

# BioSystems

## 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 thirteen (13) pages joined herewith, meet the applicable provisions of the

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

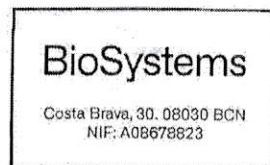
under the specifications declared by BioSystems S.A.

It means that the products:

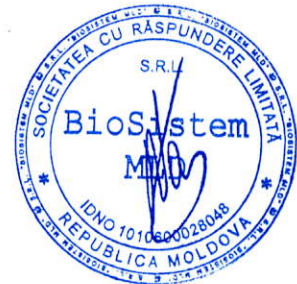
- comply with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- are classified as Other Devices (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows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

Barcelona, November 3rd, 2023

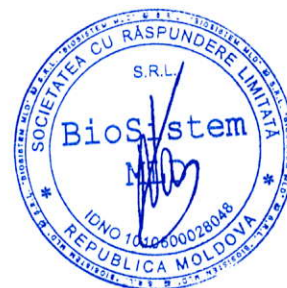
P. Vila



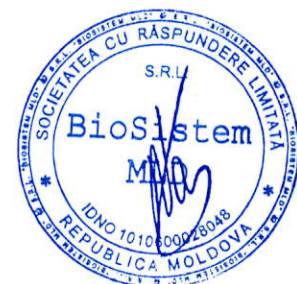
Pau Vila Cases, PhD  
CEO  
BioSystems S.A.



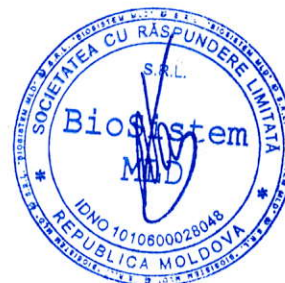
<b>CLINICAL CHEMISTRY - BIOCHEMISTRY</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>
<b>a-AMYLASE - DIRECT</b>	11583
	11550
	12550
	21550
	23550
<b>a-AMYLASE - EPS</b>	11534
	21534
	12535
<b>a-AMYLASE-PANCREATIC</b>	11799
	12799
	21799
<b>alpha-GLUCOSIDASE</b>	12522
	21522
<b>ACID PHOSPHATASE (ACP)</b>	11548
<b>ADENOSINE DEAMINASE</b>	12754
	23754
<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



ALKALINE PHOSPHATASE (ALP) - DEA	11590 11591 11597 12514 21590 23590
ASPARTATE AMINOTRANSFERASE (AST/GOT)	11830 11531 11567 11561 12531 21531 23531
BILIRUBIN (DIRECT)	11511 11545 12504 21504 23504
BILIRUBIN (TOTAL AND DIRECT)	11515 11555
BILIRUBIN (TOTAL)	11510 11544 12506 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
CHOLESTEROL HDL	11523



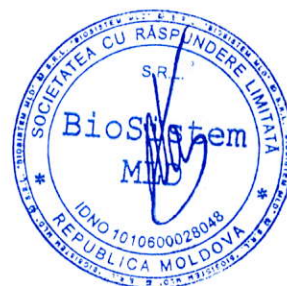
<b>CHOLESTEROL HDL DIRECT</b>	21557
	23557
	11757
	12757
	21594
<b>CHOLESTEROL HDL PRECIPITATING REAGENT</b>	23594
<b>CHOLESTEROL HDL PRECIPITATING REAGENT</b>	11648
<b>CHOLESTEROL LDL DIRECT</b>	12585
	21585
	23585
	11785
	12785
	21785
<b>CHOLESTEROL LDL PRECIPITATING REAGENT</b>	23785
<b>CHOLESTEROL LDL PRECIPITATING REAGENT</b>	11579
<b>CHOLINESTERASE (CHE)</b>	11588
	11589
	12588
	21588
<b>CITRATE</b>	11795
	11895
	23795
<b>COPPER - PAESA</b>	11837
<b>CREATINE KINASE (CK)</b>	11790
	11791
	12524
	21790
	23790
<b>CREATINE KINASE-MB (CK-MB)</b>	11792
	12566
	21792
	23792
<b>CREATININE</b>	11802
	11502
	11542
	12502
	21502
	23502
<b>CREATININE-ENZYMATIC</b>	11734
	12734
	21734
<b>FRUCTOSAMINE</b>	11046
<b>FRUCTOSE</b>	11794
	23794
<b>g-GLUTAMYLTRANSFERASE (g-GT)</b>	11584
	11520
	12520
	21520
	23520



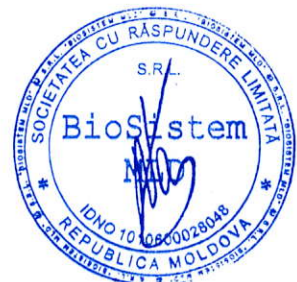
<b>GLUCOSE</b>	11803 11503 11504 11538 12503 21503 23503
<b>GLUCOSE-HEXOKINASE</b>	11656 12756 21656 23656
<b>IRON- CHROMAZUROL</b>	11546
<b>IRON-FERROZINE</b>	11509 12509 21509 23509
<b>LACTATE</b>	11736 12736 21736 23736
<b>LACTATE DEHYDROGENASE (LDH)</b>	11580 11581 12580 21580 23580
<b>LACTATE DEHYDROGENASE (LDH) - IFCC</b>	11586 11587 21586 23586
<b>LIPASE</b>	12793 23793 11760 12760 21760
<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



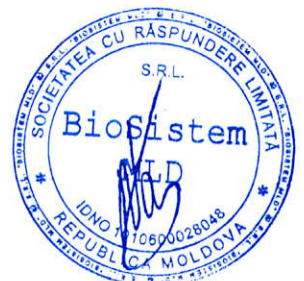
PYRIDOXAL PHOSPHATE	11666
TOTAL IRON BINDING CAPACITY (TIBC)	11554
TRIGLYCERIDES	11828 11528 11529 12528 21528 23528
UNSATURATED IRON BINDING CAPACITY (UIBC)	11835 12835 21835
UREA/BUN - COLOR	11536 11537
UREA/BUN - UV	11516 11517 11541 12516 21516 23516
URIC ACID	11821 11521 11522 11540 12521 21521 23521
ZINC	12526
ADENOSINE DEAMINASE (ADA)	12754 23754
AMMONIA	12532 23532
ANGIOTENSIN CONVERTING ENZYME (ACE)	12796 21796
b-HYDROXYBUTYRATE	12525 21525
ETHANOL	12789 21789
HOMOCYSTEINE	12737 21737 23737
OXALATE	12539 23539
OXALATE PRETREATMENT REAGENTS	11839
TOTAL BILE ACIDS	12551 21551 23551
<b>CLINICAL CHEMISTRY- TURBIDIMETRY</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>



<b>a1-ACID GLYCOPROTEIN</b>	31928 23107
<b>ALBUMIN (MICROALBUMINURIA)</b>	31324 31924 13324 22324 23324
<b>ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)</b>	61004 61005 61009
<b>ANTI-STREPTOLYSIN O (ASO)</b>	31323 31923 31031 13923 22923 23923
<b>ANTITHROMBIN III</b>	31936 13936 22936 23936
<b>APOLIPOPROTEIN A-I (APO A-I)</b>	31095 23095
<b>APOLIPOPROTEIN B (APO B)</b>	31098 23098
<b>b2-MICROGLOBULIN</b>	31920 31925 22925 23925
<b>COMPLEMENT COMPONENT C3</b>	31073 31079 13084 23103
<b>COMPLEMENT COMPONENT C4</b>	31074 31080 13085 23104
<b>C-REACTIVE PROTEIN (CRP)</b>	31321 31921 31029 13921 22921 23921
<b>C-REACTIVE PROTEIN-er (CRP-er)</b>	22942 23942
<b>C-REACTIVE PROTEIN-hs (CRP-hs)</b>	31927 13927 22927 23927



D-DIMER	21519
	31934
FERRITIN	31935
	22934
	23934
	13934
FIBRINOGEN	31600
	13600
	22804
	23804
FIBRINOGEN CLAUSS	61002
	61003
	61020
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)	31047
	13047
	22047
	22147
IMMUNOGLOBULIN A (IgA)	31071
	31077
	13082
	23101
IMMUNOGLOBULIN G (IgG)	31070
	31076
	13081
	23100
IMMUNOGLOBULIN M (IgM)	31072
	31078
	13083
	23102
PREALBUMIN	31929
	23106
PROTHROMBIN TIME (PT)	61001
RHEUMATOID FACTORS (RF)	31322
	31922
	31030
	13922
	22922
	23922
THROMBIN TIME (TT)	61000
TRANSFERRIN	31091
	31092
	31093
	13091
	22105
	23105
<b>CLINICAL CHEMISTRY- MICROCOLUMN CHROMATOGRAPHY</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>
17-HYDROXYCORTICOSTEROIDS (17-OH)	11006
17-KETOSTEROIDS	11002

