ORDIN DE PLATA NR.: 2521 TIP.DOC. 1

DATA EMITERII:joi, 21 decembrie

PLATITI: 4500-00 LEI: Patru Mii Cinci Sute lei 00 ba
ni

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.

CONTUL DE PLATI/CODUL IBAN MD95ML000000002251429243

CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR: BC"Moldindconbank"S.A. suc."Invest" Chisinau

CODUL BANCII: MOLDMD2X329

BENEFICIAR (R) IMSP SCM Gh
eorghe Paladi

CONTUL DE PLATI/CODUL IBAN MD24ML000000022518094481

CODUL FISCAL :1003600152673 /

PRESTATORUL BENEFICIAR: BC"Moldindconbank"S.A.

CODUL BANCII: MOLDMD2X

DESTINATIA PLATII:Pentru garantia pentru
oferta la procedura de achizi?ie public
a nr. ocds-b3wdp1-MD-1702368935056 din 2
2.12.2023

TIPUL TRANSFERULUI NORMAL/URGENT :N

L.S.

CODUL TRANZACTIEI:001

DATA PRIMIRII:21/12/2023

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb
DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSq
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4
DTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X
DTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

L.S. (semnatura electronica)

CONDUCATOR: ____________________

(semnatura manuala)

CONTABIL-SEF: ____________________

(semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Poiata Vitalie
Date: 2023.12.21 18:13:02 EET
Reason: MoldSign Signature
Location: Moldova

GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № **1030048**

Din / От **19.12.2023 10:30**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1010600028048

Denumirea
Наименование

Societatea cu Răspundere Limitată BIOSISTEM MLD

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **03.01.2024 10:30**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **19.12.2023 10:30**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлиности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

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: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

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

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor 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 şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

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

Asociaţii:
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 şi a întreprinzătorilor individuali şi 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

Date cu caracter personal

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

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

Дата предоставления 28.03.2023 14:26:11

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2022 - 31.12.2022

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIÎO: 40717392
Cod IDNO: 1010600028048

Sediul:
MD:
Raionul(municipiul): 106, DDF RISCANI
Cod CUATM: 0150, SEC.RISCANI
Strada: SECTORUL RISCANI STR.Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:
E-mail: zmii13@mail.ru
Numele și coordonatele al contabilului-șef: Dl (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 5 **persoane.**

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

Anexa 1

la

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE **I. Imobilizări necorporale**			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care: 2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024		
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	3559998	3384131
	din care: 3.1. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	3533108	3363063
	3.4. mijloace de transport	084		

A.	3.5. inventar și mobilier	085	26890	21068
	3.6. alte mijloace fixe	086		
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120	1162136	5250844
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	4722134	8634975
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140		
	2. Investiții financiare pe termen lung în părți afiliate, total	150		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
	2.2 împrumuturi acordate părților afiliate	152		
	2.3 împrumuturi acordate aferente intereselor de participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	4722134	8634975
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	5346	13899
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	9147976	11123640
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	9153322	11137539
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	2182471	4552459
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	208171	27696
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	1608597	2268111
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	3999239	6848266
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		

	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	9861933	10281443
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	23014494	28267248
	TOTAL ACTIVE (rd.230 + rd.420)	430	27736628	36902223
	P A S I V			
	CAPITAL PROPRIU **I. Capital social și neînregistrat**			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	( )	( )
	3. Capital neînregistrat	460		
	4. Capital retras	470	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
C.	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	26634334	22485398
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	13391573
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	26634334	35876971
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	26639734	35882371
	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
D.	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	din care: 2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	343711	5266
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	355528	143160
	6. Datorii față de personal	760	350	866
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	150263	831429
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	247042	39131
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	1096894	1019852
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	27736628	36902223

