio Elduque  
Managing director  
BioSystems S.A.



• Certified Management System  
• EN ISO 9001  
• EN ISO 13485



## **CLINICAL CHEMISTRY – BIOCHEMISTRY:**

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-EPS	Creatine Kinase-MB (CK-MB)
a-Amylase-Pancreatic	Creatinine
Acid Phosphatase (ACP)	Fructosamine
Alanine Aminotransferase (ALT/GPT)	Fructose
Albumin	g-Glutamyltransferase (g-GT)
Alkaline Phosphatase (ALP)-AMP	Glucose
Alkaline Phosphatase (ALP)-DEA	Iron – Chromazurol
AspartateAminotranferase (AST/GOT)	Iron – Ferrozine
Bilirubin (direct)	Iron Binding Capacity
Bilirubin (total and direct)	Lactate Dehydrogenase (LDH)
Bilirubin (total)	Lactate Dehydrogenase (LDH) – IFCC
Calcium – Arsenazo	Lipase
Calcium – MTB	Magnesium
Cholesterol	Phosphorus
Cholesterol HDL	Protein (total)
Cholesterol HDL direct	Protein (urine)
Cholesterol HDL Precipitating reagent	Pyridoxal Phosphate
Cholesterol LDL direct	Triglycerides
Cholesterol LDL Precipitating reagent	Urea/BUN-Color
Cholinesterase (CHE)	Urea/BUN-UV
Citrate	Uric Acid

## **CLINICAL CHEMISTRY – TURBIDIMETRY:**

a1-acid Glycoprotein	C-Reactive Protein (CRP)
Albumin (Microalbuminuria)	C-Reactive Protein-hs (CRP-hs)
Anti-Streptolysin O (ASO)	Ferritin
Antithrombin III	Immunoglobulin A (IgA)
Apolipoprotein A-I (Apo A-I)	Immunoglobulin G (IgG)
Apolipoprotein B (Apo B)	Immunoglobulin M (IgM)
b2-Microglobulin	Prealbumin
Complement Component C3	Rheumatoid Factors (RF)
Complement Component C4	Transferrin

## **CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:**

17-Hydroxycorticosteroids	Hemoglobin A1C
17-Ketosteroids	Hemoglobin A2
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)	Metanephrines
5-Hydroxyindoleacetic acid (5-HIAA)	Vanilmandelic Acid



## **CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:**

a-1-acid Glycoprotein Standard	Biochemistry Calibrator (Human)
Adenosine Deaminase (ADA) Standard	Cholesterol HDL/LDL Calibrator
Albumin (Microalbuminuria) Standard	CRP/CRP-hs Standard
Anti-Streptolysin O (ASO) Standard	Ferritin Standard
Antithrombin III Standard	Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Apolipoprotein A-I Standard	Prealbumin Standard
Apolipoprotein B Standard	Protein Calibrators
b2-Microglobulin Standard	Protein (urine) Standard
Bilirubin Standard	Rheumatoid Factors (RF) Standard
Biochemistry Calibrator	

## **CLINICAL CHEMISTRY – INSTRUMENTS:**

A15	BA400
A25	BTS-350

## **CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:**

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-Pancreatic	Creatine Kinase-MB (CK-MB)
Adenosine Deaminase (ADA)	Creatinine
Alanine Aminotransferase (ALT/GPT)	g-Glutamyltransferase (g-GT)
Albumin	Glucose
Alkaline Phosphatase (ALP)-AMP	Iron Ferrozine
Alkaline Phosphatase (ALP)-DEA	Lactate dehydrogenase (LDH)
Aspartate Aminotransferase (AST/GOT)	Lipase
Bilirubin (direct)	Magnesium
Bilirubin (total)	Phosphorus
Calcium-Arsenazo	Protein (total)
Cholesterol	Protein (urine)
Cholesterol HDL direct	Triglycerides
Cholesterol LDL direct	Urea/BUN UV
	Uric acid



## **CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:**

Albumin (Microalbuminuria)	Ferritin
Anti-Streptolysin O (ASO)	Hemoglobin A1C-Turbi (HbA1C-Turbi)
Antithrombin III	Immunoglobulin A (IgA)
Complement Component C3	Immunoglobulin G (IgG)
Complement Component C4	Immunoglobulin M (IgM)
C-Reactive Protein (CRP)	Rheumatoid Factors (RF)
C-Reactive Protein-hs (CRP-hs)	Transferrin

## **CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:**

ADA Controls	Hemoglobin A1C Control (Normal)
Biochemistry Control Serum (Human) I	Hemoglobin A2 Control
Biochemistry Control Serum (Human) II	Lipid Control Serum I
Biochemistry Control Serum I	Lipid Control Serum II
Biochemistry Control Serum II	Protein Control Serum I
CK-MB Control Serum	Protein Control Serum II
Control Urine	Rheumatoid Control Serum I
Fertility Biochemistry Control	Rheumatoid Control Serum II
Hemoglobin A1C Control (Elevated)	

## **AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):**

Anti-Adrenal Cortex Antibodies (AACA)	Anti-Thyroid Antibodies (ATA)
Anti-Endomysium Antibodies (AEA)	Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Anti-Islet Cell Antibodies (AICA)	Autoantibodies MsK/MsS (AA-MsK/MsS)
Anti-Keratin Antibodies (AKA)	Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Anti-Mitochondrial Antibodies (AMA)	Autoantibodies RK/RS (AA-RK/RS)
Anti-nDNA antibodies (nDNA)	Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)	Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)	Glomerular Basement Membrane Antibodies (GBMA)
Anti-Nuclear Antibodies RL (ANA-RL)	
Anti-Skin Antibodies (ASA)	
Anti-Smooth Muscle Antibodies (ASMA)	
Anti-Striated Muscle Antibodies (AStMA)	



## ***AUTOIMMUNITY – ELISA:***

ANA Screening  
Anti-Annexin V IgG/IgM (ANX)  
Anti-b2-Glycoprotein 1 IgG/IgM  
(b2GP1)  
Anti-Cardiolipin Antibodies (ACA-  
IgG/IgM)  
Anti-Centromere B Antibodies (CENP-  
B)  
Anti-Citrullinated Protein Antibodies  
(ACPA)  
Anti-Deamidated Gliadin Peptides IgA  
(DGP IgA)  
Anti-Deamidated Gliadin Peptides IgG  
(DGP IgG)  
Anti-dsDNA Antibodies  
Anti-GBM Antibodies - EIA (GBM)  
Anti-Gliadin Antibodies (AGA-IgG/IgA)  
Anti-Histones Antibodies (HIST)  
Anti-Insulin Antibodies (INS)  
Anti-Jo1 Antibodies  
Anti-M2 Antibodies (M2)

Anti-MPO Antibodies  
Anti-Nucleosome Antibodies (NCL)  
Anti-Phospholipid IgG/IgM (APLA)  
Anti-PR3 Antibodies  
Anti-Ribosomal P Antibodies (Rib P)  
Anti-Scl70 Antibodies  
Anti-Sm Antibodies  
Anti-Sm/RNP Antibodies  
Anti-SSA (Ro) Antibodies  
Anti-SSB (La) Antibodies  
Anti-Thyroglobulin Antibodies (Anti-Tg)  
Anti-Thyroid Peroxidase Antibodies  
(Anti-TPO)  
Anti-tTransglutaminase IgA Antibodies  
(Anti- tTG IgA)  
Anti-tTransglutaminase IgG Antibodies  
(Anti- tTG IgG)  
ASCA-IgG/IgA (ASCA)  
ENA 4-Profile  
ENA 6-Screening

## ***AUTOINMUNIDAD – INSTRUMENTOS:***

## ***AUTOIMMUNITY – INSTRUMENTS:***

iPRO



### ***RAPID TESTS – LATEX AGGLUTINATION:***

Anti-Streptolysin O (ASO) - Slide  
C-Reactive Protein (CRP) - Slide

Rheumatoid factors (RF) - Slide

### ***INFECTIOUS IMMUNOLOGY – SYPHILIS:***

RPR-Carbon

TPHA

### ***INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:***

Febrile Serodiagnostics Multiscreening

Febrile Serodiagnostics Salmonella

Brucella abortus

Brucella abortus, Rose Bengal

Proteus Ox19

Salmonella paratyphi AH

Salmonella paratyphi AO

Salmonella paratyphi BH

Salmonella paratyphi BO

Salmonella paratyphi CH

Salmonella paratyphi CO

Salmonella typhi H

Salmonella typhi O

Brucella Positive Control

Proteus Positive Control

Salmonella Positive Control

Serology Negative Control



<b>PRODUCT NAME</b>	<b>CODE</b>
<b>CLINICAL CHEMISTRY - BIOCHEMISTRY</b>	
<b>a-AMYLASE - DIRECT</b>	11583
	11550
	12550
	21550
	23550
<b>a-AMYLASE - EPS</b>	11534
	21534
<b>a-AMYLASE-PANCREATIC</b>	11799
	12799
	21799
<b>ACID PHOSPHATASE (ACP)</b>	11548
<b>ALANINE AMINOTRANSFERASE (ALT/GPT)</b>	11832
	11533
	11568
	11562
	12533
	21533
	23533
<b>ALBUMIN</b>	11573
	11547
	12547
	21547
	23547
<b>ALKALINE PHOSPHATASE (ALP) - AMP</b>	11592
	11593
	11598
	12518
	21592
	23592
<b>ALKALINE PHOSPHATASE (ALP) - DEA</b>	11590
	11591
	11597
	12514
	21590
	23590
<b>ASPARTATE AMINOTRANSFERASE (AST/GOT)</b>	11830
	11531
	11567
	11561
	12531
	21531
<b>BILIRUBIN (DIRECT)</b>	23531
	11511
	11545
	21504

PRODUCT NAME	CODE
	23504
BILIRUBIN (TOTAL AND DIRECT)	11515
	11555
BILIRUBIN (TOTAL)	11510
	11544
	21506
	23506
CALCIUM-ARSENAZO	11570
	11571
	12570
	21570
	23570
CALCIUM-CRESOLPHTHALEIN	11811
	11812
	12513
	21511
	23511
CALCIUM-MTB	11527
	11507
CARBON DIOXIDE (CO2)	11558
	11827
	12558
	21558
CHOLESTEROL	11805
	11505
	11506
	11539
	12505
	21505
	23505
	11523
CHOLESTEROL HDL DIRECT	11557
	12557
	21557
	23557
CHOLESTEROL HDL PRECIPITATING REAGENT	11648
CHOLESTEROL LDL DIRECT	11585
	12585
	21585
	23585
CHOLESTEROL LDL PRECIPITATING REAGENT	11579
CHOLINESTERASE (CHE)	11588
	11589
	21588
CITRATE	11795
	11895
	23795
CREATINE KINASE (CK)	11790
	11791
	12524
	21790

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PRODUCT NAME	CODE
	23790
CREATINE KINASE-MB (CK-MB)	11792
	12566
	21792
	23792
CREATININE	11802
	11502
	11542
	12502
	21502
	23502
CREATININE-ENZYMATIC	11734
	12734
	21734
FRUCTOSAMINE	11046
FRUCTOSE	11794
	23794
g-GLUTAMYLTRANSFERASE (g-GT)	11584
	11520
	12520
	21520
	23520
GLUCOSE	11803
	11503
	11504
	11538
	12503
	21503
	23503
GLUCOSE-HEXOKINASE	11656
	12756
	21656
	23656
IRON- CHROMAZUROL	11546
IRON-FERROZINE	11509
	12509
	21509
	23509
LACTATE	11736
	12736
	21736
	23736
LACTATE DEHYDROGENASE (LDH)	11580
	11581
	12580
	21580
	23580
LACTATE DEHYDROGENASE (LDH) - IFCC	11586
	11587
	21586
	23586

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<b>PRODUCT NAME</b>	<b>CODE</b>
<b>LIPASE</b>	11793
	12793
	23793
<b>MAGNESIUM</b>	11797
	12797
	21797
	23797
<b>PHOSPHORUS</b>	11508
	12508
	21518
	23518
<b>PROTEIN (TOTAL)</b>	11800
	11572
	11500
	11553
	12500
	21513
	23513
<b>PROTEIN (URINE)</b>	11501
	11559
	12501
	21512
	23512
<b>PYRIDOXAL PHOSPHATE</b>	11666
<b>TOTAL IRON BINDING CAPACITY (TIBC)</b>	11554
<b>TRIGLYCERIDES</b>	11828
	11528
	11529
	12528
	21528
	23528
<b>UNSATURATED IRON BINDING CAPACITY (UIBC)</b>	11835
	12835
	21835
<b>UREA/BUN - COLOR</b>	11536
	11537
<b>UREA/BUN - UV</b>	11516
	11517
	11541
	12516
	21516
<b>URIC ACID</b>	23516
	11821
	11521
	11522
	11540
	12521
21521	
23521	
<b>ZINC</b>	12526
<b>CLINICAL CHEMISTRY - TURBIDIMETRY</b>	

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<b>PRODUCT NAME</b>	<b>CODE</b>
a1-ACID GLYCOPROTEIN	31928
	23107
ALBUMIN (MICROALBUMINURIA)	31324
	31924
	13324
	22324
	23324
ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)	61004
	61005
	61009
ANTI-STREPTOLYSIN O (ASO)	31323
	31923
	31031
	13923
	22923
	23923
ANTITHROMBIN III	31936
	13936
	22936
	23936
APOLIPOPROTEIN A-I (APO A-I)	31095
	23095
APOLIPOPROTEIN B (APO B)	31098
	23098
b2-MICROGLOBULIN	31925
	22925
	23925
COMPLEMENT COMPONENT C3	31073
	31079
	13084
	23103
COMPLEMENT COMPONENT C4	31074
	31080
	13085
	23104
C-REACTIVE PROTEIN (CRP)	31321
	31921
	31029
	13921
	22921
	23921
C-REACTIVE PROTEIN-hs (CRP-hs)	31927
	13927
	22927
	23927
FERRITIN	31934
	31935
	22934
	23934
	13934

2-4-1

<b>PRODUCT NAME</b>	<b>CODE</b>
<b>FIBRINOGEN</b>	31600
	13600
	22804
	23804
<b>FIBRINOGEN CLAUSS</b>	61002
	61003
	61020
<b>HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)</b>	31047
	13047
	22047
	22147
<b>IMMUNOGLOBULIN A (IgA)</b>	31071
	31077
	13082
	23101
<b>IMMUNOGLOBULIN G (IgG)</b>	31070
	31076
	13081
	23100
<b>IMMUNOGLOBULIN M (IgM)</b>	31072
	31078
	13083
	23102
<b>PREALBUMIN</b>	31929
	23106
<b>PROTHROMBIN TIME (PT)</b>	61001
<b>RHEUMATOID FACTORS (RF)</b>	31322
	31922
	31030
	13922
	22922
23922	
<b>THROMBIN TIME (TT)</b>	61000
<b>TRANSFERRIN</b>	31091
	31092
	31093
	13091
	22105
	23105
<b>CLINICAL CHEMISTRY - MICROCOLUMN CHROMATOGRAPHY</b>	
<b>17-HYDROXYCORTICOSTEROIDS (17-OH)</b>	11006
<b>17-KETOSTEROIDS</b>	11002
<b>5-AMINOLEVULINIC ACID (ALA) / PORPHOBILINOGEN (PBG)</b>	11017
<b>5-HYDROXYINDOLEACETIC ACID (5-HIAA)</b>	11010
<b>HEMOGLOBIN A2</b>	11077
<b>METANEPHRINES</b>	11022
<b>VANILMANDELIC ACID</b>	11003
<b>CLINICAL CHEMISTRY - STANDARDS &amp; CALIBRATORS</b>	

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<b>PRODUCT NAME</b>	<b>CODE</b>
ADENOSINE DEAMINASE (ADA) STANDARD	18052
ALBUMIN (MICROALBUMINURIA) STANDARD	18011
AMMONIA/ETHANOL/CO2 CALIBRATOR	18065
ANTI-STREPTOLYSIN O (ASO) STANDARD	31119
APOLIPOPROTEIN A-I (APO A-I) STANDARD	31100
APOLIPOPROTEIN B (APO B) STANDARD	31200
b2-MICROGLOBULIN STANDARD	31122
BILIRUBIN STANDARD	11693
BIOCHEMISTRY CALIBRATOR	31075
BIOCHEMISTRY CALIBRATOR (HUMAN)	18044
CARBON DIOXIDE STANDARD	11822
	11833
CHOLESTEROL HDL/LDL CALIBRATOR	11824
COAGULATION CALIBRATOR	61006
CREATINE KINASE-MB (CK-MB) STANDARD	11750
CRP/CRP-hs STANDARD	31113
CRP-er STANDARD	31182
FERRITIN STANDARD	31127
FIBRINOGEN STANDARD	31601
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR) STANDARDS	31048
HOMOCYSTEINE STANDARDS	11603
PREALBUMIN STANDARD	31196
PROTEIN (URINE) STANDARD	31130
PROTEIN CALIBRATORS	11513
RHEUMATOID FACTORS (RF) STANDARD	31116
<b>CLINICAL CHEMISTRY - INSTRUMENTS</b>	
A15	83105
A25	83101
BA400	83400
BA200	83200
BTS-350	80175
<b>CONSUMABLES (INSTRUMENTS)</b>	
ALKALINE WASHING SOLUTION	AC17204
	AC17205
ACID WASHING SOLUTION	AC17200
	AC17201
CONCENTRATED SYSTEM LIQUID	BO11524
CONCENTRATED SYSTEM LIQUID 2	AC17206
CONCENTRATED WASHING SOLUTION	BO13416
	AC16434
Reaction Rotor	AC11485
Sample Wells (1000 units)	AC10770
WASHING SOLUTION	AC10415
	BO10771
<b>CLINICAL CHEMISTRY - BIOCHEMISTRY - REAGENTS AUTOMATED SYSTEMS A15/A25</b>	
ADENOSINE DEAMINASE (ADA)	12754
	23754
AMMONIA	12532
	23532