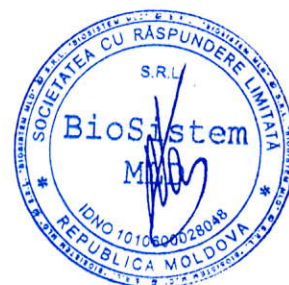




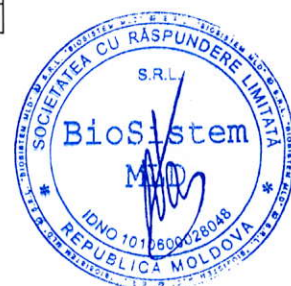
5-AMINOLEVULINIC ACID (ALA) / PORPHOBILINOGEN (PBG)	11017
5-HYDROXYINDOLEACETIC ACID (5-HIAA)	11010
HEMOGLOBIN A2	11077
METANEPHRINES	11022
VANILMANDELIC ACID	11003
<b>CLINICAL CHEMISTRY- STANDARDS &amp; CALIBRATORS</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>
ADENOSINE DEAMINASE (ADA) STANDARD	18052
ALBUMIN (MICROALBUMINURIA) STANDARD	31130
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
BIOCHEMISTRY CALIBRATOR (BOVINE)	18011
BIOCHEMISTRY CALIBRATOR (HUMAN)	18044
BILIRUBIN STANDARD	11513
CHOLESTEROL HDL/LDL CALIBRATOR	11693
COAGULATION CALIBRATOR	61006
CREATINE KINASE-MB (CK-MB) STANDARD	11824
CRP/CRP-hs STANDARD	31113
CRP-er STANDARD	31182
D-DIMER STANDARD	18077
FERRITIN STANDARD	31127
FIBRINOGEN STANDARD	31601
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR) STANDARDS	31048
HOMOCYSTEINE STANDARDS	11750
PROTEIN CALIBRATORS	31075
PROTEIN (URINE) STANDARD	11603
RHEUMATOID FACTORS (RF) STANDARD	31116



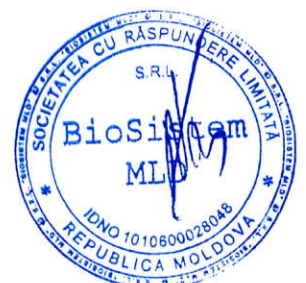
<b>CLINICAL CHEMISTRY - INTERNAL QUALITY CONTROL</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>
ADA CONTROLS	18048
AMMONIA/ETHANOL/CO2 CONTROL I	18063
AMMONIA/ETHANOL/CO2 CONTROL II	18064
b2-MICROGLOBULIN CONTROL URINE	31215
b2-MICROGLOBULIN CONTROLS	31592
BIOCHEMISTRY CONTROL SERUM (HUMAN) I	18042
BIOCHEMISTRY 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
D-DIMER CONTROLS	18078
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 I	18080
OXALATE CONTROL URINE II	18062
PROTEIN CONTROL SERUM I	31211
PROTEIN CONTROL SERUM II	31212
RHEUMATOID CONTROL SERUM	31213
RHEUMATOID CONTROL SERUM II	31214
<b>AUTOIMMUNITY-IF A (IMMUNOFLUORESCENCE)</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>
ANTI-ADRENAL CORTEX ANTIBODIES (ACA)	44574 44575 29022
ANTI-ENDOMYSIUM ANTIBODIES (AEA)	44148 44548 44715 44557 44710



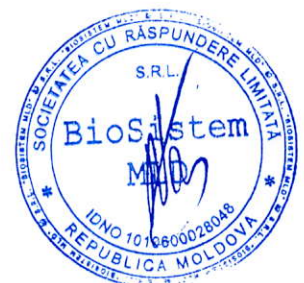
ANTI-ISLET CELL ANTIBODIES (AICA)	44609 44572
ANTI-KERATIN ANTIBODIES (AKA)	44618 44517
ANTI-MITOCHONDRIAL ANTIBODIES (AMA)	44510 44514 44511 44515
ANTI-nDNA ANTIBODIES (nDNA)	44825 44818 44817 44820 44819
ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)	44850 44851 44852 44911
ANTI-NUCLEAR ANTIBODIES HEp-2 (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
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>	
<b>PRODUCT NAME</b>	<b>CODE</b>
AACA POSITIVE CONTROL	44578
AEA POSITIVE CONTROL	44549 44893 44732
AICA POSITIVE CONTROL	44577



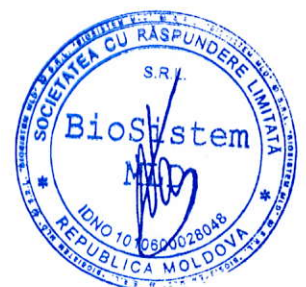
AKA POSITIVE CONTROL	44619
AMA POSITIVE CONTROL	44512
ANA-Ce POSITIVE CONTROL	44891
ANA-Ce POSITIVE CONTROL	44585
ANA-Ho POSITIVE CONTROL	44502
ANA-Ho POSITIVE CONTROL	44890
ANA-Nu POSITIVE CONTROL	44504
ANA-Sp POSITIVE CONTROL	44503
APCA POSITIVE CONTROL	44532
ASA-bm POSITIVE CONTROL	44562
ASA-is POSITIVE CONTROL	44563
ASMA POSITIVE CONTROL	44522
ASMA POSITIVE CONTROL	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
C-ANCA POSITIVE CONTROL	44912
FITC/EVANS (R)	44590
FITC/EVANS (R)	44836
FITC/EVANS (R)	44916
GBMA POSITIVE CONTROL	44678
GLYCIN	44846
<b>PRODUCT NAME</b>	<b>CODE</b>
IgA FITC/EVANS	44692
IgA FITC/EVANS	44835
IgG FITC/EVANS	44697
IgG FITC/EVANS	44834
IgG FITC/EVANS (M)	44847
IgG FITC/EVANS (M)	44882
LKM POSITIVE CONTROL	44766
MOUNTING MEDIUM	44694
nDNA POSITIVE CONTROL	44542
nDNA POSITIVE CONTROL	44894
NEGATIVE CONTROL	44696
NEGATIVE CONTROL	44889
P-ANCA POSITIVE CONTROL	44855
P-ANCA POSITIVE CONTROL	44913
PBS (10x)	44592
X-ANCA POSITIVE CONTROL	44896
<b>AUTOIMMUNITY - ELISA</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>
ANA-SCREENING	44785
ANTI-ANNEXIN V IgG/IgM (ANX)	44869
ANTI-beta-2-GLYCOPROTEIN 1 IgG/IgM (beta2GP1)	44868
ANTI-BPI ANTIBODIES	44905
ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)	44780
ANTI-CATHEPSIN G ANTIBODIES	44906
ANTI-CENTROMERE B ANTIBODIES (CENP-B)	44865



ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)	44860
ANTI-DEAMIDATED GLIADIN PEPTIDES IgA (DGP IgA)	44885
ANTI-DEAMIDATED GLIADIN PEPTIDES IgG (DGP IgG)	44884
ANTI-dsDNA ANTIBODIES	44705
ANTI-ELASTASE ANTIBODIES	44907
ANTI-GBM ANTIBODIES-EIA (GBM)	44870
ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA)	44704
ANTI-HISTONES ANTIBODIES (HIS)	44862
ANTI-INSULIN ANTIBODIES (INS)	44873
ANTI-Jo1 ANTIBODIES	44864
ANTI-LACTOFERRIN ANTIBODIES	44908
ANTI-LYSOZYME ANTIBODIES	44909
ANTI-M2 ANTIBODIES (M2)	44871
ANTI-MPO ANTIBODIES (P-ANCA)	44790
ANTI-NUCLEOSOME ANTIBODIES (NCL)	44861
ANTI-PHOSPHOLIPID IgG/IgM (APLA)	44867
ANTI-PR3 ANTIBODIES (C-ANCA)	44791
ANTI-RIBOSOMAL P ANTIBODIES (Rib P)	44866
ANTI-Sci70 ANTIBODIES	44863
ANTI-Sm ANTIBODIES	44755
ANTI-Sm/RNP ANTIBODIES	44770
ANTI-SSA (Ro) ANTIBODIES	44765
ANTI-SS-B (La) ANTIBODIES	44750
ANTI-THYROGLOBULIN ANTIBODIES (ANTI-Tg)	44796
ANTI-THYROID PEROXIDASE ANTIBODIES (ANTI- TPO)	44795
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgA (ANTI-tTG IgA)	44754
ANTI-tTRANSGLUTAMINASE ANTIBODIES IgG (ANTI-tTG IgG)	44798
ASCA-IgG/IgA (ASCA)	44872
ENA4-PROFILE	44775
ENA 6-PROFILE	44910
ENA6-SCREENING	44740
<b>RAPID TESTS - LATEX AGGLUTINATION</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>
ANTI-STREPTOLYSIN O (ASO) - SLIDE	31019 31319 31086 31448
C-REACTIVE PROTEIN (CRP) - SLIDE	31011 31311 31012 31107
RHEUMATOID FACTORS (RF) - SLIDE	31013 31313 31014 31108
<b>INFECTIOUS IMMUNOLOGY- SYPHILIS</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>



RPR-CARBON	36001 36002
<b>INFECTIOUS IMMUNOLOGY- FEBRILE ANTIGENS</b>	
<b>PRODUCT NAME</b>	<b>CODE</b>
FEBRILE SERODIAGNOSTICS SALMONELLA	33080 33081
FEBRILE SERODIAGNOSTICS PROTEUS OX19	33311
FEBRILE SERODIAGNOSTICS PROTEUS POSITIVE CONTROL	33502
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI AH	33301
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI AO	33302
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI BH	33303
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI BO	33304
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI CH	33305
FEBRILE SERODIAGNOSTICS SALMONELLA PARATYPHI CO	33306
FEBRILE SERODIAGNOSTICS SALMONELLA POSITIVE CONTROL	33510
FEBRILE SERODIAGNOSTICS SALMONELLA TYPHI H	33307
FEBRILE SERODIAGNOSTICS SALMONELLA TYPHI O	33308



# EC DECLARATION OF CONFORMITY

## According to Art.17 of Regulation 2017/746 (EU) on In Vitro Diagnostic Medical Devices

### ARCHEM SAĞLIK SANAYİ VE TİCARET ANONİM ŞİRKETİ

SRN : TR-MF-000027166

Address : MAHMUTBEY MH HALKALI CD NO 124/42 BAĞCILAR  
ISTANBUL TURKIYE

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E-mail : info@archem.com.tr

#### Product Information

Product Name : CD80 DETERGENT  
Brand Name : ARCHEM  
Classification : Class A, according to Rule 5 of IVDR Annex VIII  
Basic UDI-DI : 869901528AR00LM

Conformity Assessment: The conformity of the determined product to the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 was evaluated by issuing the EU declaration of conformity referred to in Article 17, after the technical documents specified in Annex-IV (Annex II and III) were prepared.