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2022 pînă la 31.12.2022

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	38680547	40621876
din care: venituri din vînzarea produselor și mărfurilor	011	37724557	39203671
venituri din prestarea serviciilor și executarea lucrărilor	012	951393	1390733
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vînzări	016	4597	27472
Costul vînzărilor, total	020	24434231	22086174
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	24433364	21991682
costul serviciilor prestate și lucrărilor executate terților	022		92356
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vînzărilor	026	867	2136
Profit brut (pierdere brută) (rd.010 - rd.020)	030	14246316	18535702
Alte venituri din activitatea operațională	040	5189	128694
Cheltuieli de distribuire	050	6076	15271
Cheltuieli administrative	060	1788732	3076978
Alte cheltuieli din activitatea operațională	070	1870642	1325483
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10586055	14246664

Venituri financiare, total	090	1517765	1530710
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093	30619	250190
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	1487146	1280520
Cheltuieli financiare, total	100	249562	512939
din care: cheltuieli privind dobînzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	249562	512939
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	1268203	1017771
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	1268203	1017771
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	11854258	15264435
Cheltuieli privind impozitul pe venit	170	1450263	1872862
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	10403995	13391573

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	**Capital social și neînregistrat**					
	1. Capital social	010				
	2. Capital nevărsat	020	( )	( )	( )	( )
	3. Capital neînregistrat	030				
	4. Capital retras	040	( )	( )	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	**Prime de capital**	070				
III.	**Rezerve**					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X			
	4. Profit utilizat al perioadei de gestiune	150	X	( )	( )	( )
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	**Rezerve din reevaluare**	170				
VI.	**Alte elemente de capital propriu**	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190				

SITUAŢIA FLUXURILOR DE NUMERAR

de la pînă la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobînzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investiții			
Încasări din vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Версия для печати
Сохранить

Расписка

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1_21
На фискальный период: A/2022
Дата предоставления: 28.03.2023
Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 28.03.2023 14:26:11

Версия для печати
Сохранить

Расписка 2

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1_21
На фискальный период: A/2022
Дата предоставления: 28.03.2023
Временная метка отчёта зарегистрированного в Информационной Системе НБС : 28.03.2023 14:55:24

National Bureau of Statistics (NBS) received the electronic version of the report, sent by you. The data provided is verified by NBS.

BioSystems
REAGENTS & INSTRUMENTS

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 6th, 2012

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

Inscrita R.M. Barcelona, tomo 4.538, folio 127, hoja 48.411, libro 3.864, Sección 2ª N.I.F. A08678823

CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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

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

TECHNICAL FEATURES

Random access automatic analyzer aimed at giving IVD results with photometric reading directly in the reaction rotor.

Throughput	240 test/hour
Positions refrigerated reagents	30 (20 mL y 50 mL)
Positions for racks not refrigerated	3 (rack polivalente)
Number of samples per rack	24
Maxim capacity of samples	72
Sample tubes	ø13 mm, ø15 mm (max. height 100 mm) Cups ø13 mm
Maxim capacity of reagents	52 (30 refrigerados + 22 no refrigerados)
Reagents bottles	20 mL and 50 mL
Dispensing tip	Stainless Steel
Level detection	Capacitive
Dosing pump	Ceramic Piston of high durability
Dispensing system precision	CV < 2% with 3 µL of sample
Reagent volume (Program)	10 µL - 440 µL
Sample volume (Program)	3 µL - 40 µL
System liquid botlle volume	3000 mL
Waste bottle volume	3000 mL
Washing solution bottle volume	3000 mL
Removable methacrylate rotor	120 reaction wells
Reaction volume range (program)	180 µL - 800 µL
Lightpath	6 mm
Light source	Halogen lamp 12 V, 20 W
Photometric detection system	Silicon photodiode
Measurement range	From -0.05 A to 3.0 A
Spectral range	340 nm – 900 nm
Filter configuration	340, 405, 505, 535, 560, 600, 635, 670 nm
Physical dimensions	1080 x 695 x 510 mm (long. x wide x height)
Weight	73 kg (162 lb.)

A25

CE

BioSystems, S.A reserves the right to change specifications of the instrument at any time due to technical improvements.