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PRODUCT NAME	CODE
ANGIOTENSIN CONVERTING ENZYME (ACE)	12796
	21796
b-HYDROXYBUTYRATE	12525
	21525
ETHANOL	12789
	21789
HOMOCYSTEINE	12737
	21737
	23737
OXALATE	12539
OXALATE PRETREATMENT REAGENTS	11839
TOTAL BILE ACIDS	12551
	21551
	23551
a-1-Microglobulin	22941
C-REACTIVE PROTEIN-er (CRP-er)	22942
	23942
<b>CLINICAL CHEMISTRY - INTERNAL QUALITY CONTROL</b>	
ADA CONTROLS	18048
AMMONIA/ETHANOL/CO2 CONTROL I	18063
AMMONIA/ETHANOL/CO2 CONTROL II	18064
b2-MICROGLOBULIN CONTROL URINE	31215
b2-MICROGLOBULIN CONTROLS	31592
BIOCHEMISTRY CONTROL SERUM (HUMAN) I	18042
BIOCHEMISTRY CONTROL SERUM (HUMAN) II	18043
BIOCHEMISTRY CONTROL SERUM I	18009
	18005
BIOCHEMISTRY CONTROL SERUM II	18010
	18007
BIOCHEMISTRY CONTROL URINE	18054
BIOCHEMISTRY CONTROL URINE II	18066
CK-MB CONTROL SERUM	18024
CK-MB CONTROL SERUM II	18061
COAGULATION CONTROL I	61007
COAGULATION CONTROL II	61008
CONTROL URINE	18036
	18037
FERTILITY BIOCHEMISTRY CONTROL	18053
FIBRINOGEN CONTROL PLASMA	31602
FRUCTOSAMINE CONTROL SERUM	18057
HEMOGLOBIN A1C CONTROL (ELEVATED)	18002
HEMOGLOBIN A1C CONTROL (NORMAL)	18001
HEMOGLOBIN A2 CONTROL	10011
HOMOCYSTEINE CONTROL I	18058
HOMOCYSTEINE CONTROL II	18059
LIPID CONTROL SERUM I	18040
LIPID CONTROL SERUM II	18041
OXALATE CONTROL URINE	18062
PROTEIN CONTROL SERUM I	31211
PROTEIN CONTROL SERUM II	31212

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<b>PRODUCT NAME</b>	<b>CODE</b>
RHEUMATOID CONTROL SERUM I	31213
RHEUMATOID CONTROL SERUM	31214
<b>AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE)</b>	
ANTI-ADRENAL CORTEX ANTIBODIES (AACA)	44574
	44575
	29022
ANTI-ENDOMYSIUM ANTIBODIES (AEA)	44148
	44548
	44715
	44557
	44710
ANTI-ISLET CELL ANTIBODIES (AICA)	44609
	44572
ANTI-KERATIN ANTIBODIES (AKA)	44618
	44517
ANTI-MITOCHONDRIAL ANTIBODIES (AMA)	44510
	44514
	44511
	44515
ANTI-nDNA ANTIBODIES (nDNA)	44825
	44818
	44817
	44820
	44819
ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)	44850
	44851
	44852
	44911
ANTI-NUCLEAR ANTIBODIES HEp-2 (ANA-HEp-2)	44108
	44508
	44509
	44546
	44547
ANTI-NUCLEAR ANTIBODIES RL (ANA-RL)	44506
	44507
ANTI-SKIN ANTIBODIES (ASA)	44560
	44561
ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA)	44520
	44524
	44521
	44525
ANTI-STRIATED MUSCLE ANTIBODIES (AStMA)	44649
	29017
ANTI-THYROID ANTIBODIES (ATA)	44550
	44551
	29012
AUTOANTIBODIES DUO-HEp2/ML (DUO-HEp2/ML)	44874
AUTOANTIBODIES MSK/MSS (AA-MSK/MSS)	44518
AUTOANTIBODIES MSL/MSK/MSS (AA-MSL/MSK/MSS)	44826
	44827

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<b>PRODUCT NAME</b>	<b>CODE</b>
AUTOANTIBODIES-RK/RS (AA-RK/RS)	44758
	44568
AUTOANTIBODIES-RL/RK/RS (AA-RL/RK/RS)	44558
	44648
	44570
	44639
GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)	44588
<b>AUTOIMMUNITY - IFA (IMMUNOFLUORESCENCE) - AUXILIARY REAGENTS</b>	
AACA POSITIVE CONTROL	44578
AEA POSITIVE CONTROL	44549
	44893
	44732
AICA POSITIVE CONTROL	44577
AKA POSITIVE CONTROL	44619
AMA POSITIVE CONTROL	44512
	44891
ANA-Ce POSITIVE CONTROL	44585
ANA-Ho POSITIVE CONTROL	44502
	44890
ANA-Nu POSITIVE CONTROL	44504
ANA-Sp POSITIVE CONTROL	44503
APCA POSITIVE CONTROL	44532
ASA-bm POSITIVE CONTROL	44562
ASA-is POSITIVE CONTROL	44563
ASMA POSITIVE CONTROL	44522
	44892
AStMA POSITIVE CONTROL	44883
ATA POSITIVE CONTROL	44553
BLOTTING PAPER 12	44669
BLOTTING PAPER 4	44731
BLOTTING PAPER 6	44667
BLOTTING PAPER 8	44716
C-ANCA POSITIVE CONTROL	44854
	44912
FITC/EVANS (R)	44590
	44836
	44916
GBMA POSITIVE CONTROL	44678
GLYCIN	44846
IgA FITC/EVANS	44692
	44835
IgG FITC/EVANS	44697
	44834
IgG FITC/EVANS (M)	44847
	44882
LKM POSITIVE CONTROL	44766
MOUNTING MEDIUM	44694
nDNA POSITIVE CONTROL	44542
	44894

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<b>PRODUCT NAME</b>	<b>CODE</b>
<b>NEGATIVE CONTROL</b>	44696
	44889
<b>P-ANCA POSITIVE CONTROL</b>	44855
	44913
<b>PBS (10x)</b>	44592
<b>X-ANCA POSITIVE CONTROL</b>	44896
<b>AUTOIMMUNITY - ELISA</b>	
<b>ANA-SCREENING</b>	44785
<b>ANTI-ANNEXIN V IgG/IgM (ANX)</b>	44869
<b>ANTI-beta-2-GLYCOPROTEIN 1 IgG/IgM (beta2GP1)</b>	44868
<b>ANTI-BPI ANTIBODIES</b>	44905
<b>ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)</b>	44780
<b>ANTI-CATHEPSIN G ANTIBODIES</b>	44906
<b>ANTI-CENTROMERE B ANTIBODIES (CENP-B)</b>	44865
<b>ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)</b>	44860
<b>ANTI-DEAMIDATED GLIADIN PEPTIDES IgA (DGP IgA)</b>	44885
<b>ANTI-DEAMIDATED GLIADIN PEPTIDES IgG (DGP IgG)</b>	44884
<b>ANTI-dsDNA ANTIBODIES</b>	44705
<b>ANTI-ELASTASE ANTIBODIES</b>	44907
<b>ANTI-GBM ANTIBODIES-EIA (GBM)</b>	44870
<b>ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA)</b>	44704
<b>ANTI-HISTONES ANTIBODIES (HIS)</b>	44862
<b>ANTI-INSULIN ANTIBODIES (INS)</b>	44873
<b>ANTI-Jo1 ANTIBODIES</b>	44864
<b>ANTI-LACTOFERRIN ANTIBODIES</b>	44908
<b>ANTI-LYSOZYME ANTIBODIES</b>	44909
<b>ANTI-M2 ANTIBODIES (M2)</b>	44871
<b>ANTI-MPO ANTIBODIES (P-ANCA)</b>	44790
<b>ANTI-NUCLEOSOME ANTIBODIES (NCL)</b>	44861
<b>ANTI-PHOSPHOLIPID IgG/IgM (APLA)</b>	44867
<b>ANTI-PR3 ANTIBODIES (C-ANCA)</b>	44791
<b>ANTI-RIBOSOMAL P ANTIBODIES (Rib P)</b>	44866
<b>ANTI-Sci70 ANTIBODIES</b>	44863
<b>ANTI-Sm ANTIBODIES</b>	44755
<b>ANTI-Sm/RNP ANTIBODIES</b>	44770
<b>ANTI-SSA (Ro) ANTIBODIES</b>	44765
<b>ANTI-SS-B (La) ANTIBODIES</b>	44750
<b>ANTI-THYROGLOBULIN ANTIBODIES (ANTI-Tg)</b>	44796
<b>ANTI-THYROID PEROXIDASE ANTIBODIES (ANTI-TPO)</b>	44795
<b>ANTI-tTRANSGLUTAMINASE ANTIBODIES IgA (ANTI-tTG IgA)</b>	44754
<b>ANTI-tTRANSGLUTAMINASE ANTIBODIES IgG (ANTI-tTG IgG)</b>	44798
<b>ASCA-IgG/IgA (ASCA)</b>	44872
<b>ENA 4-PROFILE</b>	44775
<b>ENA 6-PROFILE</b>	44910
<b>ENA 6-SCREENING</b>	44740
<b>AUTOIMMUNITY - INSTRUMENTS</b>	

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<b>PRODUCT NAME</b>	<b>CODE</b>
iPRO	84101
<b>RAPID TESTS - LATEX AGGLUTINATION</b>	
<b>ANTI-STREPTOLYSIN O (ASO) - SLIDE</b>	31019
	31319
	31086
	31448
<b>C-REACTIVE PROTEIN (CRP) - SLIDE</b>	31011
	31311
	31012
	31107
<b>RHEUMATOID FACTORS (RF) - SLIDE</b>	31013
	31313
	31014
	31108
<b>INFECTIOUS IMMUNOLOGY - SYPHILIS</b>	
<b>RPR-CARBON</b>	36001
	36002
<b>TPHA</b>	36005
<b>INFECTIOUS IMMUNOLOGY - FEBRILE ANTIGENS</b>	
<b>BRUCELLA ABORTUS</b>	33309
<b>BRUCELLA ABORTUS, ROSE BENGAL</b>	33315
<b>BRUCELLA POSITIVE CONTROL</b>	33509
<b>FEBRILE SERODIAGNOSTICS MULTISCREENING</b>	33001
<b>FEBRILE SERODIAGNOSTICS SALMONELLA</b>	33080
	33081
<b>PROTEUS OX19</b>	33311
<b>PROTEUS POSITIVE CONTROL</b>	33502
<b>SALMONELLA PARATYPHI AH</b>	33301
<b>SALMONELLA PARATYPHI AO</b>	33302
<b>SALMONELLA PARATYPHI BH</b>	33303
<b>SALMONELLA PARATYPHI BO</b>	33304
<b>SALMONELLA PARATYPHI CH</b>	33305
<b>SALMONELLA PARATYPHI CO</b>	33306
<b>SALMONELLA POSITIVE CONTROL</b>	33510

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America

# CERTIFICATE

No. QS5 044751 0140 Rev. 06

Certificate Holder:

**Shenzhen Mindray Bio-Medical  
Electronics Co., Ltd.**  
Mindray Building  
Keji 12th Road South  
High-Tech Industrial Park  
Nanshan  
518057 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

SH2405501

Effective Date:

2024-08-28

Expiry Date:

2026-06-30

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Date of Issue: 2024-09-25

( Renee Walker )  
Director, US Certification Body, MHS



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 06

**Overall Scope Statement:**

**Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and Accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System**

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Date of Issue: 2024-09-25

( Renee Walker )  
Director, US Certification Body, MHS



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 06

**Facility(ies):**

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
Mindray Building, Keji 12th Road South, High-Tech Industrial  
Park, Nanshan, 518057 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

**Facility Scopes:**

Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

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Date of Issue: 2024-09-25

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Director, US Certification Body, MHS



America

# CERTIFICATE

No. QS5 044751 0140 Rev. 06

**Facility(ies):****Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA**Facility Scopes:**

Design and Development, Production, Service and Distribution of Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Endoscope Light Source and Accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

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Date of Issue: 2024-09-25

( Renee Walker )  
Director, US Certification Body, MHS



# 认证证书

证书号：QS5 044751 0140 Rev. 06

证书持有者：

深圳迈瑞生物医疗电子股份有限公司

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦 518057

组织机构代码：

914403007084678371

认证标志：



认证范围：

证书范围见第2页

认证标准：

ISO 9001:2015

TÜV SÜD America Inc. 认证机构证明上述公司已经建立并保持满足上述所列标准要求的质量管理体系。

报告号：

SH2405501

生效期：

2024-08-28

到期时间：

2026-06-30

本证书信息可在国家认证认可监督管理委员会官方网站 ( [www.cnca.gov.cn](http://www.cnca.gov.cn) ) 上查询。获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

第1页共3页

日期， 2024-09-25

( Renee Walker )  
Director, US Certification Body, MHS



# 认证证书

证书号：QS5 044751 0140 Rev. 06

## 认证范围：

设计和开发、生产、服务和分销：

医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

## 深圳迈瑞生物医疗电子股份有限公司

中国深圳市南山区高新技术产业园科技南十二路迈瑞大厦

邮编：518057

设计和开发、生产、服务和分销：医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

日期：2024-09-25

( Renee Walker )  
Director, US Certification Body, MHS



# 认证证书

证书号：QS5 044751 0140 Rev. 06

深圳迈瑞生物医疗电子股份有限公司  
中国深圳市光明区南环大道1203号  
邮编：518106

设计和开发、生产、服务和分销：医用电子设备（包括病人监护仪和附件、生命体征监测仪、心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪）、以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、无线模块、无线设备、微生物分析用仪器、尿液分析用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

第3页共3页

日期， 2024-09-25

( Renee Walker )  
Director, US Certification Body, MHS



# Certificate

No. Q5 044751 0164 Rev. 06

**Holder of Certificate:** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building  
Keji 12th Road South  
High-Tech Industrial Park  
Nanshan  
518057 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production, Service and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06)

**Report No.:** SH2405501

**Valid from:** 2024-08-15  
**Valid until:** 2026-08-31

**Date,** 2024-08-15

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 044751 0164 Rev. 06

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
Mindray Building, Keji 12th Road South, High-Tech Industrial Park,  
Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Service and Distribution of:  
Active Medical Devices(intended) for monitoring, diagnosis,  
anesthesia, breathing and intensive care; In-vitro Diagnostic  
Instruments;  
Non-active accessories for breathing therapy and anesthesia; In-  
vitro diagnostic reagents and kits(intended) for hematology, clinical  
chemistry, immunology and cell analysis (For detail information  
see following pages)

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**  
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,  
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Service and Distribution of:  
Active Medical Devices(intended) for monitoring, diagnosis,  
anesthesia, breathing and intensive care; In-vitro Diagnostic  
Instruments;  
Non-active accessories for breathing therapy and anesthesia; In-  
vitro diagnostic reagents and kits(intended) for hematology, clinical  
chemistry, immunology and cell analysis (For detail information  
see following pages)

# Certificate

No. Q5 044751 0164 Rev. 06

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System.



# 认证证书

证书号: Q5 044751 0164 Rev. 06

证书持有者: 深圳迈瑞生物医疗电子股份有限公司

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦  
518057

认证标志:



认证范围:

设计和开发、生产、服务和分销: 有源医疗器械用于  
监护、诊断、麻醉、呼吸和重症监护; 体外诊断设备;  
无源附件用于呼吸治疗和麻醉; 体外诊断试剂和试剂盒  
用于血球、临床生化、免疫及细胞分析。(具体信息范围  
见附件)

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。  
TÜV 南德集团检测、认证、审定与核查准则所有适用要求也须得到遵守。详情及证书有效期请见  
[www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5_044751_0164_Rev_06)

报告号: SH2405501

生效期: 2024-08-15

有效期: 2026-08-31

发证日期, 2024-08-15

Christoph Dicks

Head of Certification/Notified Body

# 认证证书

证书号: Q5 044751 0164 Rev. 06

**认证标准:**

ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
医疗器械 - 质量管理体系 - 用于法规的要求

**生产场地:**

**深圳迈瑞生物医疗电子股份有限公司**

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦  
518057

设计和开发、生产、服务和分销: 有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护; 体外诊断设备; 无源附件用于呼吸治疗和麻醉; 体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

**深圳迈瑞生物医疗电子股份有限公司**

中华人民共和国深圳市光明区南环大道1203号 518106

设计和开发、生产、服务和分销: 有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护; 体外诊断设备; 无源附件用于呼吸治疗和麻醉; 体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

# 认证证书

证书号. Q5 044751 0164 Rev. 06

## 覆盖产品范围为:

医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪），以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
518057, P. R. China  
Tel: +86 755 26582888  
Fax: +86 755 26582500

## DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:

We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The conformity assessment route is according to 98/79/EC Annex III (not includes Section 6).