This declaration of conformity is the responsibility of our company.

We declare that the above-mentioned products meet the requirements of the in Vitro Diagnostic Medical Device regulation (EU) 2017/746 and the applicable standards above.

#### List of Directive and Standard Applied:

EN ISO 20417 2021  
EN ISO 15223-1:2016  
EN ISO 18113-1:2011  
EN ISO 14971 2019  
EN ISO 13485 2016



Published by: ERKAN UCA (General Manager)

Publication Date: 15.08.2022  
Published in: İstanbul

Rev. No 01

archem  
SAĞLIK SANAYİ VE TİCARET ANONİM ŞİRKETİ  
MAHMUTBEY MH HALKALI CD NO 124/42 BAĞCILAR  
ISTANBUL TURKIYE  
0212 444 08 92  
Stamp/Signature



**EC DECLARATION OF CONFORMITY**  
**According to Art.17 of Regulation 2017/746 (EU) on**  
**In Vitro Diagnostic Medical Devices**

**ARCHEM SAĞLIK SANAYİ VE TİCARET ANONİM ŞİRKETİ**

SRN : TR-MF-000027166

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**Product Information**

Product Name : PROBE CLEANSER

Brand Name : ARCHEM

Classification : Class A, according to Rule 5 of IVDR Annex VIII

Basic UDI-DI : 869901528AR00LM

Conformity Assessment: The conformity of the determined product to the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 was evaluated by issuing the EU declaration of conformity referred to in Article 17, after the technical documents specified in Annex-IV (Annex II and III) were prepared.

This declaration of conformity is the responsibility of our company.

**We declare that the above-mentioned products meet the requirements of the in Vitro Diagnostic Medical Device regulation (EU) 2017/746 and the applicable standards above.**

**List of Directive and Standard Applied:**

EN ISO 20417:2021  
EN ISO 15223-1:2016  
EN ISO 18113-1:2011  
EN ISO 14971:2019  
EN ISO 13485:2016



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archem  
SAĞLIK SANAYİ VE TİCARET ANONİM ŞİRKETİ  
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Stamp/Signature





# EC DECLARATION OF CONFORMITY

## According to Art.17 of Regulation 2017/746 (EU) on In Vitro Diagnostic Medical Devices

### ARCHEM SAĞLIK SANAYİ VE TİCARET ANONİM ŞİRKETİ

SRN : TR-MF-000027166

Address : MAHMUTBEY MH HALKALI CD NO 124/42 BAĞCILAR  
ISTANBUL TURKIYE

Tel : + 90 212 444 08 92

Faks : +90 212 629 98 89

E-mail : info@archem.com.tr

### Product Information

Product Name : System Wash Solution  
Brand Name : ARCHEM  
Classification : Class A, according to Rule 5 of IVDR Annex VIII  
Basic UDI-DI : 869901528AR00LM

Conformity Assessment: The conformity of the determined product to the In Vitro Diagnostic Medical Devices Regulation (EU)2017/746 was evaluated by issuing the EU declaration of conformity referred to in Article 17, after the technical documents specified in Annex-IV (Annex II and III) were prepared.

This declaration of conformity is the responsibility of our company.

We declare that the above-mentioned products meet the requirements of the In Vitro Diagnostic Medical Device regulation (EU) 2017/746 and the applicable standards above.

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Tic. Sic. No: 271100  
Vergi No: 3211000000  
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## **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**

<b>Product Name</b>	<b>Product Model</b>	<b>Accessories</b>
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 cuvette

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		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(Turibidimetry 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	/	/
Adrenocorticotrophic 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	/	/

## BC-5150

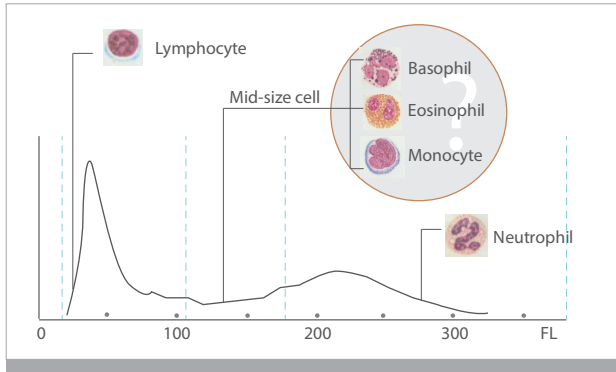
Auto Hematology Analyzer

## A "CUTE" 5-part



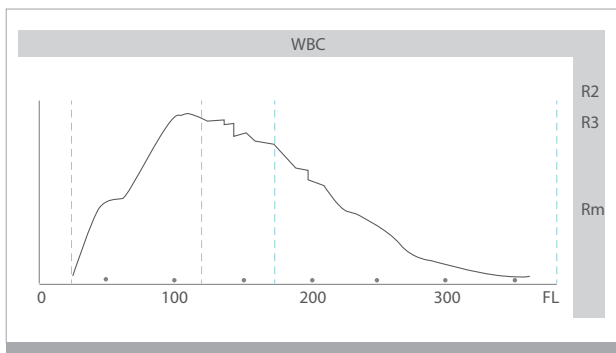
# Why do we need 5-part hematology analyzers?

## WBC differential: 3-part



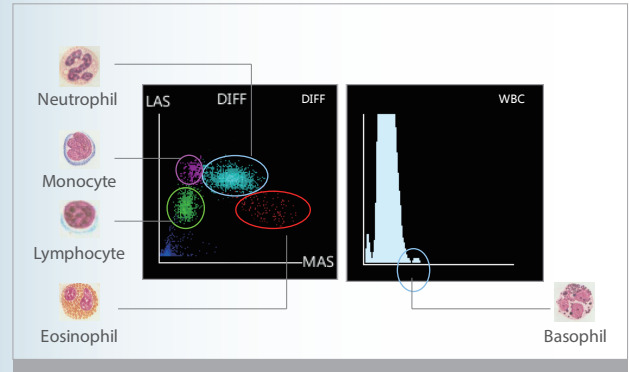
3-part hematology analyzers can not differentiate Basophil, Eosinophil and Monocyte. Additionally, Lymphocyte and Neutrophil results are easily affected by abnormal cells.

## Flag information: 3-part



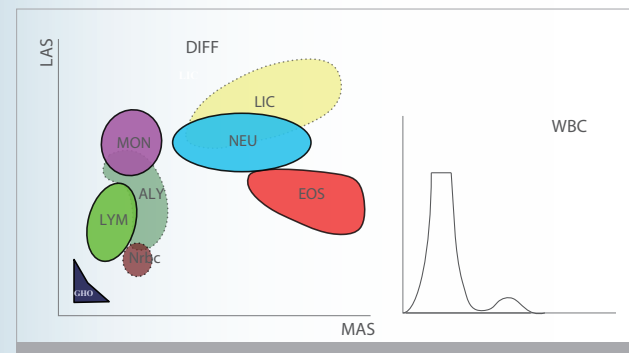
WBC histogram only indicates regional abnormal graph, it can't bring specific flags for different clinical cases.

## WBC differential: 5-part



5-part hematology analyzers can provide Lymphocyte, Monocyte, Neutrophil, Eosinophil and Basophil results for every sample. Additionally, the 5-part results are less affected by abnormal cells.

## Flag information: 5-part



5-part hematology analyzers provide more detailed and specific flag information. Users are able to clearly understand the clinical significance of flags and make a decision.



Dr Marisela Ramos, lab manager

Users are able to access our tailored innovation and intelligent diagnosis support to safeguard their diagnoses decisions with maximum confidence.

*She said: " we upgraded to a 5-part hematology analyzer 3 months ago, and it's been working very well. Our lab has lots of abnormal samples, such as Eosinophilia and Monocytosis samples. We could only get the information that the mid-size cells percentage was higher than normal level, but couldn't distinguish which kind of cells increased exactly. Now, the 5-part hematology analyzer provides flags directly, which reduces smears need to be reviewed, and significantly improves our work efficiency."*

# BC-5150

## Auto Hematology Analyzer

Based on Mindray's continuous innovation in hematology field, BC-5150 is especially tailored to assist diagnostic labs who need full CBC + 5-part results, with relatively low daily sample volume, restricted lab space and tight budget.