RANDOM ACCESS ANALYZER

A25

BioSystems
REAGENTS & INSTRUMENTS

BTS/10-2015 99699

Ginper Group | BioSystems

www.tuv.com ID 9091006696 TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Manufactured by: BioSystems S.A.
Costa Brava 30, 08030 Barcelona (Spain) Tel. +34 93 311 00 00
biosystems@biosystems.es • www.biosystems.es

Clinical Chemistry
Turbidimetry

A25

THE PERFECT SYSTEM

BioSystems has always prioritized top quality as the main goal in all its developments, aware of the capital role played by the clinical laboratory by towards the health of people. For BioSystems, quality means providing accurate and reliable results, without compromising the ease-of-use or the mechanical reliability.

BioSystems offers the **A25** as a complete system that integrates biochemistry and turbidimetry dedicated reagents designed to achieve the highest performance, with reliable and durable mechanics and optics, and Software covering major areas of laboratory management in a simple and intuitive way: a winning combination for your laboratory.

The **A25** stylish and robust design brings the state-of-the-art technology to work in any kind of environment and workload conditions, paying special attention to optimize consumption and minimize maintenance costs.

- Throughput of 240 test/hour
- System capacity for refrigerated reagents up to 30 positions with independent power supply
- Flexibility in positioning of sample (primary tubes and paediatric vials in any position) and reagents
- Use of dedicated reagents ready to use without any manipulation or transfer
- Low water consumption: 1,6 L/h
- Minimum volume in reaction cuvette: 180 µL
- Intuitive and easy to follow software, including bidirectional LIS Integration, STAT and Internal Quality Control (Levey-Jennings graphs)
- Automated daily maintenance and self-check
- Automatic and configurable management of reagent interference
- Real prozone detection function
- Calibrator automatic dilution to prepare the calibration curves
- Automatic pre and post-dilutions of samples
- All conditioning components always installed in the system
- High accuracy dispensing systems: CV < 2% for 3 µL of sample.

DEDICATED REAGENTS

Biochemistry

Cod.	Test	Presentation R1	Presentation R2	mL/Kit
12550	α-Amylase-Direct	5x20 mL		100
12799	α-Amylase-Pancreatic	1x40 mL	1x10 mL	50
12754	Adenosine Deaminase (ADA)	4x8 mL	1x10 mL	40
12533	Alanine Aminotransferase (ALT/GPT)	5x40 mL	5x10 mL	250
12547	Albumin	5x50 mL		250
12518	Alkaline Phosphatase (ALP)-AMP	5x16 mL	2x10 mL	100
12514	Alkaline Phosphatase (ALP)-DEA	5x16 mL	2x10 mL	100
12796	Angiotensin Converting Enzyme (ACE)	1x50 mL		50
12531	Aspartate Aminotransferase (AST/GOT)	5x40 mL	5x10 mL	250
12798	Bilirubin (Direct)	5x40 mL	5x10 mL	250
12510	Bilirubin (Total)	5x40 mL	5x10 mL	250
12570	Calcium-Arsenazo	10x50 mL		500
12513	Calcium-Cresolphthalein	5x40 mL	5x10 mL	250
12558	Carbon Dioxide (CO_2)	5x50 mL		250
12505	Cholesterol	10x50 mL		500
12557	Cholesterol HDL Direct	3x20 mL	1x20 mL	80
12585	Cholesterol LDL Direct	3x20 mL	1x20 mL	80
11795	Citrate*	1x40 mL	1x10 mL	50
12524	Creatine Kinase (CK)	3x12 mL	1x10 mL	45
12566	Creatine Kinase-MB (CK-MB)	3x12 mL	1x10 mL	45
12502	Creatinine	5x50 mL	5x50 mL	500
12734	Creatinine-Enzymatic	1x45 mL	1x15 mL	60
11794	Fructose*	1x40 mL	1x10 mL	50
12520	γ -Glutamyltransferase (γ-GT)	5x40 mL	5x10 mL	250
12503	Glucose	10x50 mL		500
12756	Glucose-Hexokinase	2x40 mL	2x10 mL	100
12735	Haemoglobin A1c-Enzymatic (HbA1c-ENZ)	1x50 mL	1x20 mL	70
12737	Homocysteine	1x40 mL	1x10,8 mL	50,8
12509	Iron-Ferrozine	5x40 mL	5x10 mL	250
12736	Lactate	2x40 mL	2x10 mL	100
12580	Lactate Dehydrogenase (LDH)	5x40 mL	5x10 mL	250
12793	Lipase	2x20 mL	1x8 mL	48
12797	Magnesium	5x16 mL	2x10 mL	100
12508	Phosphorus	3x24 mL	2x15 mL	100
12500	Protein (Total)	10x50 mL		500
12501	Protein (Urine+CSF)*	5x50 mL		250
12551	Total Bile Acids*	1x18 mL	1x6 mL	24
12528	Triglycerides	10x50 mL		500
12835	Unsatured Iron Binding Capacity (UIBC)	1x40 mL	1x10 mL	50
12516	Urea/BUN-UV	5x40 mL	5x10 mL	250
12521	Uric Acid	10x50 mL		500
11526	Zinc*	2x20 mL	1x10 mL	50