**Classification:** The device not in IVDD annex II and not for self testing/performance evaluation

**Product Category(ies):** Clinical Chemistry Analyzer, Hematology Analyzer, Microplate washer, Microplate reader, Urine Analyzer, Chemiluminescence Immunoassay Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Reagents for Chemiluminescence Immunoassay Analyzer, Urinalysis reagent strips.

**Products:** Attachment I

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, Germany

We hereby certify that the forgoing is a true and accurate statement.

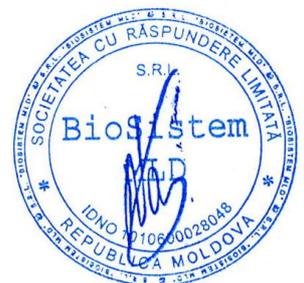
Place, Date Of Issue : Shenzhen, 2016-09-01



**Signatory name:** Chuanbin Tan

**signatory title:** Technical Regulation Manager

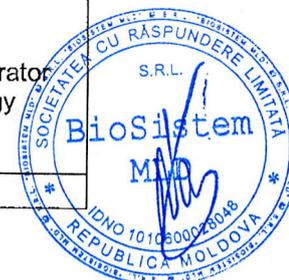
**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**



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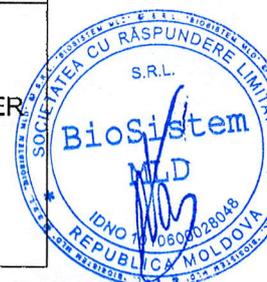
**ATTACHMENT I**

Product Name	Product Model	Accessories
Hematology Analyzer	BC-2300、 BC-2100	M-23CFL LYSE M-23D DILUENT M-23E E-Z CLEANSER M-23P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-1800、 BC-1900、 BC-2900	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator BC-3D Hematology Control SC-CAL PLUS Hematology Calibrator
Auto Hematology Analyzer	BC-3000 Plus	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3200、 BC-3200CT	M-30D DILUENT M-30R RINSE M-30CFL LYSE M-30E E-Z CLEANSER M-30P PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-5500、	M-50D DILUENT



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	BC-5200	M-50LH LYSE M-50LEO(I)LYSE M-50LEO(II)LYSE M-50LBA LYSE M-50 CLEANSER M-50P PROBE CLEANSER BC-5D Hematology Control CBC-5DMR Hematology Control SC-CAL PLUS Hematology Calibrator S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5300、 BC-5100	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-5380、 BC-5180	M-53LEO(I)LYSE M-53LEO(II)LYSE M-53LH LYSE M-53D DILUENT M-53 CLEANSER M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-2800、 BC-2600	M-18CFL LYSE M-18D DILUENT M-18R RINSE M-18E E-Z CLEANSER M-18P PROBE CLEANSER B30 Hematology Control S30 Hematology



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		Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300、 BC-3300CT、 BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5800、 BC-5600	M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-6600、 BC-6800	M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator BR60 Hematology Control
Auto Hematology Analyzer	BC-5310	M-53D DILUENT M-53LEO( I ) LYSE M-53LEO( II ) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control



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Auto Hematology Analyzer	BC-5390	M-53D DILUENT M-53LEO( I ) LYSE M-53LEO( II ) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5150、 BC-5000、 HM-500X	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER S50 Calibrator B55 Hematology Control BC-5D Hematology control SC-CAL PLUS Hematology Calibrator
Urine Analyzer	UA-66、 UA-600、 UA-600T	Urinalysis reagent strips
Auto Hematology Analyzer	BC-20s、 BC-21s、 BC-30s、 BC-31s、 HM-200X	M-30D DILUENT M-30CFL LYSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5390 CRP BC-5180 CRP	M-53D DILUENT M-5 LEO(I) LYSE M-5 LEO(II) LYSE M-53 LH LYSE LC LYSE Probe Cleanser S50 Calibrator B55 Hematology Control C-reactive Protein Control C-reactive Protein (CRP) Calibrator C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
Auto Sample Processing System	CAL 8000	/
Auto Slide Maker & Stainer	SC-120	M-68DS DILUENT PROBE CLEANSE
Automated Glycohemoglobin Analyzer	H50 H50P	Analytical Column Eluent A Eluent B Hemolysis Solution M-30P PROBE CLEANSER Hemoglobin A1c Control



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		Hemoglobin A1c Calibrator
Flow Cytometer	BriCyte E6	Sheath Fluid Cleaning Solution
Lysing Solution	/	/
CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent HLA-B27 Reagent	/	/
Laboratory Data Management Software	/	/
Mindray labXpert Software	/	/
Specific Protein Analyzer	CRP-M100	M-68DS Diluent LC Lyse CRP Cleanser Probe Cleanser
Auto Hematology Analyzer	BC-5120 BC-5130 BC-5140	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER
Chemistry Analyzer	BS-300、BS-320	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit
Chemistry Analyzer	BS-400、BS-420	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvettes



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.  
 Keji 12<sup>th</sup> Road South, Hi-tech Industrial Park, Shenzhen  
 518057, P. R. China

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Fax: +86 755 26582500

		Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	Perfect plus	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	BS-380、BS-390	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit
Chemistry Analyzer	BS-350、BS-330	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode



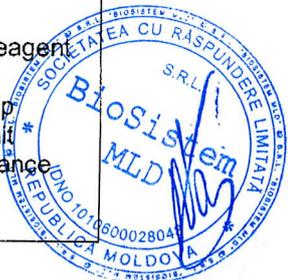
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		Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Semi-auto Chemistry Analyzer	BA-88A	/
Chemistry Analyzer	BS-120、BS-130、 BS-180	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200、BS-220	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200E/BS-220E BS-330E/BS-350E	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode



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		Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Microplate reader	MR-96A	/
Microplate washer	MW-12A	/
Chemistry Analyzer	BS-800、BS-820、 BS-800M、 BS-820M、 BS-1800、BS-1800 plus	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System (RMS)
Chemistry Analyzer	BS-2000、 BS-2000M、 BS-2200、 BS-2200M	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System (RMS)



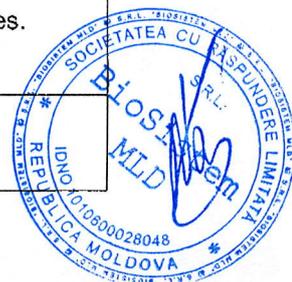
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Chemistry Analyzer	BS-600、BS-620	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit External vacuum pump unit
Chemistry Analyzer	BS-480、BS-490	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Built-in sample/reagent bar code reader Remote management system (RMS) Water supply module External air pump
Chemistry Analyzer	BS-430、BS-450、 BS-460	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode



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		Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit Probe clog detection module
Chemistry Analyzer	BS-230、BS-240	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code reader(optional)
Chemiluminescence Immunoassay Analyzer	CL-2000i、 CL-2200i	Hand-held bar code reader External vacuum pump Reaction cuvette Waste Bin
Chemiluminescence Immunoassay Analyzer	CL-1000i、 CL-1200i	Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. waste container
$\alpha$ -Amylase ( $\alpha$ -AMY) Kit (IFCC Method)	/	/



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Aspartate Aminotransferase (AST) Kit (IFCC Method)	/	/
Gamma-Glutamyltransferase (GGT) Kit (Szasz Method /IFCC stand.)	/	/
Lactate Dehydrogenase (LDH) Kit (IFCC Method)	/	/
Alanine Aminotransferase (ALT) Kit (IFCC Method)	/	/
C-Reactive Protein Kit(Turbidimetry Method)	/	/
Apolipoprotein B Kit (Turbidimetry Method)	/	/
Apolipoprotein A1 Kit (Turbidimetry Method)	/	/
Triglycerides Kit(GPO-POD Method)	/	/
Bilirubin Total Kit(DSA Method)	/	/
Creatinine Kit(Modified Jaffe Method)	/	/
Albumin Kit(Bromcresol Green Method)	/	/
Bilirubin Direct Kit(DSA Method)	/	/
Total Protein Kit(Biuret Method)	/	/
Magnesium Kit(Xylidyl Blue Method)	/	/
$\alpha$ -Hydroxybutyrate Dehydrogenase Kit(DGKC Method)	/	/
Total Cholesterol kit(CHOD-POD Method)	/	/
Alkaline Phosphatase Kit(IFCC Modified Method)	/	/
Urea Kit(Urease-GLDH,UV Method)	/	/
Uric Acid Kit(Uricase-peroxidase Method)	/	/



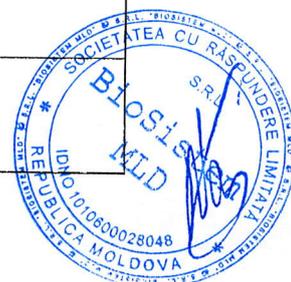
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Glucose Kit (GOD-POD Method)	/	/
Phosphorus Kit(Phosphomolybdate Method)	/	/
Calcium Kit(Arsenazo III Method)	/	/
Lipoprotein(a) Kit(Turbidimetry Method)	/	/
Complement C3 Kit(Turbidimetry Method)	/	/
Complement C4 Kit(Turbidimetry Method)	/	/
Immunoglobulin M Kit(Turbidimetry Method)	/	/
Immunoglobulin G Kit(Turbidimetry Method)	/	/
Prealbumin Kit(Turbidimetry Method)	/	/
Glucose Kit (HK Method)	/	/
Immunoglobulin A Kit(Turbidimetry Method)	/	/
Bilirubin Total Kit(VOX Method)	/	/
Creatine Kinase Kit(IFCC Method)	/	/
Total Bile Acids Kit(Enzymatic Cycling assay)	/	/
Creatinine Kit(Sarcosine Oxidase Method)	/	/
HDL-Cholesterol kit(Direct Method)	/	/
Bilirubin Direct Kit(VOX Method)	/	/
LDL-Cholesterol Kit(Direct Method)	/	/
Creatine Kinase-MB Kit(IFCC Method)	/	/



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HDL&LDL Cholesterol Control P	/	/
Prealbumin Control N&P	/	/
Lipids Calibrator	/	/
Specific Proteins Calibrator	/	/
Multi Sera Calibrator	/	/
CK-MB Calibrator	/	/
Lipoprotein(a) Calibrator	/	/
Multi Control Sera N Multi Control Sera P	/	/
Prealbumin Calibrator	/	/
Lipoprotein(a) Control N&P	/	/
Lipids Control N Lipids Control P	/	/
CK-MB Control N CK-MB Control p	/	/
Specific Proteins Control N Specific Proteins Control P	/	/
Cholinesterase(CHE) Kit (DGKC Method)	/	/
Carbon Dioxide (CO2) Kit (Enzymic Method)	/	/
Iron (Fe) Kit (Colorimetric Assay)	/	/
Fructosamine (FUN) Kit(Colorimetric Assay)	/	/
Antibodies Against Streptolysin O Kit(Particle-enhanced Immunoturbidimetric Assay Method	/	/
Homocysteine Kit(Enzymatic Assay Method)	/	/
Rheumatoid Factor Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/



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Lipase Kit(Enzymatic Colorimetric Assay Method)	/	/
Hemoglobin A1c Kit (Enzymatic Assay Method)	/	/
Unsaturated Iron Binding Capacity (UIBC) Kit (Colorimetric Method)	/	/
Microalbumin (MALB) Kit	/	/
Ferritin (FER) Kit	/	/
Transferrin (TRF) Kit	/	/
TRF Calibrator	/	/
TRF Control	/	/
FER Calibrator	/	/
Multimun Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
$\alpha$ -L-Fucosidase Kit (CNPf method)	/	/
5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/
Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
$\beta$ 2-Microglobulin Kit (Turbidimetry Method)	/	/
5'-NT Calibrator	/	/
5'-NT Control	/	/
ADA Control	/	/
ADA Calibrator	/	/
AFU Control	/	/
ASO Calibrator	/	/
CysC Calibrator	/	/



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CysC Control	/	/
HbA1c Calibrator	/	/
HCY Calibrator	/	/
HS-CRP Calibrator	/	/
RF Calibrator	/	/
TBA Control	/	/
β2-MG Calibrator	/	/
β2-MG Control	/	/
Free Triiodothyronine (CLIA)	/	/
Free Thyroxine (CLIA)	/	/
Total Triiodothyronine (CLIA)	/	/
Total Thyroxine (CLIA)	/	/
Thyroid-stimulating Hormone (CLIA)	/	/
Follicle Stimulating Hormone (CLIA)	/	/
Luteinizing Hormone (CLIA)	/	/
Prolactin (CLIA)	/	/
Estradiol (CLIA)	/	/
Estriol (CLIA)	/	/
Testosterone (CLIA)	/	/
Progesterone (CLIA)	/	/
Total β Human Chorionic Gonadotropin (CLIA)	/	/
Free T3 Calibrators	/	/
Free T4 Calibrators	/	/
Total T3 Calibrators	/	/
Total T4 Calibrators	/	/
TSH Calibrators	/	/
FSH Calibrators	/	/
LH Calibrators	/	/
Prolactin Calibrators	/	/
Estradiol Calibrators	/	/
Estriol Calibrators	/	/
Testosterone Calibrators	/	/
Progesterone Calibrators	/	/
Total β HCG Calibrators	/	/



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Thyroid Function Multi Control	/	/
Reproductive Multi Control	/	/
Carcinoembryonic Antigen (CLIA)	/	/
Alpha-fetoprotein (CLIA)	/	/
Cancer Antigen 125 (CLIA)	/	/
Cancer Antigen 15-3 (CLIA)	/	/
Carbohydrate Antigen 19-9 (CLIA)	/	/
CEA Calibrators	/	/
AFP Calibrators	/	/
CA125 Calibrators	/	/
CA15-3 Calibrators	/	/
CA19-9 Calibrators	/	/
Ferritin (CLIA)	/	/
Ferritin Calibrators	/	/
Wash Buffer	/	/
Substrate solution	/	/
Antistreptolysin "O" (ASO) Kit (Latex Immunoturbidimetric Method)	/	/
Antistreptolysin "O" Calibrator	/	/
ASO/CRP/RF triple Control	/	/
Cystatin C (CysC) Kit (Latex Immunoturbidimetric Method)	/	/
Cystatin C Calibrator	/	/
Cystatin C Control	/	/
Full Range C-Reactive Protein (FR-CRP) Kit(Latex Immunoturbidimetric Method)	/	/
C-reactive Protein Calibrator	/	/
Rheumatoid Factor (RF) Kit(Immunoturbidimetric Method)	/	/
Rheumatoid Factor Calibrator	/	/
$\beta$ 2-Microglobulin ( $\beta$ 2-MG) Kit (Latex Immunoturbidimetric Method)	/	/
$\beta$ 2-Microglobulin Control	/	/
$\beta$ 2-Microglobulin Calibrator (for Serum)	/	/
$\beta$ 2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/



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Retinol Binding Protein (RBP) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Glucose-6-Phosphate Dehydrogenase (G6PD) Kit (UV Enzymatic Method)	/	/
Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Immunoglobulin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
$\beta$ -Hydroxybutyrate ( $\beta$ -HB) Kit (Enzymatic Colorimetric Method)	/	/
High Sensitivity C-reaction Protein Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
HbA1c control N	/	/
HbA1c control P	/	/
Rheumatism Control N	/	/
Rheumatism Control P	/	/
HCY Control N	/	/
HCY Control P	/	/
FUN Control P	/	/
CO2 Control N	/	/
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/
MYO Calibrator	/	/
IgE Calibrator	/	/
$\beta$ -HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
$\beta$ -HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I (CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide (CLIA)	/	/
BNP Calibrators	/	/
Myoglobin (CLIA)	/	/
MYO Calibrators	/	/