As the lightest and most compact 5-part hematology analyzer so far from Mindray, BC-5150 is a highly user-friendly and innovative analyzer that offers cost efficient CBC and 5-part white cell differential results. It is targeted to fulfill and exceed the demands of our global customers by providing more accurate, more efficient and more innovative solutions for labs.

WBC 5-part differentiation, 25 reportable parameters and 12 research parameters, 3 histograms and 3 scattergrams

Whole blood mode, Capillary whole blood mode and Prediluted mode

Tri-angle Laser scatter + Chemical dye + Flow cytometry technology

Dedicated optical counting channel for Basophil measurement

Powerful capability of flagging abnormal cells

10.4 inch large TFT touch screen with user-friendly software

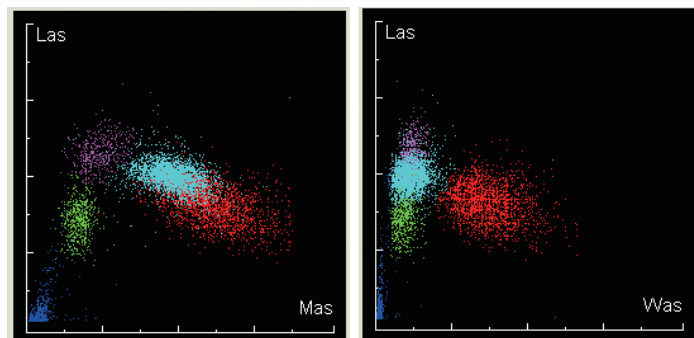
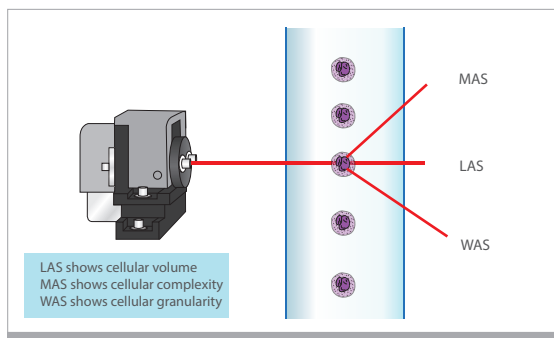
Large storage capacity: up to 250,000 samples

Throughput: 60 samples per hour

Sample volume is only 15 $\mu$ L which is ideal for pediatrics

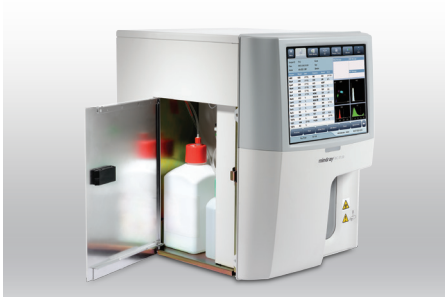


Tri-angle laser scatter + focused flow + chemical dye, creating the possibility for a better 5-part WBC differentiation even on samples with high Eosinophil.





BC-5150, the 5-part hematology analyzer offers a great solution for clinical labs, especially for those who have limited space. Its compact foot-print is a result of innovative technology improvements, including miniaturized semi-conductor laser source, highly integrated electronic boards and optimized liquid handling system.



## Compact

Two kinds of lyse reagents are located inside of BC-5150, which helps the small labs to save space.



## Utility

The 10.4 inch TFT touch screen with a wide viewing angle, brings convenience to clinicians. Users can complete all instrument operations on the screen, practically eliminating the need for an external PC.



BC-5150 inherits its convenient and proven powerful software design from BC-6800 and BC-3600 platforms, the friendly interface is ideal for small sized labs.

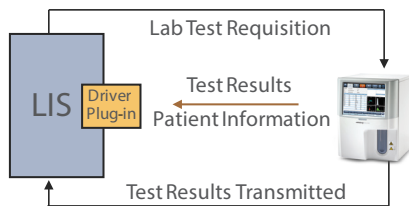


Running capillary blood through the sample probe directly is more convenient for the users in children's hospitals, etc. For Prediluted mode, BC-5150 has higher dilution ratio than other 5-part hematology analyzers, thus it brings a better mixing effect.



4 USB ports are located on the instrument's left side. They permit BC-5150 users to transmit data conveniently and connect with printers, keyboard, mouse, barcode scanner, etc.

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BC-5150 supports bi-directional LIS with test results and patient information. HL7 protocol is supported as well.

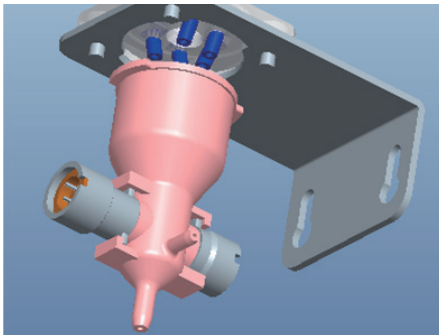
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## Technology

Compared with traditional helium neon laser or argon laser, semi-conductor laser has smaller size, lower cost and longer life cycle.

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Improved DC impedance technology is used to count and size the RBC and PLT. The smaller counting aperture (50  $\mu\text{m}$  in diameter) provides better performance on samples with low PLT.

---



## Efficient

Only three routine reagents are required. These have 2 years shelf life and also less consumed by BC-5150. Original QC and calibrator are also provided to ensure the hematology analyzer's traceability and testing quality.

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## Technical Specifications

### Principles

Impedance method for RBC and PLT counting  
Cyanide free reagent for hemoglobin test  
Flow Cytometry (FCM) + Tri-angle laser scatter + Chemical dye method for WBC 5-part differential analysis and WBC counting

### Parameters

25 parameters: WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#, Mon#, Neu#, Eos#, Bas#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC.

12 research parameters including LIC%, LIC#, ALY%, ALY#, PLT Clumps#, PLT Clumps%, Lip#, Lip%, NRBC#, NRBC%, Blast#, Blast%

3 histograms for WBC, RBC and PLT

3 scattergrams for WBC differential

### Reagent

M-52D Diluent, M-52DIFF Lyse, M-52LH Lyse, Probe Cleanser

### Performance

Parameter	Linearity Range	Precision	Carryover
WBC	0-500×10 <sup>9</sup> /L	≤2% (4-15×10 <sup>9</sup> /L)	≤0.5%
RBC	0-8×10 <sup>12</sup> /L	≤1.5% (3.5-6.0×10 <sup>12</sup> /L)	≤0.5%
HGB	0-250g/L	≤1.5% (110-180g/L)	≤0.6%
PLT	0-5000×10 <sup>9</sup> /L	≤6.0% (100-149×10 <sup>9</sup> /L) ≤4.0% (150-500×10 <sup>9</sup> /L)	≤1.0%

### Sample Volume

Prediluted mode	20 μL
Whole blood mode	15 μL
Capillary whole blood mode	15 μL

### Throughput

60 samples per hour

### Display

10.4 inch TFT Touch Screen

### Multi-language

Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

### Data Storage Capacity

Up to 250,000 results including numeric and graphical information

### Communication

LAN port supports HL7 protocol

### Interface

USB, LAN

Support bi-directional LIS

### Printout

External Thermal printer / Laser printer / Inkjet printer, various printout formats and user-defined formats

### Operating Environment

Temperature: 10°C~30°C

Humidity: 20%~85%

Air pressure: 70 kPa~106 kPa

### Power requirement

100V-240V

50Hz/60Hz

### Dimension and Weight

Depth(400 mm) x width(320 mm) x height(410 mm)

Weight :24kg

# BS-620M

## Биохимический анализатор

### Технические характеристики

#### Функционал системы:

Производительность: 600 фотометрических тестов в час, до 800 тестов в час с ISE модулем

Принципы измерений: Абсорбционная фотометрия, турбидиметрия

Методы анализа: до 77 фотометрических тестов + 3 ISE электрода + 3 сывороточных индекса

Методики: Конечная точка, фиксированное время, кинетика, ISE

#### Работа с образцами:

SDM: 120 образцов на 12 штативах, непрерывная загрузка образцов, приоритетная подача срочных образцов

Объем образца: 1,5–45 мкл с шагом 0,1 мкл

Образец HbA1c: Цельная кровь для анализа на HbA1c

Пробозаборник: Определение уровня жидкости, определение сгустков, защита от столкновений

#### Работа с реагентами:

Лоток для реагентов: 80 позиций с системой охлаждения (2–8°C)

Объем реагента: 10–200 мкл с шагом 0,5 мкл

Зонд для реагентов: Определение уровня жидкости, определение пузырьков, защита от столкновений

#### Встроенное устройство считывания штрих-кодов:

Устройства считывания штрих-кодов с образцов и реагентов поддерживают такие системы кодирования, как Codabar, ITF (2 из 5 чередующийся), Code 128, Code 39, UPC/EAN и Code 93; Может обмениваться данными с ЛИС в двунаправленном режиме

#### Реакционная система:

Реакционный объем: 70–300 мкл

Температура реакции: 37°C с колебанием температуры 0,1°C

Реакционные кюветы: 124 кюветы

многоразового использования с

8-ступенчатой автоматической промывкой

#### Оптическая система:

Источник света: Галоген-вольфрамовая лампа

Фотометр: Фотометр с дифракционной решеткой

Длина волны: 16 длин волн (340 нм, 380 нм, 412 нм, 450 нм, 480 нм, 505 нм, 546 нм, 570 нм, 605 нм, 630 нм, 660 нм, 700 нм, 740 нм, 770 нм, 800 нм, 850 нм)