*** Standard included**

Turbidimetry

Cod.	Test	Presentation R1	Presentation R2	mL/Kit
13324	Albumin (Microalbuminuria)	1x40 mL	1x10 mL	50
13923	Anti-Streptolysin O (ASO)	1x40 mL	1x10 mL	50
13936	Antithrombin III	1x40 mL	1x10 mL	50
13084	Complement Component C3	1x50 mL		50
13085	Complement Component C4	1x50 mL		50
13921	C-Reactive Protein (CRP)	2x40 mL	2x10 mL	100
13927	C-Reactive Protein-hs (CRP-hs)	1x40 mL	1x10 mL	50
13160	Cystatin C	1x45 mL	1x15 mL	60
13934	Ferritin	1x30 mL	1x15 mL	45
13600	Fibrinogen	1x40 mL	1x10 mL	50
13047	Hemoglobin A1C-Direct (Hb A1C-Direct)	1x50 mL	1x10 mL	60
13044	Hemoglobin A1C-Turbi (Hb A1C-Turbi)	1x40 mL	1x10 mL	50
13082	Immunoglobulin A (IgA)	1x50 mL		50
13081	Immunoglobulin G (IgG)	1x50 mL		50
13083	Immunoglobulin M (IgM)	1x50 mL		50
13922	Rheumatoid Factors (RF)	1x40 mL	1x10 mL	50
13091	Transferrin	1x50 mL		50

BioSystems has developed a wide range of reagents intensively evaluated in different workload conditions and validated to achieve the highest performance in A25 and A15 systems. These systems comply with the requirements of European IVD Directive (98/79/EC) and as a consequence are CE marked. BioSystems recommends their use according to the instructions and applications validated by BioSystems.

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

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

Product: Auto Hematology Analyzer

Model: BC-760[B], BC-760[R], BC-780[R]

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

Conformity Assessment Route: IVDD Annex III (excluding Section 6)

GMDN: 35476

We declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Standards Applied: List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2022-3-30

Place, Date of Issue: 2022-3-30

Signature: .....

Name of Authorized Signatory: Mr.WangXinBing

Position Held in Company: Deputy Director, Technical Regulation Department

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem IDNO 1010600028048 REPUBLICA MOLDOVA

Declaration of Conformity V 1.0

Applied Standards List

Product:	**Auto Hematology Analyzer** **BC-760[B], BC-760[R], BC-780[R]**

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-3:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2016	Graphical symbols for use in the labelling of medical devices
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN 61010-1:2010+A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN IEC 61010-2-081:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN IEC 61010-2-010:2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 62304:2015	Medical device software- Software life cycle processes
IEC 62366-1：2015	Medical devices — Application of usability engineering to medical devices
EN IEC 63000：2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. BioSistem MLD 1010600028048 REPUBLICA MOLDOVA