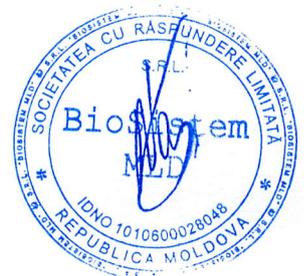
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Creatine kinase MB(CLIA)	/	/
CK-MB Calibrators	/	/
Thyroglobulin(CLIA)	/	/
Thyroglobulin Calibrators	/	/
Antibody to thyroglobulin(CLIA)	/	/
Anti-Tg Calibrators	/	/
Antibody to thyroid peroxidase(CLIA)	/	/
Anti-TPO Calibrators	/	/
Insulin(CLIA)	/	/
Insulin Calibrators	/	/
C-Peptide(CLIA)	/	/
C-Peptide Calibrators	/	/
Cortisol(CLIA)	/	/
Cortisol Calibrators	/	/
Dehydroepiandrosterone sulfate(CLIA)	/	/
DHEA-S Calibrators	/	/
Adrenocorticotropic hormone(CLIA)	/	/
ACTH Calibrators	/	/
Cardiac Marker Multi Control	/	/
Thyroid Function Multi Control	/	/
Immunoassay Multi Control	/	/
ACTH Control	/	/
Anti-thyroid Antibodies Control	/	/
System Detection Solution	/	/
System Wash Solution	/	/
ClinChem Multi Control (level 1)	/	/
ClinChem Multi Control (level 2)		
Sample Diluent	/	/
HCY Control	/	/
Homocysteine (HCY) Kit (Enzymatic Cycling Method)	/	/
Total Protein in Urine/CSF(TPUC) Kit (Pyrogallol Red-Molybdate Method)	/	/
TPUC Control	/	/
25-OH-Vitamin D Total (CLIA)	/	/



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25-OH-Vitamin D Total Calibrators	/	/
Parathyroid hormone (CLIA)	/	/
PTH Calibrators	/	/
Calcitonin (CLIA)	/	/
Calcitonin Calibrators	/	/
Folate(CLIA)	/	/
Folate Calibrators	/	/
Vitamin B12(CLIA)	/	/
Vitamin B12 Calibrators	/	/
Metabolic Multi Control	/	/
Red Blood Cell Folate Releasing Reagent	/	/
Cancer Antigen 72-4 (CLIA)	/	/
Neuron-specific enolase (CLIA)	/	/
CYFRA 21-1 (CLIA)	/	/
Antibody to Treponema pallidum (CLIA)	/	/
CA72-4 Calibrators	/	/
Cyfra21-1 Calibrators	/	/
Anti-TP Calibrators	/	/
NSE Calibrators	/	/
Tumor Marker Multi Control	/	/
NSE Control	/	/
Anti-TP Control	/	/



BioSystems

# Clinical analysis product list

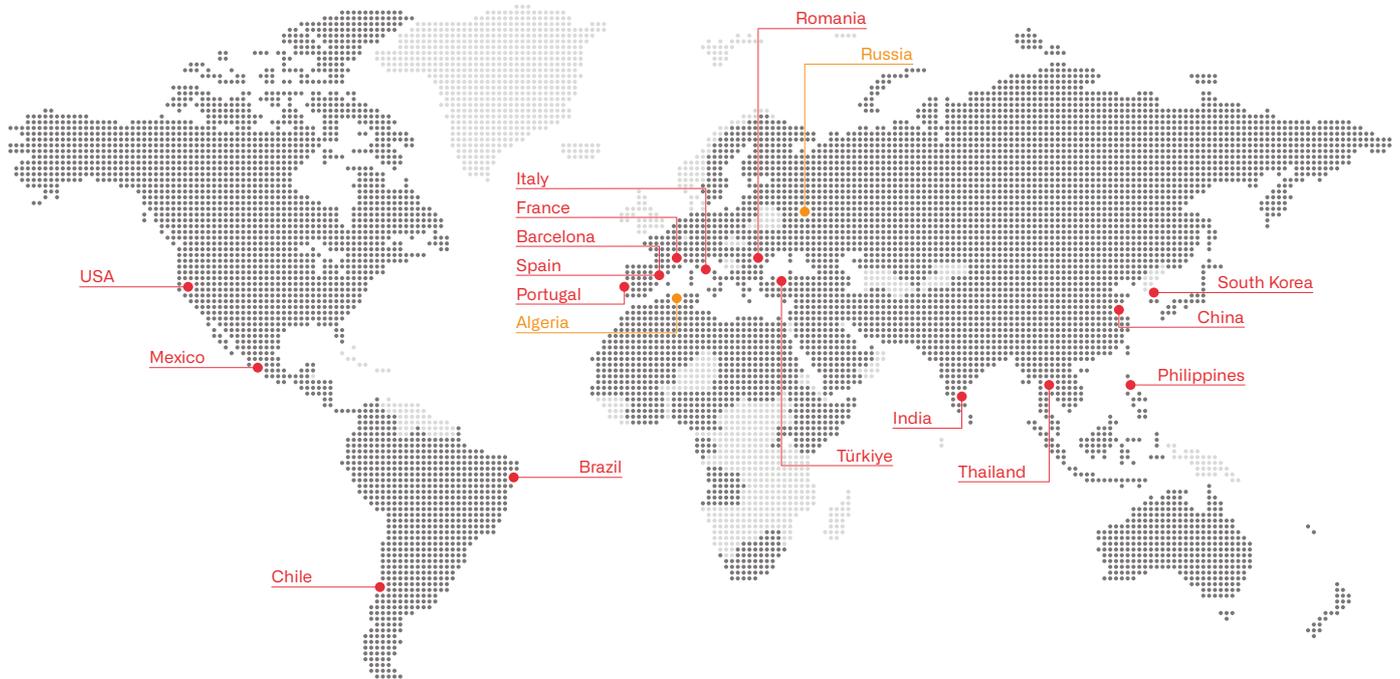
Clinical analysis

human - centred biotech



A global  
biotechnology  
company  
that develops  
analytical  
solutions in the  
way you need.

# +40 years offering quality products



Argentina  
Brazil  
Chile  
China  
France  
India  
Italy  
Korea  
Mexico  
Philippines  
Portugal  
Romania  
Russia  
Spain  
Thailand  
Türkiye  
USA

**+100** Markets with distributor partners

**25K** Users served

**+780** People in 17 countries

**02** Manufacturing sites

**45K** Analysers over 40 years

# Summary

## Analysers & devices

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BioSystems BTS	6
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Analysers  
& devices



# BioSystems BTS

Semi-Automatic Analyser  
with LED Technology

The new generation of photometer, created and co-developed together with users.

## Highlights

Optical LED Technology for the highest precision.

Accurate and reliable results with BioSystems reagents.

User-friendly and intuitive software interface.

Fully connectivity to PC (LIS) and smart devices (smartphones and tablets).

Very low maintenance; no lamp replacement and minimal energy consumption.

## Item

## Quantity

## Code

BTS analyser

1 unit

83000

Printer paper roll

5 rolls

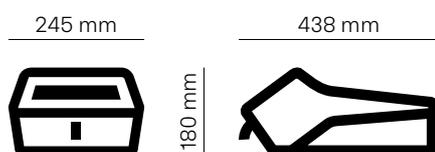
AC17433

Washing solution bottle

10 x 100 mL

AC10415

## Dimensions





01. CONCENTRATION TEST

02. ASSASSINANCE TEST

03. ANALYSIS WORK

04. TEST COMPARISON

05. HISTORICAL DATA

# BioSystems A15

## Automatic Random Access Analyser

A compact system with maximum robustness that adapts to your laboratory.

### Highlights

Optimal onboard capacity for refrigerated and non-refrigerated reagents.

Intuitive system with seamless connection to LIS.

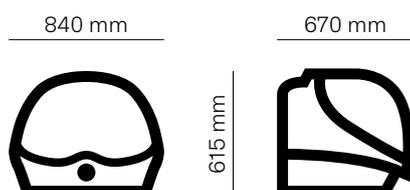
Open user configuration of test parameters.

Sustainable design with low water consumption.

Optimal reagent standardization for effective use of consumables.

Item	Quantity	Code
A15 analyser	-	83105
A15C analyser, with cooling system for 20 refrigerated reagents	-	83105C
Concentrated system liquid	1000 mL	BO11524
Concentrated washing solution	100 mL	BO13416
Reaction rotor	10 units	AC11485
Sample wells (pediatric cups)	1000 units	AC10770
Reagent bottles 50 mL + caps	10 units	BO11493
Amber reagent bottles 50 mL + caps	10 units	BO11494
Halogen lamp A15 6V/10W	5 units	LA10429
Silicon caps	100 units	AC17487
External barcode reader	1 unit	AC14681

### Dimensions





# BioSystems A15S

## Automatic Random Access Analyser – Fecal System

We make fecal analysis easier.

### Highlights

Integral system for fecal analysis avoiding contaminations with other sample types.

Dedicated software for specific fecal analysis.

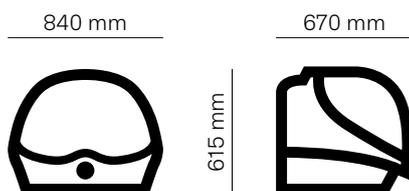
Same tube can be used for fecal occult blood and fecal calprotectin testing.

Liquid calibrators and controls ready to use.

Latex enhanced immunoturbidimetric reagents for fecal occult blood and fecal calprotectin detection in fecal samples.

Item	Quantity	Code
A15S analyser	-	83105S
Concentrated system liquid	1000 mL	BO11524
Concentrated washing solution	100 mL	BO13416
Reaction rotor	10 units	AC11485
Sample wells (pediatric cups)	1000 units	AC10770
Halogen lamp A15 6V/10W	5 units	LA10429
External barcode reader	1 unit	AC14681
Stool sample rack	1 unit	AC17738
Stool Probe	1 unit	AC17342

### Dimensions





**BioSystems**

FECAL OCCULT  
BLOOD (FOB)

LABORATORY ONLY  
LABORATORY ONLY  
LABORATORY ONLY  
08-31

LABORATORY ONLY  
LABORATORY ONLY  
LABORATORY ONLY  
08-31

LABORATORY ONLY  
LABORATORY ONLY  
LABORATORY ONLY  
08-31

# BioSystems A25

## Automatic Random Access Analyser

Increase your laboratory workload with a reliable system.

### Highlights

Optimal reagent standardization for effective use of consumables.

Intuitive system with seamless connection to LIS.

Open user configuration of test parameters.

Repetition with automatic pre-dilution and post-dilution possibilities.

Sustainable design with low water consumption.

Item	Quantity	Code
A25 analyser	-	83101-V2
Concentrated system liquid	1000 mL	BO11524
Concentrated washing solution	100 mL	BO13416
Reaction rotor	10 units	AC11485
Sample wells (pediatric cups)	1000 units	AC10770
Reagent bottles 50 mL + caps	10 units	BO11493
Reagent bottles 20 mL + caps	10 units	BO11494
Amber reagent bottles 50 mL + caps	10 units	BO13442
Halogen lamp A25 12V/20W	5 units	LA10418
Silicon caps	100 units	AC17487
External barcode reader	1 unit	AC14681

### Dimensions





# BioSystems BA200

## Full Automatic Random Access Analyser

Our main goal is to optimise the laboratory workflow and improve the user experience.

### Highlights

High reagent and sample capacity (88 positions), the highest grade in flexibility.

Barcoded dedicated reagents with highly accurate dispensing.

Reaction rotor washing station and continuous evaluation of cuvette status.

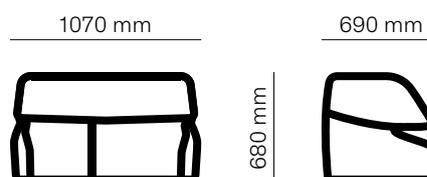
Dynamic Baseline with SMART LED Technology.

Compact system with low maintenance.

Item	Quantity	Code
BA200 analyser/BA200 analyser with ISE module*	-	83200/83200ISE
Wheeled table + computer support	1 unit	AC17346
Wheeled table	1 unit	AC17345
Reaction rotor	10 units	AC11485
Concentrated washing solution	500 mL	AC16434
Acid washing solution (WS1)	4 x 20 mL	AC17201
Alkaline washing solution (WS2)	4 x 15 mL	AC17205
Sample wells (pediatric cups)	1000 units	AC10770
Reagent bottles 60 mL + caps	10 units	AC16362
Reagent bottles 20 mL + caps	10 units	AC16363
Ambar reagent bottles 60 mL + caps	10 units	AC16364
Ambar reagent bottles 20 mL + caps	10 units	AC16365
Silicon caps	100 units	AC17487
<b>(ISE Module)</b>		
Sodium Electrode (Na <sup>+</sup> )	1 unit	5201
Potassium Electrode (K <sup>+</sup> )	1 unit	5202
Chloride Electrode (Cl <sup>-</sup> )	1 unit	5207
Reference Electrode	1 unit	5204
Lithium Electrode (Li <sup>+</sup> )	1 unit	5205
Spacer Electrode	1 unit	5206
Reagent pack Na <sup>+</sup> /K <sup>+</sup> /Cl <sup>-</sup> /Li <sup>+</sup>	1 unit	5420
Urine diluent 125 mL	125 mL	5412
Urine diluent 500 mL	500 mL	5408
ISE Cleaning solution Kit	1 unit	5421
Bi-level quality control kit (Na <sup>+</sup> /K <sup>+</sup> /Cl <sup>-</sup> /Li <sup>+</sup> )	1 unit	2814
Tri-level quality control kit (Na <sup>+</sup> /K <sup>+</sup> /Cl <sup>-</sup> /Li <sup>+</sup> )	1 unit	2815

\* Benchtop analyser, does not come with support.

### Dimensions





BioSystems  
BA200

# BioSystems BA400

## Full Automatic Random Access Analyser

We understand your needs. We guarantee maximum flexibility with maximum performance.

### Highlights

Automatic hemolysis on whole blood samples and fast sample loading.

The highest reagent and sample capacity, each with a specific rotor.

Reaction rotor washing station and continuous evaluation of cuvette status.

Dynamic Baseline with SMART LED Technology.

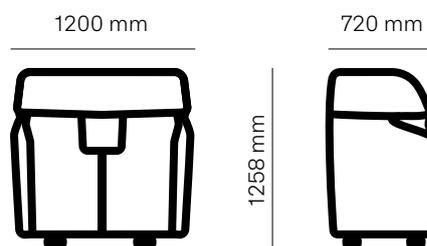
Minimum user maintenance.

Item	Quantity	Code
BA400 analyser*/ BA400 analyser with ISE module	-	83400/83400ISE
Extra segments for segmented samples rotor (pediatric adapters inc.)	3 units	AC17457
Reaction rotor	10 units	AC11485
Concentrated washing solution	500 mL	AC16434
Acid washing solution (WS1)	4 x 20 mL	AC17201
Alkaline washing solution (WS2)	4 x 15 mL	AC17205
High alkaline washing solution (WS3)**	2 x 60 mL	AC17800
Sample wells (pediatric cups)	1000 units	AC10770
Reagent bottles 60 mL + caps	10 units	AC16362
Reagent bottles 20 mL + caps	10 units	AC16363
Ambar reagent bottles 60 mL + caps	10 units	AC16364
Ambar reagent bottles 20 mL + caps	10 units	AC16365
Silicon caps	100 units	AC17487
<i>(ISE Module)</i>		
Sodium Electrode (Na <sup>+</sup> )	1 unit	5201
Potassium Electrode (K <sup>+</sup> )	1 unit	5202
Chloride Electrode (Cl <sup>-</sup> )	1 unit	5207
Reference Electrode	1 unit	5204
Lithium Electrode (Li <sup>+</sup> )	1 unit	5205
Spacer Electrode	1 unit	5206
Reagent pack Na <sup>+</sup> /K <sup>+</sup> /Cl <sup>-</sup> /Li <sup>+</sup>	1 unit	5420
Urine diluent 125 mL	125 mL	5412
Urine diluent 500 mL	500 mL	5408
ISE Cleaning solution Kit	1 unit	5421
Bi-level quality control kit (Na <sup>+</sup> /K <sup>+</sup> /Cl <sup>-</sup> /Li <sup>+</sup> )	1 unit	2814
Tri-level quality control kit (Na <sup>+</sup> /K <sup>+</sup> /Cl <sup>-</sup> /Li <sup>+</sup> )	1 unit	2815

\* FDA approved.

\*\* Check the need of use.

### Dimensions





BioSystems  
BA400

# BioSystems COAX

## Semi-Automated Coagulometer

The optimal complement  
to your to your laboratory routine.

### Highlights

Three models available: 1, 2 or 4 optical channels.

Ready for the daily routine and the upcoming requirements.

High quality results.

Fully open system.

Color touch screen display.

Item	Quantity	Code
COAX coagulometer 1 optic channel	-	85001
COAX coagulometer 2 optic channels	-	85002
COAX coagulometer 4 optic channels	-	85004
Cuvettes	500 units	85020

### Dimensions

115 mm

90 mm



225 mm





CDAX

BioSystems

99/20 11/20118  
Fill 00.00  
PT 00.25  
Optic  
Optic

REAGENT  
CALIBRATION TIME

# BioSystems iPRO

## Immunofluorescence Processor

Improved to work more and better in less space.

### Highlights

Adaptable racks to 3 sample tube types  
(13 mm x 75 mm, 15 mm x 100 mm or 2 mL).