Диапазон поглощения: 0–3,5 коэф (конверсия 10 мм)

#### Контроль и калибровка:

Режим калибровки: Линейная (одноточечная, двухточечная и многоточечная), Logit-Log 4P, Logit-Log 5P, Сплайн, экспоненциальная, полиномиальная, параболическая

Правила контроля качества: Система правил Вестгарда, Twin plot

#### Операционный блок:

Операционная система: Сенсорный экран (дополнительно), Windows 10 (64 бит)

Интерфейс: RS-232, сетевой порт, USB/параллельный порт

#### Условия эксплуатации:

Источник питания: 200–240 В, 50/60 Гц, 1700 В-А или 110/115 В, 60 Гц, 1700 В-А

Температура: 15–30°C

Относительная влажность: 35–85 %

Размеры: 1380 мм (длина)\*860 мм (ширина)\*1200 мм (высота)

Вес: 350 кг



[www.mindray.com](http://www.mindray.com)

№ изделия: RU-BS-620M-210285X8P-20220902  
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# mindray

Качественное медицинское обслуживание для всех

# mindray

## BS-620M

Биохимический анализатор

# Мощный и эффективный



# BS-620M

Мощный и эффективный

mindray

BS-620M



## Гибкое управление образцами

- Перемещение партии образцов
- Непрерывная загрузка образцов на штативы
- Приоритетная подача срочных образцов (STAT-образцов)
- Незамедлительный повторный анализ



## Анализ цельной крови на гликированный гемоглобин (HbA1c)

- Сертификация согласно NGSP и прослеживаемость согласно IFCC
  - Встроенный гемолиз без подготовки образцов
- Значительная интерференция вариантов гемоглобина отсутствует
  - Более низкий предел обнаружения гемоглобина, снижение количества повторных анализов



## Интегрированный ионоселективный модуль

- 1 пробирка для крови для выполнения анализов на электролиты и биохимических анализов фотометрическими методами
- Длительный срок службы ионоселективных электродов
- Простота эксплуатации и технического обслуживания



## Надежная система тестирования

- Отличные показатели сигмаметрии мирового уровня при использовании оригинальных реагентов
- Интеллектуальное обнаружение аномальных реакций, сигнализация и автоматический повтор анализа для минимизации ошибочных результатов

Небольшая  
занимаемая  
площадь:

**1,2 м<sup>2</sup>**

600 фотометрических  
тестов в час, до 800  
тестов в час cISE  
модулем



## Анализ цельной крови на гликированный гемоглобин (HbA1c)



Встроенный гемолиз образцов цельной крови для повышения эффективности работы  
Предварительная обработка без вмешательства оператора для снижения риска биологического загрязнения и вероятности ошибок, связанных с человеческим фактором  
120 тестов/час при исследовании на HbA1c для сокращения времени выполнения анализа

## Гибкое управление образцами

### Непрерывная загрузка образцов

Непрерывная загрузка образцов на штативы  
До 120 позиций для образцов  
Увеличение времени работы без участия оператора



### Быстрый запуск для повторного анализа образцов

Автоматический запуск для анализа образцов  
Автоматическая приоритетная подача срочных образцов и повторный анализ

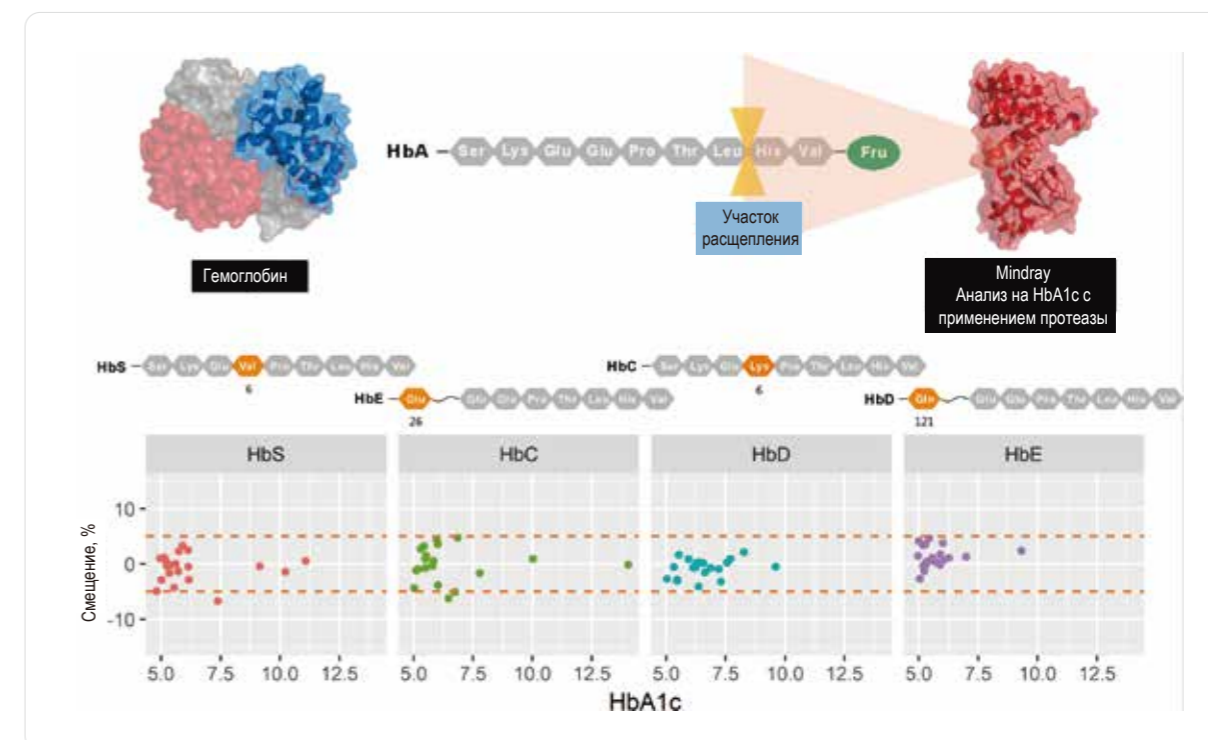
### Приоритетная подача срочных образцов (STAT-образцов)

Выделенная позиция для срочных образцов,  
аспирация 1 минута  
Быстрый отчет о результатах ISE+CO2 за 7 минут

### Интеллектуальное разбавление

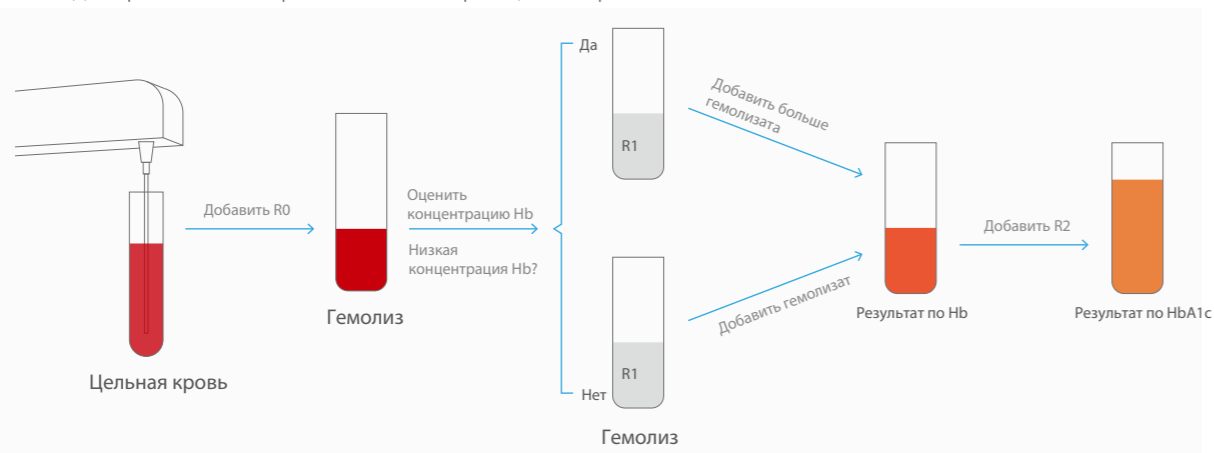
Запатентованная функция интеллектуального разбавления  
Оперативное получение результатов

Благодаря реагенту HbA1c компании Mindray при использовании ферментативного метода анализа можно точно определять гликированные N-концевые аминокислоты из бета-цепей гемоглобина, что позволяет эффективным образом избежать интерференции вариантов гемоглобина (HbS, HbC, HbE и HbD) и других производных гемоглобина (лабильный HbA1c, карбамелированный Hb и ацетилированный Hb). Ферментативный метод анализа на гликированный гемоглобин (HbA1c) компании Mindray дает надежные и экономически эффективные результаты с самого первого измерения и сокращает количество последующих подтверждающих исследований.



## Нижний предел обнаружения гемоглобина для анализа на HbA1c

Выполняется оценка концентрации гемоглобина в процессе гемолиза и заблаговременное начало тестов на увеличение концентрации в образцах с низкой концентрацией гемоглобина. Данная функция позволяет понизить предел обнаружения и расширить линейную область определения концентрации гемоглобина с целью уменьшения количества повторных тестов и снижения отходов реагентов при анализе образцов с признаками анемии.