BC-760 & BC-780

Auto Hematology Analyzer with ESR

Key Specifications

Principles
WBC (IMG/Neu/Mon/Lym/Eos/Bas), NRBC/RET*, PLT-H/PLT-O*/IPF:
SF Cube ^ Cell Analysis Technology
^S: Scatter; F: Fluorescence; Cube: 3D analysis

RBC, PLT
Focusing Flow-DC Impedance Method

HGB
Colorimetric method

ESR
Photometric method

Number of measuring parameters (whole blood): 109
Number of reportable parameters: 41
WBC Bas# Bas% Neu# Neu% Eos# Eos% Lym# Lym% Mon# Mon% IMG# IMG% RET%* RET#* RHE* IRF* LFR* MFR* HFR* RBC HGB MCV MCH MCHC RDW-CV RDW-SD HCT NRBC# NRBC% PLT PLT-I PLT-H PLT-O* MPV PDW PCT P-LCR P-LCC IPF ESR
Number of research parameters: 68*

Number of measuring parameters (body fluid): 18
Number of reportable parameters: 7
WBC-BF TC-BF# MN# MN% PMN# PMN% RBC-BF
Number of research parameters: 11

Sample volume
CD (whole blood): 25ul CD+ESR
(whole blood): 160ul Predilute: 20ul

Data storage capacity
Up to 150,000 results including numeric and graphical information *

Throughput
CD 80t/h CDR 45t/h CD+ESR 40t/h

Analysis Mode

Sample Type	Analysis Mode
Whole blood	CBC, CBC + DIFF, CBC + DIFF+RET*, CD + ESR, CDR + ESR*, CD/WBC-3X, CDR/PLT-5X*, and other modes
Predilute	CBC, CBC + DIFF, CDR*, and other modes
Body fluid	CBC + DIFF

Physical Specifications

Dimensions
840D x 655W x 600H mm

Weight
≤70.6Kg

Voltage
100V-240V~ (±10%)

Frequency
50Hz/60Hz (±1Hz)

Power input
600VA

External output
LANx1 , USB x 4 (Specifications: DC 5V; 500mA; USB2.0 x 3; USB3.0 x 1)

Normal Operating Environment

Ambient temperature:
10℃ ~ 35℃

Relative humidity:
30% ~ 85%

Atmospheric pressure:
70.0kPa ~ 106.0kPa^
^Note : Required altitude for normal operation:
-400m ~ +3000m

Performance

Parameter	Linearity Range	Precision	Carryover
WBC	0-500×10^9 /L	≤2.5% (≥4.51×10^9 /L)	≤ 1.0%
RBC	0-8.60×10^{12}/L	≤1.5% (≥3.5×10^{12}/L)	≤ 1.0%
HGB	0-260g/L	≤1.0% (110-180g/L)	≤ 1.0%
HCT	0-75%	≤1.5% (30%-50%)	≤ 1.0%
PLT*	0-5000×10^9 /L	≤ 1.5(SD) (≤20×10^9/L)^ ≤ 2.5% (≥100×10^9/L)^	≤ 1.0%
RET*	0-0.8×10^{12}/L	≤15% (RBC ≥ 3.00×10^{12}/L RET%: 1.00% ~ 4.00%)	≤ 1.0%
ESR		≤1.8(SD)(0~20mm/h)	≤ 1.0%

Note: Applicable only to CDR/PLT-O 5x and CR/PLT-O 5x models

Items marked with an aerisk (*) apply only to BC-780

www.mindray.com

P/N:ENG-BC-760 & BC-780 ESR-210285X6P-20220115

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mindray
healthcare within reach