Reagents reservoirs: 1 L washing solution bottle,  
3 L waste bottle, 3 L buffer bottle.

Needle with conductimetric level detector.

Slide washing flux system utilizing  
simultaneous dispensing and aspirating probes.

On-board automatic barcode and Data-matrix reader.

Item	Quantity	Code
iPRO processor	-	84101
PBS (10x)	100 mL	44592
PBS (10x)	500 units	44962
Concentrated washing solution	100 mL	BO13416
iPRO dilution tubes (1.1 mL)	120 strips	AC14682

### Dimensions





Years of experience developing our own  
fluorescence module

### Highlights

Optical system infinity-corrected plan objectives (10x/0.25, 20x/0.40, 40x/0.65 and 100x/1.25).

High power blue LED fluorescence light (470-480 nm).

Automatic light switch-off thanks to the iCare function.

High speed camera: with sCMOS Sony sensor and high speed USB 3.0 connection.

Intuitive and user-friendly software.

### Item

imLD (optical microscope, fluorescence module, trinocular head)

Trinocular head

Digital camera

Fluorescence module

10x/0.25 objective

20x/0.40 objective

40x/0.65 objective

100x/1.25 objective\*

### Code

84201

AC17455

AC17454

AC17462

AC17540

AC17541

AC17542

AC17543

\* This item is not included in the 84201 code and should be order separately.

### Dimensions

220 mm

400 mm



610 mm







# Reagents



# Benefits of our reagents

## **Optimize your workflow**

---

Enhance efficiency and streamline your workflow. With multiple presentations and volumes available, our ready-to-use reagents easily adapt to your needs. Enjoy the convenience of extended shelf life (up to 36 months) and high on-board stability, allowing you to optimize your processes and save valuable time.

## **Reduce risks, ensure results**

---

For our user's convenience, our reagents are automated to our systems, which means that are easy to handle. All our assays are also validated according to reference methods and using different sample types, offering excellent accuracy and more reliable patient results.

## **Systemic solutions**

---

We seek to offer a complete solution to our users. By using our reagents together with our analysers and processors, optimal results are guaranteed. Standards and controls traceable to reference materials are available for all Clinical Biochemistry tests and most Autoimmune tests.

## **Get advice and support**

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We offer additional material as brochures, scientific articles, technical sheets, and technical support for all our reagents. Improve the patient care with all the help and advice tools provided by BioSystems.

## **Expand your biochemistry special tests panel**

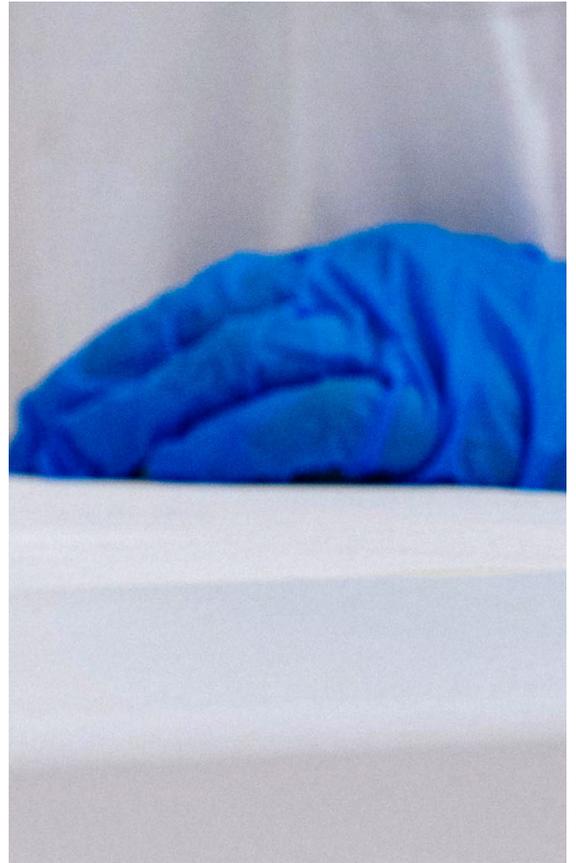
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Our large special tests panel allows the evaluation of very specific parameters which, by their nature, are useful to the clinical specialist for differential diagnosis or monitoring of various uncommon pathological conditions. Find the whole panel inside.

## **Facilities and assistance through the process**

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Ease your diagnostic routine with our complete portfolio of products and the automation system that matches your needs. Altogether, it allows you to perform the diagnosis of the most prevalent and relevant diseases.



Biochemistry  
reagents



# Tests sorted by panels



## Anemia

Ferritin  
 Glucose-6-Phosphate Dehydrogenase  
 Haptoglobin  
 Iron  
 Lactate Dehydrogenase (LDH)  
 Total Iron Binding Capacity (TIBC)  
 Transferrin  
 Unsaturated Iron Binding Capacity (UIBC)



## Cardiac

Albumin (Microalbuminuria)  
 Apolipoprotein A-1 (APO A-1)  
 Apolipoprotein B (APO B)  
 Cholesterol  
 Cholesterol LDL  
 Cholesterol HDL  
 C-Reactive Protein hs (CRP-hs)  
 Creatine Kinase (CK)  
 Creatine Kinase-MB (CK-MB)  
 Homocysteine  
 Lactate  
 Lactate Dehydrogenase (LDH)  
 Non-Esterified Fatty Acids (NEFA)  
 Triglycerides



## Diabetes

Albumin (Microalbuminuria)  
 $\beta$ -Hydroxybutyrate  
 Fructosamine  
 Glucose  
 Glucose-hexokinase  
 Hemoglobin A1C-Direct (HbA1C-DIR)



## Fertility

Citrate  
 Fructose  
 Zinc  
 $\alpha$ -Glucosidase



## Gastric

Fecal Calprotectin (FCAL)  
 Fecal Occult Blood (FOB)



## Hemostasis

D-Dimer  
 Fibrinogen  
 Haptoglobin



## Immune

Adenosine Deaminase (ADA)  
 $\beta$ 2-Microglobulin  
 Complement Component C3  
 Complement Component C4  
 Immunoglobulin A (IgA)  
 Immunoglobulin G (IgG)  
 Immunoglobulin M (IgM)



## Infectious

Adenosine Deaminase (ADA)  
 Angiotensin Converting Enzyme (ACE)  
 Anti-Streptolysin O (ASO)  
 Zinc



## Inflammatory

$\alpha$ 1-Acid Glycoprotein  
 Acid Phosphatase (ACP)  
 Anti-Streptolysin O (ASO)  
 C-Reactive Protein (CRP)  
 C-Reactive Protein-hs (CRP-hs)  
 C-Reactive Protein-er (CRP-er)  
 Rheumatoid Factors (RF)



## Ions

Ammonia  
 Calcium  
 Carbon Dioxide (CO<sub>2</sub>)  
 Copper  
 Iron  
 Magnesium  
 Phosphorus



## Lipid

Apolipoprotein A-1 (APO A-1)  
 Apolipoprotein B (APO B)  
 Cholesterol  
 Cholesterol LDL  
 Cholesterol HDL  
 Non-Esterified Fatty Acids (NEFA)  
 Triglycerides



## Liver

Alanine Aminotransferase (ALT/GPT)  
 Albumin  
 Alkaline Phosphatase  
 Ammonia  
 Aspartate Aminotransferase (AST/GOT)  
 Bilirubin (Direct)  
 Bilirubin (Total)  
 Ceruloplasmin  
 Cholinesterase (CHE)  
 Ethanol  
 $\gamma$ -Glutamyl Transferase ( $\gamma$ -GT)  
 Lactate Dehydrogenase (LDH)  
 Prealbumin  
 Protein (Total)  
 Total Bile Acids



## Pancreatic

$\alpha$ -Amylase  
 $\alpha$ -Amylase Pancreatic  
 Glucose  
 Glucose-hexokinase  
 Lipase



## Renal

Albumin (Microalbuminuria)  
 Ammonia  
 Citrate  
 Creatinine  
 Magnesium  
 Oxalate  
 Phosphorus  
 Protein (Urine+CSF)  
 Urea/BUN  
 Uric Acid

# Tests sorted alphabetically

Test	Code	RA	RB	mL/Kit	Comment
<b>α1-ACID GLYCOPROTEIN</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31928	1 x 50 mL	-	50	
BA Automated System	23107	1 x 60 mL	1 x 15 mL	75	
<b>α-AMYLASE DIRECT</b>					
<i>Direct Substrate</i>					
Manual	11583	5 x 5 mL	-	25	
	11550	6 x 25 mL	-	150	
A15/A25 Automated System	12550	5 x 20 mL	-	100	
BA Automated System	21550	8 x 20 mL	-	160	
	23550	4 x 20 mL	-	80	
<b>α-AMYLASE-EPS</b>					
<i>IFCC</i>					
Manual	11534	1 x 32 mL	1 x 8 mL	40	WR
A15/A25 Automated System	12535	1 x 32 mL	1 x 8 mL	40	WR
BA Automated System	21534	2 x 60 mL	2 x 15 mL	150	
<b>α-AMYLASE PANCREATIC</b>					
<i>Immunoinhibition</i>					
Manual	11799	1 x 20 mL	1 x 5 mL	25	
A15/A25 Automated System	12799	1 x 40 mL	1 x 10 mL	50	
BA Automated System	21799	2 x 60 mL	2 x 15 mL	150	
<b>α-GLUCOSIDASE</b>					
<i>Glucose oxidase/Peroxidase</i>					
A15/A25 Automated System	12522	2 x 20 mL	2 x 5 mL	50	Std Inc
BA Automated System	21522	2 x 20 mL	2 x 5 mL	50	Std Inc
<b>ACID PHOSPHATASE (ACP)</b>					
<i>Naphtyl phosphate/Pentanediol</i>					
Manual (Total + Non prostatic)	11548	4x10 mL	lyophilised	40	WR
<b>ADENOSINE DEAMINASE (ADA)</b>					
<i>Adenosine-Glutamate Dehydrogenase</i>					
Manual / A15/A25 Automated System	12754	4 x 8 mL	1 x 10 mL	40	WR
BA Automated System	23754	2 x 16 mL	1 x 10 mL	40	WR
<b>ALANINE AMINOTRANSFERASE (ALT/GPT)</b>					
<i>IFCC</i>					
Manual	11832	1 x 40 mL	1 x 10 mL	50	WR
	11533	1 x 160 mL	1 x 40 mL	200	WR
	11568	1 x 400 mL	1 x 100 mL	500	WR
	11562	1 x 800 mL	1 x 200 mL	1000	WR
A15/A25 Automated System	12533	5 x 40 mL	5 x 10 mL	250	WR
BA Automated System	21533	8 x 60 mL	8 x 15 mL	600	
	23533	4 x 60 mL	4 x 15 mL	300	
Pyridoxal Phosphate (ALT)	11667	1 x 5 mL			
<b>ALBUMIN</b>					
<i>Bromocresol Green</i>					
Manual	11573	1 x 250 mL	-	250	Std Inc
	11547	2 x 250 mL	-	500	Std Inc
A15/A25 Automated System	12547	5 x 50 mL	-	250	
BA Automated System	21547	10 x 60 mL	-	600	
	23547	4 x 60 mL	-	240	

In **bold italics**: methods | **WR**: Working Reagent | **RA**: Reagent A Preparation | **RB**: Reagent B Preparation | **Std Inc**: Standard Included

Test	Code	RA	RB	mL/Kit	Comment
<b>ALBUMIN (MICROALBUMINURIA)</b>					
<i>Immunoturbidimetric latex assay</i>					
Manual	31324	1 x 16 mL	1 x 4 mL	20	WR
	31924	1 x 40 mL	1 x 10 mL	50	WR
A15/A25 Automated System	13324	1 x 40 mL	1 x 10 mL	50	WR
BA Automated System	22324	4 x 60 mL	4 x 15 mL	300	
	23324	1 x 60 mL	1 x 15 mL	75	
<b>ALKALINE PHOSPHATASE (ALP)-AMP</b>					
<i>AMP Buffer (IFCC)</i>					
Manual	11592	1 x 40 mL	1 x 10 mL	50	WR
	11593	1 x 160 mL	1 x 40 mL	200	WR
	11598	4 x 100 mL	2 x 50 mL	500	WR
A15/A25 Automated System	12518	5 x 16 mL	2 x 10 mL	100	WR
BA Automated System	21592	4 x 60 mL	4 x 15 mL	300	
	23592	1 x 60 mL	1 x 15 mL	75	
<b>ALKALINE PHOSPHATASE (ALP)-DEA</b>					
<i>Diethanolamine Buffer</i>					
Manual	11590	1 x 40 mL	1 x 10 mL	50	WR
	11591	4 x 40 mL	4 x 10 mL	200	WR
	11597	4 x 100 mL	2 x 50 mL	500	WR
A15/A25 Automated System	12514	5 x 16 mL	2 x 10 mL	100	WR
BA Automated System	21590	4 x 60 mL	4 x 15 mL	300	
	23590	1 x 60 mL	1 x 15 mL	75	
<b>AMMONIA</b>					
<i>Glutamate Dehydrogenase</i>					
Manual / A15/A25 Automated System	12532	1 x 20 mL	1 x 7 mL	27	RA
BA Automated System	23532	1 x 20 mL	1 x 7 mL	27	RA
<b>ANGIOTENSIN CONVERTING ENZYME (ACE)</b>					
<i>FAPGG</i>					
Manual / A15/A25 Automated System	12796	1 x 50 mL	-	50	
BA Automated System	21796	2 x 60 mL	-	120	
<b>ANTI-STREPTOLYSIN O (ASO)</b>					
<i>Immunoturbidimetric latex assay</i>					
Manual	31323	1 x 16 mL	1 x 4 mL	20	WR
	31923	1 x 40 mL	1 x 10 mL	50	WR
	31031	2 x 160 mL	2 x 40 mL	400	WR
A15/A25 Automated System	13923	1 x 40 mL	1 x 10 mL	50	WR
BA Automated System	22923	2 x 60 mL	2 x 15 mL	150	
	23923	1 x 60 mL	1 x 15 mL	75	
<b>APOLIPOPROTEIN A-1 (APO A-1)</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31095	1 x 40 mL	1 x 10 mL	50	
BA Automated System	23095	1 x 60 mL	1 x 15 mL	75	
<b>APOLIPOPROTEIN B (APO B)</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31098	1 x 40 mL	1 x 10 mL	50	
BA Automated System	23098	1 x 60 mL	1 x 15 mL	75	

Test	Code	RA	RB	mL/Kit	Comment
<b>ASPARTATE AMINOTRANSFERASE (AST/GOT)</b>					
<i>IFCC</i>					
Manual	11830	1 x 40 mL	1 x 10 mL	50	WR
	11531	1 x 160 mL	1 x 40 mL	200	WR
	11567	1 x 400 mL	1 x 100 mL	500	WR
	11561	1 x 800 mL	1 x 200 mL	1000	WR
A15/A25 Automated System	12531	5 x 40 mL	5 x 10 mL	250	WR
BA Automated System	21531	8 x 60 mL	8 x 15 mL	600	
	23531	4 x 60 mL	4 x 15 mL	300	
Pyridoxal Phosphate (AST)	11666	1 x 5 mL			
<b>β-HYDROXYBUTYRATE</b>					
<i>Hydroxybutyrate Dehydrogenase/Diaphorase</i>					
Manual / A15/A25 Automated System	12525	1 x 40 mL	1 x 10 mL	50	
BA Automated System	21525	1 x 60 mL	1 x 15 mL	75	
<b>β2-MICROGLOBULIN</b>					
<i>Immunoturbidimetric latex assay</i>					
Manual	31920	1 x 800 mL	1 x 200 mL	1000	WR
	31925	1 x 40 mL	1 x 10 mL	50	WR
BA Automated System	23925	1 x 60 mL	1 x 15 mL	75	
<b>BILIRUBIN (DIRECT)</b>					
<i>Diazotized Sulfanilic</i>					
Manual	11511	4 x 40 mL	4 x 10 mL	200	WR
	11545	2 x 400 mL	2 x 100 mL	1000	WR
<b>BILIRUBIN (DIRECT) DPD</b>					
<i>Dichlorophenyl Diazonium</i>					
A15/A25 Automated System	12504	5 x 40 mL	5 x 10 mL	250	
BA Automated System	21504	4 x 60 mL	4 x 15 mL	300	
	23504	1 x 60 mL	1 x 15 mL	75	
<b>BILIRUBIN (TOTAL)</b>					
<i>Diazotized Sulfanilic</i>					
Manual	11510	4 x 40 mL	4 x 10 mL	200	WR
	11544	2 x 400 mL	2 x 100 mL	1000	WR
<b>BILIRUBIN (TOTAL) DPD</b>					
<i>Dichlorophenyl Diazonium</i>					
A15/A25 Automated System	12506	5 x 40 mL	5 x 10 mL	250	
BA Automated System	21506	8 x 60 mL	8 x 15 mL	600	
	23506	4 x 60 mL	4 x 15 mL	300	
<b>BILIRUBIN (TOTAL AND DIRECT)</b>					
<i>Diazotized Sulfanilic</i>					
Manual	11515	2 x 50 mL	2 x 50 mL	200	WR
	11555	1 x 500 mL	1 x 500 mL	1000	WR
<b>CALCIUM-ARSENAZO</b>					
<i>Arsenazo III</i>					
Manual	11570	1 x 200 mL	-	200	Std Inc
	11571	1 x 500 mL	-	500	Std Inc
A15/A25 Automated System	12570	10 x 50 mL	-	500	
BA Automated System	21570	10 x 60 mL	-	600	
	23570	4 x 60 mL	-	240	