## Интегрированный ионоселективный модуль

### Встроенный ионоселективный модуль

- Выдача результатов по Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>
- 1 пробирка для крови для выполнения анализов на электролиты и биохимических анализов фотометрическими методами



### Эффективное и простое управление

- До 300 тестов в час
- Срок службы электродов Na/K/референтных электродов до 9 месяцев
- Автоматическая калибровка
- Малый расход
- Простота эксплуатации и технического обслуживания

## Надежная система тестирования



### Высокий уровень показателей сигматрии

Оригинальные реагенты и утвержденный протокол применения снижают процент неточностей и погрешностей, что способствует достижению отличных показателей сигматрии мирового уровня. Система с более высоким показателем сигма позволяет лабораториям обеспечивать высокий уровень качества при меньших затратах, а также повышает уверенность и удовлетворенность медицинских работников.

### Интеллектуальное обнаружение аномальных реакций

Мощное программное обеспечение со встроенными алгоритмами, которые могут отслеживать реакцию на наличие отклонений, подавать сигналы тревоги и запускать автоматический повтор анализа образцов, у которых наблюдаются отклонения от нормы во время тестирования, например, истощение субстрата, нехватка кислорода, хук-эффекты и пр. Такой интеллектуальный подход с функциями обнаружения, сигнализации и автоматического повтора анализа минимизирует количество ложных результатов и риск постановки неправильного диагноза, а также позволяет получить точные и надежные результаты исследований.



**mindray**

# BS-2000 Modular System

Clinical Chemistry Solution





# Mindray Clinical Chemistry Solution

## High Throughput

2000 photometric tests/hour

Up to 600 tests/hour for ISE

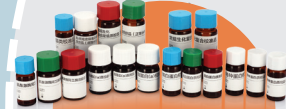
Up to four modules integrated capability

Flexible scalability

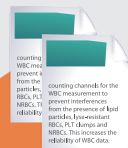
High Performance Instrument



BS-2000  
Modular System



Original Calibrators  
and Controls



Quality Management  
System

Professional Service

## Advanced Software

Results traceability

Reflex function

Flexible STAT & rerun

Real-time status monitoring

CAUTION  
LIQUID PROBE COLLISION  
The PLT test probe is primary  
probe. Do not touch the probe  
tip.

WARNING  
Do not touch the probe tip.

WARNING  
Do not touch the probe tip.

## Reliable Results

- Advanced mechanical system
- Complete reference system
- Integral traceability system
- International traceability certificate

Reliable Results

Standardization  
Laboratory

Reference  
Laboratory

Dedicated Chemistry  
Reagents

Dedicated Reagent System

## Dedicated Reagent System

- Wide panel clinical chemistry assays
- Original calibrators and controls
- Reliable performance
- ISO standard quality

WARNING  
MOVING PARTS  
Do not touch when in operation.

CAUTION  
AVOID FACE COLLISION  
Ensure that the face cover is properly  
closed. Do not remove the cover  
when in operation.

WARNING  
MOVING PARTS  
Do not touch when in operation.

# BS-2000 Modular System

## Reagent Carousel 2

1. 70 positions (40 outer and 30 inner) for R2 and R4
2. 2°C-8°C constant cooling compartment
3. Reagents can be online loaded while instrument is running

## Probe R21 and Probe R22

1. 10µl-200µl, with increment of 0.5µl
2. Bubble detection, liquid level detection
3. Collision protection and auto recovery from collision

## Probe R11 and Probe R12

1. 80µl-200µl, with increment of 0.5µl
2. Bubble detection, liquid level detection
3. Collision protection and auto recovery from collision

## Reagent Carousel 1

1. 70 positions (40 outer and 30 inner) for R1 and R3
2. 2°C-8°C constant cooling compartment
3. Reagents can be online loaded while instrument is running

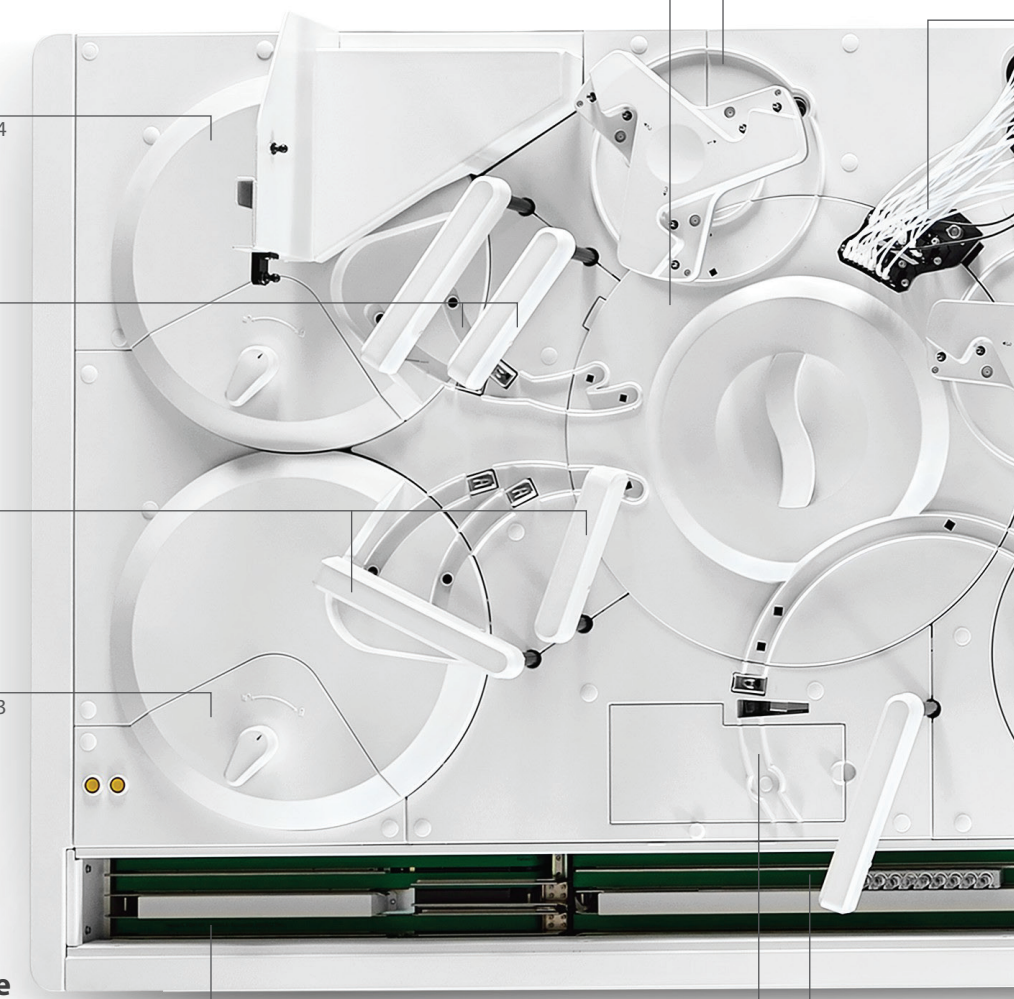
## Return Lane

## Reaction Carousel

1. 80µl minimum reaction volume
2. 412 glass cuvettes for permanent use
3. Direct solid heating

## 6-head Sample Mixer

1. Flat mixing bar with high efficiency
2. Two-step washing with pre-heated detergent and water
3. Easy replacement and maintenance



## Indirect ISE

- Low sample volume, high ISE analysis throughput, and cost-effective electrodes.
- Independent buffer aspiration system – buffer syringe transfers ISE reagent to mixer through ISE buffer nozzle.

## Dual-needle S

1. 1.5µl-25µL, with increment of 0.5µl
2. Clog detection, bubble detection and tracking
3. Collision protection and auto recovery from collision

# System Layout

## 6-head Reagent Mixers

Efficiency  
Pre-heated  
Maintenance



## 8-stage Cuvette Wash Station

1. Cuvette washing with pre-heated detergent and water
2. Independent water blank measurement



## Sample Delivery Module (SDM)

1. Patented double-layer & basket delivery design, up to 600 sample positions
2. Continuous sample loading and off loading
3. 5 types of racks

## Sample Carousel

1. 140 positions for different types of sample tubes
2. 25 positions in cooling compartment for calibrators and controls
3. Flexible for STAT, rerun or other routine samples with higher priority

## Individual STAT Lane

1. 32s quick response
2. One touch to initiate analysis

## Sample Probe

Measurement of 0.1µL  
Sensitivity for low level detection, level  
control and auto recovery

## Passing Lane

1. Higher priority for STAT, calibrator, control and rerun racks
2. For routine sample racks to be transferred to other analytical unit(s)

## Normal Lane

# Advanced Software



## User-friendly Interface

- Unified platform for BS-2000 series, BS-800 series, BS-480 and future instrument
- Real-time status monitoring of analytical unit, SDM and carousels



## Real-time QC Status Monitoring

- Westgard Rules and Two-Control Evaluation check
- Levey-Jennings chart and Twin-Plot chart for review
- Real-time alarm and locating when QC result(s) is out of range
- Auto QC setup capability

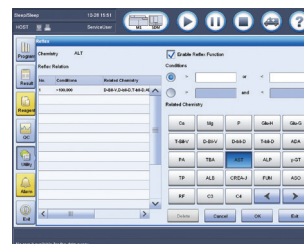
## Traceable Test Results

- Reagent, calibrator and control information can be recalled from archive history
- User-friendly, intuitive software design, easy to trace results



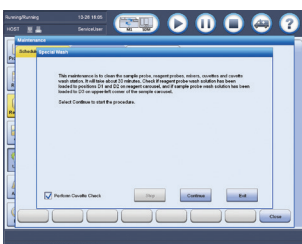
## Reflex Function

- Pre-defined reflexive assays will be performed automatically when preset criteria is met
- Each assay may involve multiple reflexive criterias
- Each criteria may initiate up to a maximum of 20 relevant assays



## Test Summary

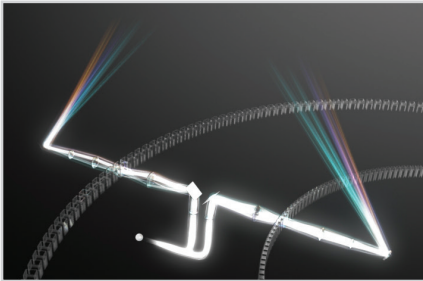
- Test summary during certain period, including calibration, QC, sample, valid tests and rerun tests
- Facilitate to computation of total test costs within a defined period
- The summary can be archived into excel files or printed for review and backup



## Step-by-step Maintenance Guide

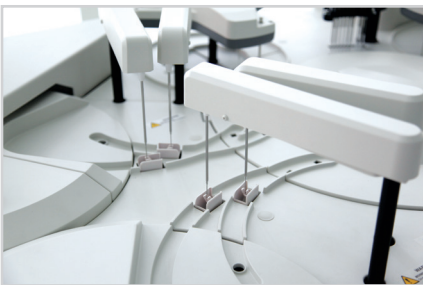
- Scheduled maintenance and maintenance guide for chemistries and ISE
- Ensure performance reliability and reduce unnecessary service calls
- Error report transferrable to service engineers for immediate troubleshooting; minimize instrument downtime

# Reliable Results



## Enhanced Optical System

- Dual-optical system with same light source
- Dual-lens and dual-diaphragm technology
- 80 $\mu$ L minimum reaction volume



## High Precision Aspirating

- 1.5 $\mu$ L-25 $\mu$ L, with increment of 0.1 $\mu$ L for sample probe
- Non-touch dispensing for sample
- 80 $\mu$ L-200 $\mu$ L, with increment of 0.5 $\mu$ L for R11 and R12 probes
- 10 $\mu$ L-200 $\mu$ L, with increment of 0.5 $\mu$ L for R21 and R22 probes

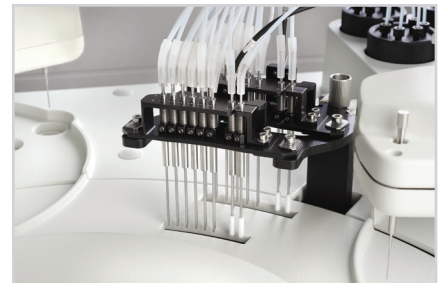
## High Performance Reaction System

- Two 6-head mixing units for reagent and samples
- Direct solid heating for reaction carousel
- Glass cuvettes for permanent use



## Efficient Washing System

- Interior & exterior probe washing with high pressure pre-heated water
- Programmable enhanced washing with detergent for reagent and sample probes
- 8-stage cuvette wash station, washing cuvettes with pre-heated detergent and water
- Two-step mixer washing with pre-heated detergent and water



## Stable Cooling Compartment

- 2°C-8°C constant cooling compartment for reagents
- Constant cooling compartment for calibrators and controls in sample carousel



## Accurate, Reliable Results

To ensure accuracy, reliability and correlation of diagnostic data, Mindray utilizes the International Standard in result reporting. To assure ease of report retrieving, Mindray establishes the Mindray Clinical Chemistry Measurement System for result traceability.



### Standard reference system

- Adopt JCTLM reference system
- IFCC primary method for enzyme, ID/MS method for substrate
- NIST, IRMM reference materials



JCTLM, Joint Committee On Traceability In Laboratory Medicine

NIST, National Institute of Standards and Technology, USA

IRMM, Institute for Reference Materials and Measurements, EU

IFCC, International Federation of Clinical Chemistry and Laboratory Medicine

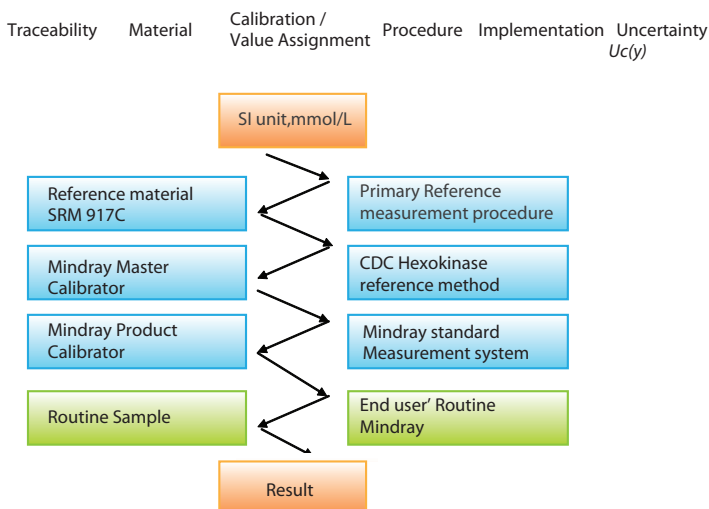
### Complete traceability process

- Complete calibration hierarchy and traceability chain based on ISO standard (EN/ISO17511) from reference system to routine measurement system

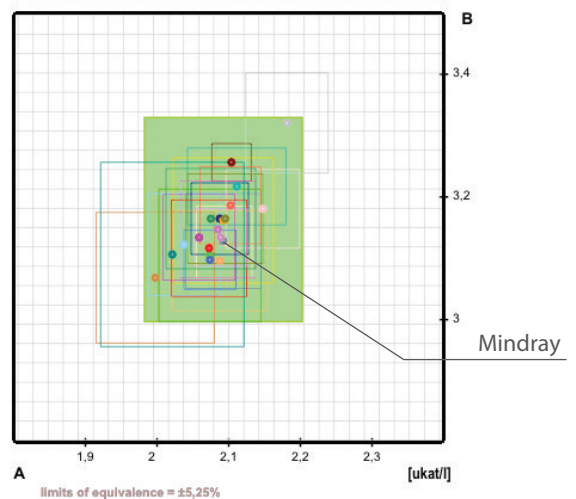
### Proficiency testing for reference measurement

- Participate RELA (External quality control for reference laboratory) to verify the accuracy of the value assignment procedure.

#### Traceability chain of Mindray measurement system (Glu)



ALT



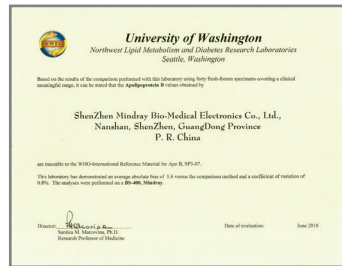
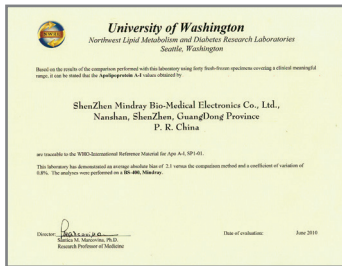
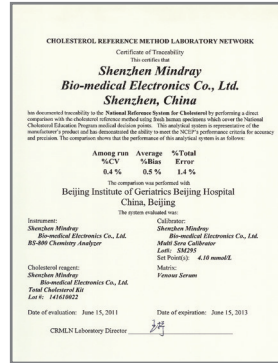
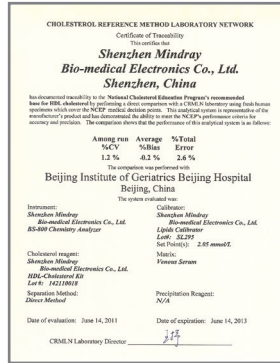
## International standardization certification

- International Standardization certificates of Cholesterol and Hba1c from CRMLN and NGSP.

More information refers to website (<http://www.cdc.gov>).