Test	Code	RA	RB	mL/Kit	Comment
<b>CALCIUM-CRESOLPHTHALEIN</b>					
<i>O-Cresolphthalein Complexone</i>					
Manual	11811	1 x 160 mL	1 x 40 mL	200	Std Inc, WR
	11812	1 x 400 mL	2 x 50 mL	500	Std Inc, WR
A15/A25 Automated System	12513	5 x 40 mL	5 x 10 mL	250	
BA Automated System	21511	8 x 60 mL	8 x 15 mL	600	
	23511	2 x 60 mL	2 x 15 mL	150	
<b>CALCIUM-MTB</b>					
<i>Methylthymol Blue</i>					
Manual	11527	2 x 50 mL	2 x 50 mL	200	Std Inc, WR
	11507	1 x 250 mL	1 x 250 mL	500	Std Inc, WR
<b>CARBON DIOXIDE (CO<sub>2</sub>)</b>					
<i>Phosphoenolpyruvate Carboxylase/Malate Dehydrogenase</i>					
Manual / A15/A25 Automated System	11558	1 x 50 mL	-	50	
BA Automated System	21558	2 x 60 mL	-	120	
<b>CERULOPLASMIN</b>					
<i>Turbidimetry</i>					
A15/A25 Automated System	13340	1 x 40mL	1 x 10mL	50	
BA Automated System	22340	1 x 40mL	1 x 10mL	50	
<b>CHOLESTEROL</b>					
<i>Cholesterol Oxidase/Peroxidase</i>					
Manual	11805	1 x 50 mL	-	50	Std Inc
	11505	1 x 200 mL	-	200	Std Inc
	11506	1 x 500 mL	-	500	Std Inc
	11539	1 x 1000 mL	-	1000	Std Inc
A15/A25 Automated System	12505	10 x 50 mL	-	500	
BA Automated System	21505	10 x 60 mL	-	600	
	23505	4 x 60 mL	-	240	
<b>CHOLESTEROL HDL</b>					
<i>Phosphotungstate/ Mg<sup>2+</sup>-Cholesterol Oxidase/Peroxidase</i>					
Manual	11523	2 x 50 mL	2 x 50 mL	200	Std Inc
<b>CHOLESTEROL HDL DIRECT</b>					
<i>TOOS</i>					
Manual	11757	1x60mL	1x20mL	80	
A15/A25 Automated System	12757	3x20mL	1x20mL	80	
BA Automated System	21594	4x60mL	4x20mL	320	
	23594	1x60mL	1x20mL	80	
<b>CHOLESTEROL HDL PRECIPITATING REAGENT</b>					
<i>Phosphotungstate/ Mg<sup>2+</sup></i>					
Manual	11648	1 x 50 mL	-	50	Std Inc
<b>CHOLESTEROL LDL DIRECT</b>					
<i>TOOS</i>					
Manual	11785	1x60mL	1x20mL	80	
A15/A25 Automated System	12785	3x20mL	1x20mL	80	
BA Automated System	21785	2x60mL	2x20mL	160	
	23785	1x60mL	1x20mL	80	
<b>CHOLESTEROL LDL PRECIPITATING REAGENT</b>					
<i>Polyvinyl Sulphate/ Polyethyleneglycol</i>					
Manual	11579	1 x 20 mL	-	20	

Test	Code	RA	RB	mL/Kit	Comment
<b>CHOLINESTERASE (CHE)</b>					
<i>Butyrylthiocholine</i>					
Manual	11588	1 x 40 mL	1 x 10 mL	50	WR
	11589	4 x 40 mL	4 x 10 mL	200	WR
A15/A25 Automated System	12588	1 x 40 mL	1 x 10 mL	50	WR
BA Automated System	21588	2 x 60 mL	2 x 15 mL	150	
<b>CITRATE</b>					
<i>Citrate Lyase/ Malate Dehydrogenase</i>					
Manual / A15/A25 Automated System	11895	1 x 20 mL	1 x 5 mL	25	RB + Std Inc
	11795	2 x 20 mL	2 x 5 mL	50	RB + Std Inc
BA Automated System	23795	2 x 20 mL	2 x 5 mL	50	RB + Std Inc
<b>COMPLEMENT COMPONENT C3</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31084	1 x 20 mL	-	20	
	31073	1 x 50 mL	-	50	
	31079	1 x 250 mL	-	250	
A15/A25 Automated System	13084	1 x 50 mL	-	50	
BA Automated System	23103	1 x 60 mL	1 x 15 mL	75	
<b>COMPLEMENT COMPONENT C4</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31085	1 x 20 mL	-	20	
	31074	1 x 50 mL	-	50	
	31080	1 x 250 mL	-	250	
A15/A25 Automated System	13085	1 x 50 mL	-	50	
BA Automated System	23104	1 x 60 mL	1 x 15 mL	75	
<b>COPPER - PAESA</b>					
<i>3,5-DiBr-PAESA</i>					
Manual	11837	1 x 40 mL	1 x 10 mL	50	RA + Std Inc
<b>C-REACTIVE PROTEIN (CRP)</b>					
<i>Immunoturbidimetric latex assay</i>					
Manual	31321	1 x 16 mL	1 x 4 mL	20	WR
	31921	1 x 40 mL	1 x 10 mL	50	WR
	31029	2 x 160 mL	2 x 40 mL	400	WR
A15/A25 Automated System	13921	2 x 40 mL	2 x 10 mL	100	WR
BA Automated System	22921	4 x 60 mL	4 x 15 mL	300	
	23921	1 x 60 mL	1 x 15 mL	75	
<b>C-REACTIVE PROTEIN hs (CRP-hs)</b>					
<i>Immunoturbidimetric latex assay, High Sensitivity</i>					
Manual	31927	1 x 40 mL	1 x 10 mL	50	WR
A15/A25 Automated System	13927	1 x 40 mL	1 x 10 mL	50	WR
BA Automated System	22927	2 x 60 mL	2 x 15 mL	150	
	23927	1 x 60 mL	1 x 15 mL	75	
<b>C-REACTIVE PROTEIN-er (CRP-er)</b>					
<i>Immunoturbidimetric latex assay, Extended Range</i>					
BA Automated System	22942	2 x 60 mL	2 x 15 mL	150	
	23942	1 x 60 mL	1 x 15 mL	75	

Test	Code	RA	RB	mL/Kit	Comment
<b>CREATINE KINASE (CK)</b>					
<i>IFCC</i>					
Manual	11790	1 x 40 mL	1 x 10 mL	50	WR
	11791	4 x 40 mL	4 x 10 mL	200	WR
A15/A25 Automated System	12524	3 x 12 mL	1 x 10 mL	45	WR
BA Automated System	21790	2 x 60 mL	2 x 15 mL	150	
	23790	1 x 60 mL	1 x 15 mL	75	
<b>CREATINE KINASE-MB (CK-MB)</b>					
<i>Immunoinhibition</i>					
Manual	11792	1 x 40 mL	1 x 10 mL	50	WR
A15/A25 Automated System	12566	3 x 12 mL	1 x 10 mL	45	WR
BA Automated System	21792	2 x 60 mL	2 x 15 mL	150	
	23792	1 x 60 mL	1 x 15 mL	75	
<b>CREATININE</b>					
<i>Jaffé-compensated</i>					
Manual	11802	1 x 50 mL	1 x 50 mL	100	Std Inc, WR
	11502	2 x 50 mL	2 x 50 mL	200	Std Inc, WR
	11542	1 x 500 mL	1 x 500 mL	1000	Std Inc, WR
A15/A25 Automated System	12502	5 x 50 mL	5 x 50 mL	500	WR
BA Automated System	21502	5 x 60 mL	5 x 60 mL	600	
	23502	5 x 20 mL	5 x 20 mL	200	
<b>CREATININE ENZYMATIC</b>					
<i>Enzymatic</i>					
Manual	11734	1 x 60 mL	1 x 20 mL	80	Std Inc
A15/A25 Automated System	12734	1 x 45 mL	1 x 15 mL	60	
BA Automated System	21734	2 x 60 mL	2 x 20 mL	160	
<b>D-DIMER (DD)</b>					
<i>Immunoturbidimetric latex assay</i>					
Manual / A15/A25 Automated System	13519	1 x 20 mL	1 x 10 mL	30	
BA Automated System	21519	1 x 20 mL	1 x 10 mL	30	
<b>ETHANOL</b>					
<i>Alcohol Dehydrogenase</i>					
Manual / A15/A25 Automated System	12789	1 x 20 mL	1 x 7 mL	27	
BA Automated System	21789	2 x 20 mL	2 x 7 mL	54	
<b>FECAL CALPROTECTIN (FCAL)</b>					
<i>Turbidimetry</i>					
A15S Automated System	12330	1 x 40 mL	1 x 10 mL	50	Reagent C included (1 x 10 mL)
STOOL Collection Tube	31329	-	-	50 tubes	
<b>FECAL OCCULT BLOOD (FOB)</b>					
<i>Turbidimetry</i>					
A15S Automated System	12325	1 x 40 mL	1 x 10 mL	50	Reagent C included (1 x 10 mL)
STOOL Collection Tube	31329	-	-	50 tubes	

Test	Code	RA	RB	mL/Kit	Comment
<b>FERRITIN</b>					
<i>Immunoturbidimetric latex assay</i>					
Manual	31934	1 x 10 mL	1 x 5 mL	15	WR
	31935	1 x 30 mL	1 x 15 mL	45	WR
A15/A25 Automated System	13934	1 x 30 mL	1 x 15 mL	45	WR
BA Automated System	22934	2 x 40 mL	2 x 20 mL	120	
	23934	1 x 40 mL	1 x 20 mL	60	
<b>FIBRINOGEN</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31600	1 x 40 mL	1 x 10 mL	50	
A15/A25 Automated System	13600	1 x 40 mL	1 x 10 mL	50	
BA Automated System	23804	1 x 60 mL	1 x 15 mL	75	
<b>FRUCTOSAMINE</b>					
<i>NBT</i>					
Manual	11046	2 x 50 mL	-	100	Std Inc
<b>FRUCTOSE</b>					
<i>Hexokinase/ Phosphoglucose Isomerase</i>					
Manual / A15/A25 Automated System	11794	1 x 40 mL	1 x 10 mL	50	Std Inc, WR
BA Automated System	23794	1 x 60 mL	1 x 15 mL	75	Std Inc
<b>γ-GLUTAMYL TRANSFERASE (γ-GT)</b>					
<i>IFCC</i>					
Manual	11584	1 x 40 mL	1 x 10 mL	50	WR
	11520	1 x 160 mL	1 x 40 mL	200	WR
A15/A25 Automated System	12520	5 x 40 mL	5 x 10 mL	250	WR
BA Automated System	21520	4 x 60 mL	4 x 15 mL	300	
	23520	2 x 60 mL	2 x 15 mL	150	
<b>GLUCOSE</b>					
<i>Glucose Oxidase/ Peroxidase</i>					
Manual	11803	1 x 50 mL	-	50	Std Inc
	11503	1 x 200 mL	-	200	Std Inc
	11504	1 x 500 mL	-	500	Std Inc
	11538	1 x 1000 mL	-	1000	Std Inc
A15/A25 Automated System	12503	10 x 50 mL	-	500	
BA Automated System	21503	10 x 60 mL	-	600	
	23503	4 x 60 mL	-	240	
<b>GLUCOSE-6-PHOSPHATE DEHYDROGENASE</b>					
<i>Glucose-6-Phosphate</i>					
Manual / A15/A25 Automated System	12603	1 x 40 mL	1 x 10 mL	50	Std Inc
BA Automated System	21603	1 x 60 mL	1 x 15 mL	75	Std Inc
<b>GLUCOSE-HEXOKINASE</b>					
<i>Hexokinase</i>					
Manual	11656	1 x 160 mL	1 x 40 mL	200	Std Inc, WR
A15/A25 Automated System	12756	2 x 40 mL	2 x 10 mL	100	
BA Automated System	21656	4 x 60 mL	4 x 15 mL	300	
	23656	1 x 60 mL	1 x 15 mL	75	
<b>HAPTOGLOBIN</b>					
<i>Immunoturbidimetric assay</i>					
Manual / A15/A25 Automated System	13218	1 x 40 mL	1 x 10 mL	50	
BA Automated System	23218	1 x 40 mL	1 x 10 mL	50	

Test	Code	RA	RB	mL/Kit	Comment
<b>HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)</b>					
<i>Immunoturbidimetric latex assay</i>					
Manual	31047	1 x 50 mL	1 x 10 mL	60	
A15/A25 Automated System	13047	1 x 50 mL	1 x 10 mL	60	
BA Automated System	22047	2 x 60 mL	2 x 12 mL	144	
	22147	1 x 60 mL	1 x 12 mL	72	
<b>HOMOCYSTEINE</b>					
<i>Enzymatic Cycling</i>					
A15/A25 Automated System	12737	1 x 40 mL	1 x 10.8 mL	50.8	
BA Automated System	23737	1 x 20 mL	1 x 5.4 mL	25.4	
<b>IMMUNOGLOBULIN A (IgA)</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31082	1 x 20 mL	-	20	
	31071	1 x 50 mL	-	50	
	31077	1 x 250 mL	-	250	
A15/A25 Automated System	13082	1 x 50 mL	-	50	
BA Automated System	23101	1 x 60 mL	1 x 15 mL	75	
<b>IMMUNOGLOBULIN G (IgG)</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31081	1 x 20 mL	-	20	
	31070	1 x 50 mL	-	50	
	31076	1 x 250 mL	-	250	
A15/A25 Automated System	13081	1 x 50 mL	-	50	
BA Automated System	23100	1 x 60 mL	1 x 15 mL	75	
<b>IMMUNOGLOBULIN M (IgM)</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31083	1 x 20 mL	-	20	
	31072	1 x 50 mL	-	50	
	31078	1 x 250 mL	-	250	
A15/A25 Automated System	13083	1 x 50 mL	-	50	
BA Automated System	23102	1 x 60 mL	1 x 15 mL	75	
<b>IRON-CHROMAZUROL</b>					
<i>Chromazurol B</i>					
Manual	11546	4 x 50 mL	-	200	Std Inc
<b>IRON-FERROZINE</b>					
<i>Ferrozine</i>					
Manual	11509	4 x 40 mL	4 x 10 mL	200	Std Inc, WR
A15/A25 Automated System	12509	5 x 40 mL	5 x 10 mL	250	
BA Automated System	21509	4 x 60 mL	4 x 15 mL	300	
	23509	2 x 60 mL	2 x 15 mL	150	
<b>LACTATE</b>					
<i>Lactate Oxidase/ Peroxidase</i>					
Manual	11736	1 x 40 mL	1 x 10 mL	50	WR
A15/A25 Automated System	12736	2 x 40 mL	2 x 10 mL	100	
BA Automated System	21736	4 x 60 mL	4 x 15 mL	300	
	23736	1 x 60 mL	1 x 15 mL	75	