CRMLN (Cholesterol Reference Method of Laboratory Network)

NGSP(National glycosylated hemoglobin standardization program)



## Matched calibrators and controls

- Dedicated calibrators with traceability and specific target value
- Convenient design of multi items of calibrators and controls combined into one vial
- Long shelf life of lyophilized powder

## Dedicated, high-quality reagents

- Diagnostic function test panels

Test panels such as : Hepatic panel, renal panel, pancreatic panel, lipid panel, cardiac panel, diabetic panel, rheumatic factor panel

- Reliable analysis performance

EP series standard (CLSI)-evaluate and optimize reagent system for reliable performance in precision, linearity, stability, specificity and anti-interference capability

- ISO standard manufacturing

Mindray follow straightly the ISO Certified manufacturing process to ensure every lot of reagent in production are of supreme quality





# Reagent Menu

## Hepatic Panel

---

Alanine Aminotransferase (ALT)  
Aspartate Aminotransferase (AST)  
Alkaline Phosphatase (ALP)  
γ-GlutamylTransferase (γ-GT)  
Bilirubin Direct (Bil-D) DSA Method  
Bilirubin Direct (Bil-D) VOX Method  
Bilirubin Total (Bil-T) DSA Method  
Bilirubin Total (Bil-T) VOX Method  
Total Protein (TP)  
Albumin (ALB)  
Total Bile Acids (TBA)  
Prealbumin (PA)  
Cholinesterase (CHE)  
α-L-fucosidase (AFU)  
5'-nucleotidase (5'-NT)

## Renal Panel

---

Urea (UREA)  
Creatinine (CREA) Modified Jaffé Method  
Creatinine (CREA)Sarcosine Oxidase Method  
Uric Acid (UA)  
Carbon dioxide (CO2)  
Microalbumin  
β2-Microglobulin (β2-MG)  
Cystatin C (CysC)  
Retinol binding protein( RBP)

## Cardiac panel

---

Creatine Kinase (CK)  
Creatine Kinase-MB (CK-MB)  
Lactate Dehydrogenase (LDH)  
α-Hydroxybutyrate Dehydrogenase(α-HBDH)  
High sensitive C-reactive protein (HS-CRP)  
Homocysteine (HCY)  
Myoglobin(MYO)  
D-Dimer(D-Dimer)

## Inorganic & Anemia

---

Iron (Fe)  
Ferritin (FER)  
Transferrin (TRF)  
Calcium (Ca)  
Magnesium (Mg)  
Phosphorus (P)  
Unsaturated iron binding capacity (UIBC)  
Glucose-6-phosphate dehydrogenase (G6PD)

## Lipid Panel

---

Total Cholesterol (TC)  
Triglycerides (TG)  
HDL-Cholesterol (HDL-C)  
LDL-Cholesterol (LDL-C)  
Apolipoprotein A1 (ApoA1)  
Apolipoprotein B (ApoB)  
Lipoprotein(a) [Lp(a)]

## Immune Panel

---

Immunoglobulin A (IgA)  
Immunoglobulin G (IgG)  
Immunoglobulin M (IgM)  
Immunoglobulin E (IgE)  
Complement C3 (C3)  
Complement C4 (C4)

## Diabetes Panel

---

Glucose (Glu) GOD-POD Method  
Glucose (Glu) HK Method  
Hemoglobin A1c (HbA1c)  
Fructosamine (FUN)  
β-Hydroxybutyrate(β-HB)

## Rheumatism Panel

---

C-reactive protein (CRP)  
Rheumatoid Factor (RF)  
Antistreptolysin "O"(ASO)

## Pancreatitis Panel

---

α-Amylase (α-AMY)  
Lipase (LIP)

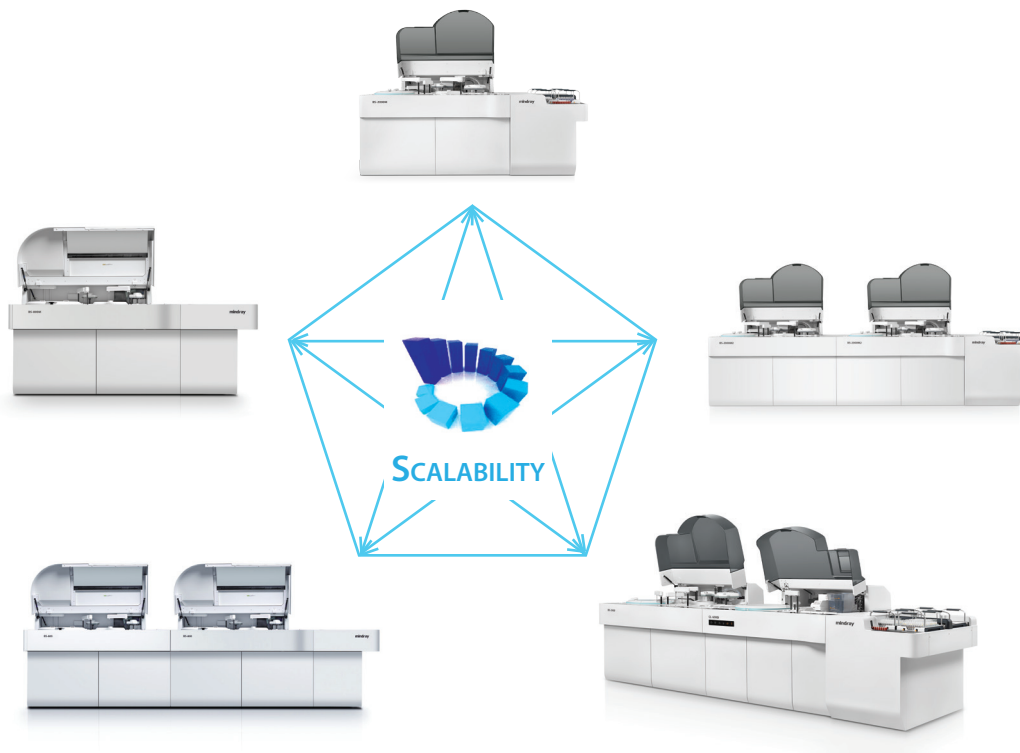
## Lung Panel

---

Adenosine Deaminase (ADA)  
Angiotensin Converting Enzyme(ACE)



## Flexible Scalability



BS-2000 Modular System, the highest throughput chemistry system ever designed by Mindray, is a brand new solution package for hospitals and clinical laboratories with high sample volumes. It combines innovation and high performance into a fully integrated solution, together with the complete line of original reagents, calibrators with metrological traceability and controls. It offers customers a versatile solution with high efficiency, automation and scalability. Furthermore it will lay the foundation for further modular integration with Mindray's future products.



## Technical Specifications \*

### System function

Fully automated, discrete, random access, STAT sample priority  
Throughput: 2000 photometric tests/hour, up to 600 tests/hour for ISE  
Measuring Principles: Colorimetry, Turbidimetry and Indirect ISE method  
Methodology: End-point, Fix-time, Kinetic, optional ISE

### Sample Handling

Sample Carousel: 140 positions, 25 cooling positions for calibrators and controls  
Sample Delivery Module (SDM): Patented double-layer & basket delivery design, up to 600 sample positions  
Sample Racks: 10 samples/rack  
Sample Probe: Liquid level detection, clot & bubble detection, horizontal and vertical collision protection  
Sample Volume: 1.5 $\mu$ l-25 $\mu$ l, with increment of 0.1 $\mu$ l  
Probe Washing: Interior and exterior probe washing  
Programmable enhanced washing with detergent  
Carry over < 0.1%  
Automatic Sample Dilution: Pre-dilution, post-dilution and auto-dilution for sample  
Dilution ratio: 4~134  
Barcode Reader: Integrated bar code scanner in SDM  
Sample carousel barcode scanner (optional)

### Reagent Handling

Reagent Carousel: 140 positions  
Refrigerated compartment (2~8 $^{\circ}$ C)  
Reagent Bottle: Mindray 20ml and 62ml  
Barcode Reader: Bar code scanner for two reagent carousels  
Reagent Probe: Liquid level detection, clot & bubble detection, horizontal and vertical collision protection  
Reagent Volume: 80 $\mu$ l-200 $\mu$ l, with increment of 0.5 $\mu$ l for R11 & R12 probes  
10 $\mu$ l-200 $\mu$ l, with increment of 0.5 $\mu$ l for R21 & R22 probes  
Probe Washing: Automatic interior and exterior probe washing  
Programmable enhanced washing with detergent  
Carry over < 0.1%  
Reagent Loading: Reagent bottles can be online loaded while instrument is running

### Reaction System

Reaction Carousel: 412 permanent glass cuvettes with 8-stage automatic washing  
Cuvette: Optical length 5mm  
Reaction Volume: 80 $\mu$ l-280 $\mu$ l  
Reaction Temperature: 37 $^{\circ}$ C with fluctuation of  $\pm$  0.1 $^{\circ}$ C  
Mixing Unit: Two 6-head highly polished mixing bar units for reagent mixing and sample mixing; two-step washing with pre-heated detergent and water

### Optical System

Light Source: 12V/50W Halogen-tungsten lamp  
Photometer: Holographic concave flat-field gratings  
Wavelength: 13 wavelengths: 340nm~850nm  
Absorption Range: 0~3.5A (10mm conversion)  
Resolution: 0.0001Abs

### ISE Module (Optional)

Indirect Method, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup> tests, with 22 $\mu$ l sample volume  
Throughput: up to 600 tests/hour

### Operation Unit

Operation System: Window XP Professional or Windows 7 Professional (32bit)

### Working Conditions

Power Supply: 110V/115V~, 60Hz; 220V-240V~, 50Hz; 220V/230V~, 60Hz  
Input Power: 4500VA for each analytical unit, SDM: 800VA  
Operating Temperature: 15 $^{\circ}$ C~30 $^{\circ}$ C  
Relative Humidity: 35%RH~85%RH, without condensation  
Water consumption: <85L/hour De-ionized water  
Dimension: 1600mm(Length) $\times$ 1050mm(Depth) $\times$ 1300mm (Height)  
for each analytical units, 710mm(Length) $\times$ 1020mm(Depth)  
 $\times$ 1000mm(Height) for SDM  
Weight:  $\leq$ 550Kg for each analytical unit, 150kg for SDM

\*For single analytical unit