Test	Code	RA	RB	mL/Kit	Comment
<b>LACTATE DEHYDROGENASE (LDH)</b>					
<i>Pyruvate</i>					
Manual	11580	1 x 40 mL	1 x 10 mL	50	WR
	11581	1 x 160 mL	1 x 40 mL	200	WR
A15/A25 Automated System	12580	5 x 40 mL	5 x 10 mL	250	WR
BA Automated System	21580	8 x 60 mL	8 x 15 mL	600	
	23580	4 x 60 mL	4 x 15 mL	300	
<b>LACTATE DEHYDROGENASE (LDH)-IFCC</b>					
<i>IFCC</i>					
Manual/ A15/A25 Automated System	11587	1 x 160 mL	1 x 40 mL	200	WR (Manual)
	11586	1 x 40 mL	1 x 10 mL	50	WR
BA Automated System	21586	8 x 60 mL	8 x 15 mL	600	
	23586	2 x 60 mL	2 x 15 mL	150	
<b>LIPASE</b>					
<i>DGGR</i>					
Manual	11760	1 x 20 mL	1 x 10 mL	30	Std Inc
A15/A25 Automated System	12760	1 x 20 mL	1 x 10 mL	30	
BA Automated System	21760	1 x 20 mL	1 x 10 mL	30	
<b>MAGNESIUM</b>					
<i>Xylidyl Blue</i>					
Manual	11797	4 x 40 mL	4 x 10 mL	200	Std Inc, WR
A15/A25 Automated System	12797	5 x 16 mL	2 x 10 mL	100	WR
BA Automated System	21797	2 x 60 mL	2 x 15 mL	150	
	23797	1 x 60 mL	1 x 15 mL	75	
<b>NON-ESTERIFIED FATTY ACIDS (NEFA)</b>					
<i>Acyl-CoA Oxidase/Peroxidase</i>					
A15/A25 Automated System	12540	2 x 20 mL	2 x 7 mL	54	RA, RB
BA Automated System	21840	2 x 20 mL	2 x 7 mL	54	RA, RB
<b>OXALATE</b>					
<i>Oxalate Oxidase/Peroxidase</i>					
Manual / A15/A25 Automated System	12539	1 x 20 mL	1 x 5 mL	1 x 25 mL R1 + 20 tubes (pretreatment reagent)	Std Inc, RB
Pretreatment Reagents	11839	-	-	5 x 25 mL R1 + 100 tubes	
BA Automated System (w/o tubes and pretreatment reagent)	23539	1 x 20 mL	1 x 5 mL	25	Std Inc, RB
<b>PHOSPHORUS</b>					
<i>Phosphomolybdate/UV</i>					
Manual	11508	3 x 40 mL	1 x 50 mL	170	Std Inc, WR
A15/A25 Automated System	12508	3 x 24 mL	2 x 15 mL	100	
BA Automated System	21518	4 x 50 mL	4 x 20 mL	280	
	23518	1 x 50 mL	1 x 20 mL	70	
<b>PREALBUMIN</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31929	1 x 50 mL	-	50	
BA Automated System	23106	1 x 60 mL	1 x 15 mL	75	

Test	Code	RA	RB	mL/Kit	Comment
<b>PROTEIN (TOTAL)</b>					
<i>Biuret</i>					
Manual	11800	1 x 50 mL	-	50	Std Inc
	11572	1 x 250 mL	-	250	Std Inc
	11500	2 x 250 mL	-	500	Std Inc
	11553	1 x 1000 mL	-	1000	Std Inc
A15/A25 Automated System	12500	10 x 50 mL	-	500	
BA Automated System	21513	2 x 60 mL	2 x 20 mL	160	
	23513	1 x 60 mL	1 x 20 mL	80	
<b>PROTEIN (URINE+CSF)</b>					
<i>Pyrogallol Red</i>					
Manual	11501	4 x 50 mL	-	200	Std Inc
	11559	2 x 250 mL	-	500	Std Inc
A15/A25 Automated System	12501	5 x 50 mL	-	250	Std Inc
BA Automated System	21512	8 x 20 mL	-	160	
	23512	4 x 20 mL	-	80	
<b>RHEUMATOID FACTORS (RF)</b>					
<i>Immunoturbidimetric latex assay</i>					
Manual	31322	1 x 16 mL	1 x 4 mL	20	
	31922	1 x 40 mL	1 x 10 mL	50	
	31030	2 x 160 mL	2 x 40 mL	400	
A15/A25 Automated System	13922	1 x 40 mL	1 x 10 mL	50	
BA Automated System	22922	4 x 60 mL	4 x 15 mL	300	
	23922	1 x 60 mL	1 x 15 mL	75	
<b>TOTAL BILE ACIDS</b>					
<i>Enzymatic Cycling</i>					
Manual / A15/A25 Automated System	12551	1 x 18 mL	1 x 6 mL	24	Std Inc
BA Automated System	23551	1 x 60 mL	1 x 20 mL	80	
<b>TOTAL IRON BINDING CAPACITY (TIBC)</b>					
<i>Fe<sup>3+</sup> / Magnesium Hydroxide Carbonate</i>					
Manual	11554	50 mL	3 g	50	
<b>TRANSFERRIN</b>					
<i>Immunoturbidimetric assay</i>					
Manual	31091	1 x 20 mL	-	20	
	31092	1 x 50 mL	-	50	
	31093	1 x 250 mL	-	250	
A15/A25 Automated System	13091	1 x 50 mL	-	50	
BA Automated System	22105	2 x 60 mL	2 x 15 mL	150	
	23105	1 x 60 mL	1 x 15 mL	75	
<b>TRIGLYCERIDES</b>					
<i>Glycerol Phosphate Oxidase/Peroxidase</i>					
Manual	11828	1 x 50 mL	-	50	Std Inc
	11528	4 x 50 mL	-	200	Std Inc
	11529	2 x 250 mL	-	500	Std Inc
A15/A25 Automated System	12528	10 x 50 mL	-	500	
BA Automated System	21528	10 x 60 mL	-	600	
	23528	4 x 60 mL	-	240	

Test	Code	RA	RB	mL/Kit	Comment
<b>UNSATURATED IRON BINDING CAPACITY (UIBC)</b>					
<i>Ferrozine</i>					
Manual	11835	1 x 40 mL	1 x 10 mL	50	
A15/A25 Automated System	12835	1 x 40 mL	1 x 10 mL	50	
BA Automated System	21835	2 x 60 mL	2 x 15 mL	150	
<b>UREA/ BUN-COLOR</b>					
<i>Urease/ Salicylate</i>					
Manual	11536	2 x 50 mL	2 x 50 mL	200	Std Inc, RA
	11537	1 x 250 mL	1 x 250 mL	500	Std Inc, RA
<b>UREA/ BUN-UV</b>					
<i>Urease/ Glutamate Dehydrogenase</i>					
Manual	11516	4 x 40 mL	4 x 10 mL	200	Std Inc, WR
	11517	2 x 200 mL	2 x 50 mL	500	Std Inc, WR
	11541	1 x 800 mL	1 x 200 mL	1000	Std Inc, WR
A15/A25 Automated System	12516	5 x 40 mL	5 x 10 mL	250	WR
BA Automated System	21516	8 x 60 mL	8 x 15 mL	600	
	23516	4 x 60 mL	4 x 15 mL	300	
<b>URIC ACID</b>					
<i>Uricase/Peroxidase</i>					
Manual	11821	1 x 50 mL	-	50	Std Inc
	11521	1 x 200 mL	-	200	Std Inc
	11522	1 x 500 mL	-	500	Std Inc
	11540	1 x 1000 mL	-	1000	Std Inc
A15/A25 Automated System	12521	10 x 50 mL	-	500	
BA Automated System	21521	10 x 60 mL	-	600	
	23521	4 x 60 mL	-	240	
<b>ZINC</b>					
<i>Bromo-PAPS</i>					
Manual / A15/A25 Automated System	12526	2 x 20 mL	1 x 10 mL	50	Std Inc, RA



# Calibrators & standards

Code	Quantity	Included parameters
<b>ADENOSINE DEAMINASE (ADA)</b> 18052	1 x 1 mL	Adenosine deaminase (ADA)
<b>ALBUMIN (MICROALBUMINURIA)</b> 31130	1 x 1 mL	Albumin (Microalbuminuria)
<b>AMMONIA, ETHANOL, CO<sub>2</sub></b> 18065	2 x 5 mL	Ammonia, Ethanol, Carbon dioxide
<b>ANTI-STREPTOLYSIN O (ASO)</b> 31119	1 x 1 mL	Anti-Streptolysin O (ASO)
<b>APOLIPOPROTEIN A-I</b> 31100	1 x 1 mL	Apolipoprotein A-I
<b>APOLIPOPROTEIN B</b> 31200	1 x 1 mL	Apolipoprotein B
<b>β<sub>2</sub>-MICROGLOBULIN</b> 31122	1 x 1 mL	β <sub>2</sub> -Microglobulin
<b>BIOCHEMISTRY (BOVINE)</b> 18011	5 x 5 mL	ACP, Albumin, ALP, ALT/GPT, AST/GOT, α-Amylase, β-Hydroxybutyrate, Total bilirubin, Calcium, Cholesterol, Chloride, CK, Copper, Creatinine, Direct bilirubin, Iron, Lactate, LDH, Lipase, Glucose, γ-GT, Magnesium, NEFA, Phosphorus, Potassium, Sodium, Total bile acids, Total protein, Triglycerides, UIBC, Urea, Uric acid, and Zinc.
<b>BIOCHEMISTRY (HUMAN)</b> 18044	5 x 5 mL	ACE, ACP, Albumin, ALP, ALT/GPT, AST/GOT, α-Amylase, α-Amylase Pancreatic, β-Hydroxybutyrate, Direct Bilirubin, Total Bilirubin, Calcium, Chloride, Cholesterol, Direct HDL-Cholesterol, Direct LDL-Cholesterol, Cholinesterase, CK, γ-GT, Copper, Creatinine, Glucose, Iron, Lactate, LDH, Lipase, Magnesium, NEFA, Phosphorus, Potassium, Total Bile Acids, Total Protein, Triglycerides, Sodium, UIBC, Urea, Uric acid, and Zinc.
<b>BILIRUBIN</b> 11513	1 x 5 mL	Bilirubin
<b>CERULOPLASMIN</b> 31340	5 x 1 mL	Ceruloplasmin
<b>CHOLESTEROL HDL/LDL</b> 11693	1 x 1 mL	HDL Cholesterol Direct/ LDL Cholesterol Direct
<b>CREATININE KINASE-MB (CK-MB)</b> 11824	1 x 1 mL	CK-MB
<b>C-REACTIVE PROTEIN (CRP/CRP-hs)</b> 31113	1 x 1 mL 1 x 5 mL	CRP CRP-hs

Code	Quantity	Included parameters
<b>C-REACTIVE PROTEIN (CRP-er)</b> 31182	1 x 3 mL	CRP-er
<b>D-DIMER</b> 18077	4 x 0.5 mL	D-Dimer
<b>FECAL CALPROTECTIN (FCAL)</b> 31331	1 x 2 mL	Fecal calprotectin
<b>FECAL OCCULT BLOOD (FOB)</b> 31326	1 x 2 mL	Fecal occult blood
<b>FERRITIN</b> 31127	1 x 3 mL	Ferritin
<b>FIBRINOGEN</b> 31601	1 x 1 mL	Fibrinogen
<b>HAPTOGLOBIN</b> 31947	1 x 5 mL	Haptoglobin
<b>HbA1C-DIRECT</b> 31048	4 x 0.5 mL	HbA1C
<b>HOMOCYSTEINE</b> 11750	5 x 1 mL	Homocysteine
<b>PROTEIN CALIBRATOR</b> 31075	5 x 1 mL	$\alpha$ 1-Acid glycoprotein, IgA, IgG, IgM, Complement C3 and C4, Prealbumin and Transferrin
<b>PROTEIN (URINE)</b> 11603	1 x 5 mL	Protein (Urine)
<b>RHEUMATOID FACTORS (RF)</b> 31116	1 x 3 mL	Rheumatoid Factor (RF)



# Controls

Code	Quantity	Components	Included parameters
<b>ADA</b>			
18048	2 x 1 mL	LEVEL I and II	Adenosine deaminase
<b>AMMONIA, ETHANOL, CO<sub>2</sub></b>			
18063	3 x 5 mL	LEVEL I	Ammonia, Ethanol, Carbon dioxide
18064	3 x 5 mL	LEVEL II	
<b>BIOCHEMISTRY SERUM</b>			
18009	5 x 5 mL	LEVEL I	ACP, Albumin, ALP, ALT/GPT, AST/GOT, α-Amylase, β-Hydroxybutyrate, Direct and total bilirubin, Calcium, Chloride, Cholesterol, HDL-Cholesterol, CK, Copper, Creatinine, Glucose, γ-GT, Iron, LDH, Lactate, Lipase, Magnesium, NEFA, Phosphorus, Potassium, Protein Total, Sodium, Total bile acids, Triglycerides, UIBC, Urea, Uric acid and Zinc
18005	20 x 5 mL		
18010	5 x 5 mL	LEVEL II	
18007	20 x 5 mL		
<b>BIOCHEMISTRY SERUM (HUMAN)</b>			
18042	5 x 5 mL	LEVEL I	ACE, ACP, Albumin, ALP, ALT/GPT, AST/GOT, α-Amylase, α-Amylase pancreatic, β-Hydroxybutyrate, Direct and total bilirubin, Calcium, Chloride, Cholesterol, Direct Cholesterol-HDL, Direct Cholesterol-LDL, Cholinesterase, CK, Copper, Creatinine, Glucose, γ-GT, Iron, Lactate, LDH, Lipase, Magnesium, NEFA, Phosphorus, Potassium, Protein total, Sodium, Total bile acids, Triglycerides, UIBC, Urea, Uric acid and Zinc
18043	5 x 5 mL	LEVEL II	
<b>BIOCHEMISTRY URINE</b>			
18054	1 x 5 mL	LEVEL I	Albumin, α-Amylase, α-Amylase pancreatic, Calcium, Chloride, Citrate, Creatinine, Glucose, Magnesium, Phosphorus, Potassium, Protein urine, Sodium, Urea and Uric acid
18066	1 x 5 mL	LEVEL II	
<b>β<sub>2</sub>-MICROGLOBULIN</b>			
31592	2 x 1 mL	LEVEL I and II	β <sub>2</sub> -Microglobulin
<b>β<sub>2</sub>-MICROGLOBULIN URINE</b>			
31215	1 x 3 mL		β <sub>2</sub> -Microglobulin
<b>CREATINE KINASE-MB</b>			
18024	1 x 1 mL	LEVEL I	CK, and CK-MB
18061	1 x 1 mL	LEVEL II	
<b>D-DIMER</b>			
18078	2 x 1 mL	LEVEL I and II	D-Dimer
<b>FECAL CALPROTECTIN (FCAL)</b>			
31332	2 x 1 mL	LEVEL I and II	Fecal Calprotectin
<b>FECAL OCCULT BLOOD (FOB)</b>			
18068	2 x 1 mL	LEVEL I and II	Fecal Occult Blood
<b>FERTILITY BIOCHEMISTRY</b>			
18053	1 x 1 mL		Citrate, Fructose, α-Glucosidase and Zinc
<b>FIBRINOGEN</b>			
31602	1 x 1 mL		Fibrinogen

Code	Quantity	Components	Included parameters
<b>FRUCTOSAMINE</b>			
18057	1 x 1 mL		Fructosamine
<b>GLUCOSE-6-PHOSPHATE DEHYDROGENASE</b>			
18083	2 x 0.5 mL	NORMAL and LOW	Glucose-6-phosphate dehydrogenase
<b>HEMOGLOBIN A1C</b>			
18001	1 x 0.5 mL	NORMAL	HbA1c Direct turbidimetry
18002	1 x 0.5 mL	ELEVATED	
<b>HOMOCYSTEINE</b>			
18058	1 x 1 mL	LEVEL I	Homocysteine
18059	1 x 1 mL	LEVEL II	
<b>LIPID SERUM</b>			
18040	3 x 1 mL	LEVEL I	Apolipoprotein A-I, Apolipoprotein B, Cholesterol, Cholesterol-HDL, Cholesterol-LDL and Triglycerides
18041	3 x 1 mL	LEVEL II	
<b>OXALATE URINE</b>			
18080	1 x 5 mL	LEVEL I	Oxalate
18062	1 x 5 mL	LEVEL II	
<b>PROTEIN SERUM</b>			
31211	3 x 1 mL	LEVEL I	α1-Acid Glycoprotein, Ceruloplasmin, Complement C3 and C4, C-Reactive protein-hs, Ferritin, Haptoglobin, IgA, IgG, IgM, Prealbumin, Transferrin
31212	3 x 1 mL	LEVEL II	
<b>RHEUMATOID SERUM</b>			
31213	3 x 1 mL	LEVEL I	Anti-Streptolysin O, C-Reactive protein, Rheumatoid Factors, CRPer
31214	3 x 1 mL	LEVEL II	



# Coagulation reagents

Test	Code	Quantity
<b>PROTHROMBIN TIME (PT)</b>		
Rabbit Brain Thromboplastin	61001	4 x 5 mL
<b>ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)</b>		
APTT A: Rabbit Brain Cephalin and Micronized Silica	61004	4 x 4 mL
APTT B: CaCl <sub>2</sub> buffer solution	61005	4 x 16 mL
APTT A + APTT B	61009	4 x 4 mL + 1 x 16 mL
<b>FIBRINOGEN CLAUSS</b>		
Fibrinogen A: Human Thrombin	61002	4 x 2 mL
Fibrinogen B: Imidazol buffer solution	61003	4 x 15 mL
Fibrinogen A + Fibrinogen B	61020	4 x 2 mL + 4 x 15 mL
<b>THROMBIN TIME (TT)</b>		
Human Thrombin	61000	4 x 3 mL
<b>COAGULATION CALIBRATOR</b>		
Prothrombin Time (PT) and Fibrinogen Clauss	61006	4 x 1 mL
	61015	2 x 1 mL
<b>COAGULATION CONTROL</b>		
LEVEL I: PT, APTT, TT and Fibrinogen Clauss	61007	4 x 1 mL
	61012	2 x 1 mL
LEVEL II: PT, APTT and Fibrinogen Clauss	61008	4 x 1 mL
	61013	2 x 1 mL

# Rapid tests (Agglutination)

Code	Quantity
<b>Latex Seroagglutination</b>	

## ANTI-STREPTOLYSIN O (ASO) - SLIDE

31448	1 x 3 mL
31019	50 tests
31086	150 tests

## C-REACTIVE PROTEIN (CRP) - SLIDE

31107	1 x 3 mL
31011	50 tests
31012	150 tests

- Seroagglutination test
- Available for slide test
- High specificity and sensitivity

## RHEUMATOID FACTORS (RF) - SLIDE

31108	1 x 3 mL
31013	50 tests
31014	150 tests

## Syphilis Serodiagnostics

### RPR-CARBON

36001	100 tests
36002	500 tests



Code	Quantity	Additional information
<b>Febril Serodiagnostics</b>		

### SALMONELLA

33080	8 x 100 tests	Salmonella paratyphi AO, Salmonella paratyphi AH, Salmonella paratyphi BO, Salmonella paratyphi BH, Salmonella paratyphi CO, Salmonella paratyphi CH, Salmonella typhi H, Salmonella typhi O
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### FEBRILE ANTIGENS

33301	5 mL	Salmonella paratyphi AH
33302	5 mL	Salmonella paratyphi AO
33303	5 mL	Salmonella paratyphi BH
33304	5 mL	Salmonella paratyphi BO
33305	5 mL	Salmonella paratyphi CH
33306	5 mL	Salmonella paratyphi CO
33307	5 mL	Salmonella typhi H
33308	5 mL	Salmonella typhi O
33510	1 mL	Positive Control Salmonella
33503	1 mL	Serology Negative Control

- Available for slide and tube test.
- Seroagglutination test.
- High sensitivity and specificity.



**Autoimmunity  
reagents**



# Immunofluorescence tests

Code	Quantity	Description
<b>ANTI-NUCLEAR ANTIBODIES HEp-2 (ANA-HEp-2)</b>		
<b>HEp-2 cells</b>		
44108	24 tests	Complete kit, 6 wells
44508	60 tests	Complete kit, 6 wells
44509	120 tests	Complete kit, 12 wells
44546	10 slides	Slide box, 6 wells
44547	10 slides	Slide box, 12 wells
<b>ANTI-nDNA ANTIBODIES (nDNA)</b>		
<b>Crithidia luciliae</b>		
44825	24 tests	Complete kit, 6 wells
44818	60 tests	Complete kit, 6 wells
44817	120 tests	Complete kit, 12 wells
44820	10 slides	Slide box, 6 wells
44819	10 slides	Slide box, 12 wells
<b>ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)</b>		
<b>Ethanol fixed ANCA</b>		
44850	24 tests	Complete kit, 6 wells
44851	60 tests	Complete kit, 6 wells
44852	10 slides	Slide box, 6 wells
<b>Formalin fixed ANCA</b>		
44878	10 slides	Slide box, 6 wells
44898	60 tests	Complete kit, 6 wells
<b>ANTI-ENDOMYSIUM ANTIBODIES (AEA)</b>		
<b>Monkey Oesophagus (Endomysium)</b>		
44548	48 tests	Complete kit, 4 wells
44715	96 tests	Complete kit, 8 wells
44557	12 slides	Slide box, 4 wells
44710	12 slides	Slide box, 8 wells
<b>AUTOANTIBODIES RL/RK/RS (ANA-AMA-ASMA-APCA-LKM)</b>		
<b>Rat Liver/Kidney/Stomach</b>		
44558	48 tests	Complete kit, 4 wells
44648	96 tests	Complete kit, 8 wells
44570	12 slides	Slide box, 4 wells
44639	12 slides	Slide box, 8 wells
<b>AUTOANTIBODIES MsL/MsK/MsS (ANA-AMA-ASMA-APCA-LKM)</b>		
<b>Mouse Liver/Kidney/Stomach</b>		
44826	12 slides	Slide box, 4 wells
44827	12 slides	Slide box, 8 wells
<b>GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)</b>		
<b>Monkey Kidney</b>		
44588	12 slides	Slide box, 4 wells
<b>ANTI-ADRENAL CORTEX ANTIBODIES (AACA)</b>		
<b>Monkey Adrenal</b>		
44575	48 tests	Complete kit, 4 wells*
44574	12 slides	Slide box, 4 wells

Code	Quantity	Description
<b>ANTI-STRIATED MUSCLE ANTIBODIES (AStMA)</b>		
44649	12 slides	<b>Rat Striated Muscle</b> Slide box, 4 wells
<b>ANTI-ISLET CELL ANTIBODIES (AICA)</b>		
44609	48 tests	<b>Monkey Pancreas</b> Complete kit, 4 wells*
44572	12 slides	Slide box, 4 wells
<b>ANTI-THYROID ANTIBODIES (ATA)</b>		
44550	48 tests	<b>Monkey Thyroid</b> Complete kit, 4 wells*
44551	12 slides	Slide box, 4 wells
<b>ANTI-SKIN ANTIBODIES (ASA)</b>		
44560	48 tests	<b>Monkey Esophagus</b> Complete kit, 4 wells*
44561	12 slides	Slide box, 4 wells
<b>ANTI-KERATIN ANTIBODIES (AKA)</b>		
44618	48 tests	<b>Rat Esophagus</b> Complete kit, 4 wells*
44517	12 slides	Slide box, 4 wells
<b>TISSUE SLIDES FOR RESEARCH USE ONLY (RUO)</b>		
44571		<b>Monkey Heart</b>
44573		<b>Monkey Ovary</b>
44685		<b>Monkey Sciatic Nerve</b>
44684		<b>Monkey Cerebellum</b>
44589		<b>Monkey Hypophysis</b>
44688		<b>Monkey Jejunum</b>
44638		<b>Monkey Submaxillary</b>
44566		<b>Monkey Testicle</b>
44567		<b>Monkey Hypothalamus</b>
44725		<b>Monkey Hippocampus</b>
44683		<b>Monkey Optic Nerve</b>

# Conjugates

Code	Quantity	Description
<b>For Monkey tissues</b>		
<b>IgG FITC/Evans (M)</b>		
44847	3.5 mL	Anti-(Monkey adsorbed) IgG FITC conjugate, contains Evans Blue.
44882	10 mL	For use with GBMA, AICA, ATA, ASA and AACA.
<b>IgG FITC/Evans (M) hs</b>		
44914	3.5 mL	High sensitive Anti-(Monkey absorbed) IgG FITC conjugate, contains Evans Blue.
44915	10 mL	For use with AEA.
<b>IgA FITC/Evans</b>		
44692	3.5 mL	Anti-IgA FITC conjugate, contains Evans Blue.
44835	10 mL	For use with AEA.
<b>For Rat and Mouse tissues</b>		
<b>FITC/Evans (R)</b>		
44590	3.5 mL	Anti-(Rat adsorbed) IgG, IgA, IgM FITC Conjugate, contains Evans Blue.
44836	10 mL	For use with ANA, AMA, ASMA, APCA and LKM.
<b>For HEp-2, nDNA, ANCA and Rat and Mouse tissues</b>		
<b>IgG FITC/Evans</b>		
44697	3 mL	Anti-IgG FITC conjugate, contains Evans Blue.
44834	10 mL	For use with HEp-2, nDNA, ANCA, AStMA, AKA, ANA, AMA, ASMA, APCA and LKM
<b>Auxiliary Reagents</b>		
<b>Miscellaneous</b>		
44592	100 mL	PBS (10x)
44962	500 mL	PBS (10x)
44694	3 mL	Mounting medium
44846	10 mL	Glycin (for GBMA)
44897	100 u.	Coverslips (24 x 60 mm)

# Controls

Code	Quantity	Description
44696	0.3 mL	Negative Control
44889	2.0 mL	Negative Control
44502	0.3 mL	Anti-Nuclear Antibodies-Homogeneous Positive Control
44890	2.0 mL	Anti-Nuclear Antibodies-Homogeneous Positive Control
44585	0.3 mL	Anti-Nuclear Antibodies-Centromere Positive Control
44504	0.3 mL	Anti-Nuclear Antibodies-Nucleolar Positive Control
44503	0.3 mL	Anti-Nuclear Antibodies-Speckled Positive Control
44549	0.3 mL	Anti-Endomysium Antibodies IgA Positive Control
44893	2.0 mL	Anti-Endomysium Antibodies IgA Positive Control
44732	0.3 mL	Anti-Endomysium Antibodies IgG Positive Control
44512	0.3 mL	Anti-Mitochondrial Antibodies Positive Control
44891	2.0 mL	Anti-Mitochondrial Antibodies Positive Control
44522	0.3 mL	Anti-Smooth Muscle Antibodies Positive Control
44892	2.0 mL	Anti-Smooth Muscle Antibodies Positive Control
44553	0.3 mL	Anti-Thyroid Antibodies Positive Control
44542	0.3 mL	Anti-nDNA Antibodies Positive Control
44894	2.0 mL	Anti-nDNA Antibodies Positive Control
44854	0.3 mL	C-ANCA Positive Control
44912	2.0 mL	C-ANCA Positive Control
44855	0.3 mL	P-ANCA Positive Control
44913	2.0 mL	P-ANCA Positive Control

# ELISA

Code	Quantity	Description
<b>ANA-SCREENING</b>		
44785	96 tests	Purified SSA(Ro), SSB(La), Sm/RNP, RNP (70, A and C), Sm, Scl70, Jo1, dsDNA, ssDNA, nucleosomes, total histones, PMScl 100, Centromere B
<b>ENA 6-SCREENING</b>		
44740	96 tests	SSA (Ro), SSB (La), Sm, Sm/RNP, Jo1, Scl70
<b>ANTI-Sm ANTIBODIES</b>		
44755	96 tests	Highly purified human antigen
<b>ANTI-Sm/RNP ANTIBODIES</b>		
44770	96 tests	Highly purified human antigen
<b>ANTI-SSA (Ro) ANTIBODIES</b>		
44765	96 tests	Highly purified antigen
<b>ANTI-SSB (La) ANTIBODIES</b>		
44750	96 tests	Highly purified antigen
<b>ANTI-CENTROMERE B ANTIBODIES (CENP-B)</b>		
44865	96 tests	Recombinant antigen
<b>ANTI-Jo1 ANTIBODIES</b>		
44864	96 tests	Highly purified antigen
<b>ANTI-Scl70 ANTIBODIES</b>		
44863	96 tests	Highly purified antigen
<b>ANTI-HISTONES ANTIBODIES (HIST)</b>		
44862	96 tests	Highly purified antigen
<b>ANTI-NUCLEOSOME ANTIBODIES (NCL)</b>		
44861	96 tests	Purified antigen
<b>ANTI-dsDNA ANTIBODIES</b>		
44705	96 tests	Calf thymus antigen
<b>ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)</b>		
44860	96 tests	Highly purified antigen
<b>ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)</b>		
44780	96 tests	Highly purified antigen
<b>ANTI-PHOSPHOLIPID ANTIBODIES IgG/IgM (APLA)</b>		
44867	96 tests	Mixture of cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and human $\beta$ 2-Glycoprotein 1
<b>ANTI-<math>\beta</math>2-GLYCOPROTEIN 1 ANTIBODIES IgG/IgM (<math>\beta</math>2-GP1)</b>		
44868	96 tests	Highly purified antigen
<b>ANTI-ANNEXIN V ANTIBODIES IgG/IgM (ANX)</b>		
44869	96 tests	Highly purified antigen

Code	Quantity	Description
<b>ANTI-PR3 ANTIBODIES</b>		
44791	96 tests	Purified human antigen
<b>ANTI-MPO ANTIBODIES</b>		
44790	96 tests	Purified human antigen
<b>ANTI-GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBM)</b>		
44870	96 tests	Highly purified antigen
<b>ANTI-tTRANSGLUTAMINASE IgA ANTIBODIES (Anti-tTG IgA)</b>		
44754	96 tests	Recombinant human antigen activated by calcium and gliadin
<b>ANTI-tTRANSGLUTAMINASE IgG ANTIBODIES (Anti-tTG IgG)</b>		
44798	96 tests	Recombinant human antigen activated by calcium and gliadin
<b>ANTI-DEAMIDATED GLIADIN (DGP-IgG)</b>		
44884	96 tests	Synthetic deamidated gliadin
<b>ANTI-DEAMIDATED GLIADIN (DGP-IgA)</b>		
44885	96 tests	Synthetic deamidated gliadin
<b>ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES IgG/IgA (ASCA)</b>		
44872	96 tests	Highly purified mannan from <i>Saccharomyces cerevisiae</i>
<b>ANTI-THYROGLOBULIN ANTIBODIES (anti-TG)</b>		
44796	96 tests	Highly purified human antigen
<b>ANTI-INSULIN ANTIBODIES</b>		
44873	96 tests	Mixture of recombinant and purified insulin
<b>ANTI-M2 ANTIBODIES (M2)</b>		
44871	96 tests	Highly purified mitochondrial M2 subtype antigen



Prevecal



# External quality control

## International External Quality Assessment Scheme

**PREVECAL**

- Yearly programme for the comparison of results between laboratories.
- Monthly and quarterly measurements of different control materials.
- The final report summarises all monthly and quarterly reports, and shows additional data on performance.
- On-line participation through [www.prevecal.net](http://www.prevecal.net).

Code	Quantity	Components
<b>Clinical Chemistry</b>		
<b>PREVECAL BIOCHEMISTRY BOVINE*</b> 18027	12 x 5 mL	Albumin, ALP, ALT/GPT, AST/GOT, α-Amylase, Total Bilirubin, Calcium, Chloride, Cholesterol, HDL-Cholesterol, CK, Creatinine, Glucose, γ-GT, Inorganic Phosphate, Iron, Lactate**, LDH, Lipase, Magnesium, Potassium, Proteins, Sodium, Triglycerides, Urea, Uric acid and Zinc**.
<b>PREVECAL BIOCHEMISTRY HUMAN*</b> 18045	12 x 5 mL	ALT, Albumin, α-Amylase, α-Amylase Pancreatic**, AST, β-Hydroxybutyrate**, Direct and Total Bilirubin, Calcium, Chloride, Cholesterol, Cholinesterase, HDL-Cholesterol, CK, Creatinine, ALP, Phosphorus, Glucose, γ-GT, Iron, Lactate**, LDH, LDL-Cholesterol, Lipase, Magnesium, Potassium, Proteins, Sodium, Triglycerides, Urea, Uric Acid and Zinc**.
<b>PREVECAL RHEUMA*</b> 31009	12 x 1 mL	Anti-streptolysin O, C-reactive Protein and Rheumatoid Factors.
<b>PREVECAL PROTEINS*</b> 31010	12 x 1 mL	α1-Acid Glycoprotein**, CRP-hs**, Immunoglobulins (A, G and M), Complements C3 and C4, Ferritin, Prealbumin** and Transferrin.
<b>PREVECAL URINE**</b> 18067	12 x 5 mL	Albumin, α-Amylase, α-Amylase Pancreatic, Calcium, Chloride, Citrate, Creatinine, Glucose, Inorganic Phosphate, Magnesium, Potassium, Protein Urine, Sodium, Urea and Uric Acid.
<b>PREVECAL COAGULATION**</b> 18082	12 x 1 mL	Fibrinogen Clauss, Prothrombin Time, Partially Activated Thromboplastin Time, Thrombin Time.

\*Accredited according to ISO 17043.

\*\* Not accredited according to ISO 17043.

Code	Quantity	Components
<b>Autoimmunity</b>		
<b>PREVECAL HEp-2 IFA**</b> 18046	12 x 0.3 mL	Anti-HEp-2 Cells Antibodies.
<b>PREVECAL ANCA**</b> 18056	4 x 0.3 mL	Anti-Neutrophil Cytoplasmic Antibodies.
<b>PREVECAL nDNA**</b> 18047	12 x 0.3 mL	Anti-nDNA Antibodies.
<b>PREVECAL CELIAC**</b> 18051	4 x 0.3 mL	Anti-Endomysium, Anti-tTG IgA Anti-deaminated gliadin antibodies.

All kits include general instructions.

\*\* Not accredited according to ISO 17043.



BioS  
PREVECAL  
BIOCHEMISTRY  
5 mL

APR

PREVECAL  
BIOCHEMISTRY HUMAN

PREVECAL  
BIOCHEMISTRY HUMAN

PREVECAL  
BIOCHEMISTRY HUMAN

JUN

SEP

JUL

PREVECAL  
BIOCHEMISTRY HUMAN

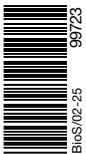
PREVECAL  
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PREVECAL  
BIOCHEMISTRY HUMAN

PREVECAL  
BIOCHEMISTRY HUMAN  
REF 18045  
LOT 55418  
Year: 2024  
EXTERNAL QUALITY CONTROL PROGRAM  
12 x 5 mL

BioSystems



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