BC-760 & BC-780
Auto Hematology Analyzer with ESR

Above and Beyond

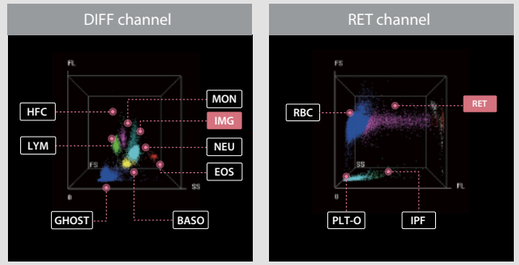
DESIGN AWARD 2021

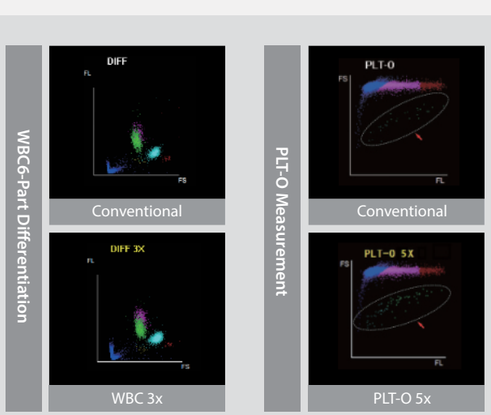
Above your expectations

SF Cube fluorescent technology allows reliable counting and differentiation of abnormal samples

More refined and reliable cell differentiation

3D fluorescent analysis technology allows reliable differentiation of immature and other abnormal cells, such as immature granulocytes (IMGs), reticulocytes (RETs*), and immature platelet fraction (IPF).



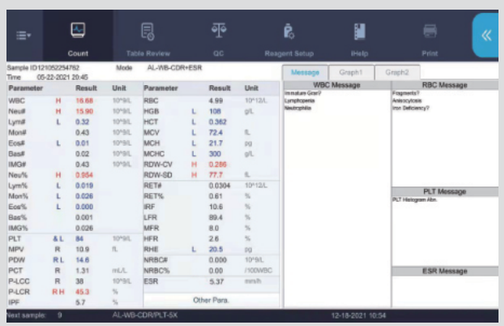


More reliable measurements for low-value samples

The BC-760 & BC-780 3D fluorescence analysis platform is designed with multiple counting WBC-3x and PLT-O 5x analysis modes to help ensure higher reliability for low-value WBC and PLT samples. In addition, the PLT de-aggregation function can reduce the cumbersome review work.

More comprehensive alarm messages for abnormalities

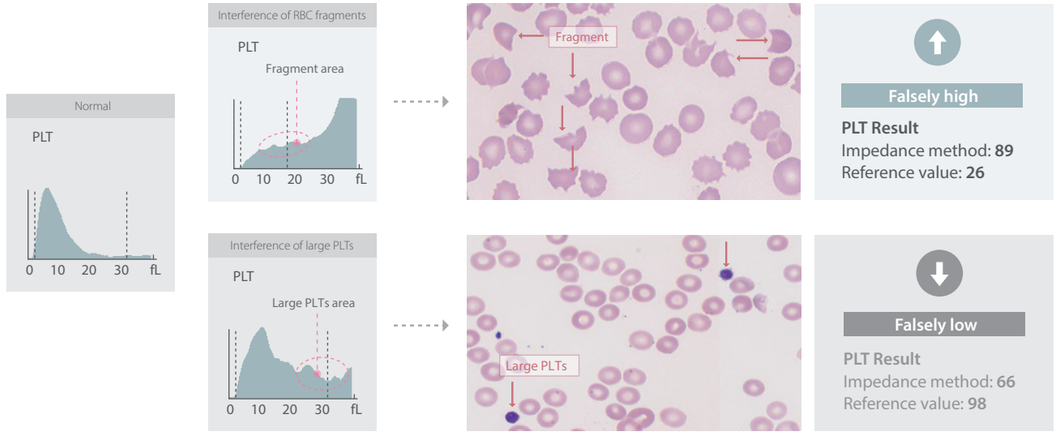
The analyzer provides a detailed list of over 40 prompt messages, including WBC message, RBC message, and PLT message. This allows laboratory technicians to intuitively and quickly identify abnormal samples and proceed further with the samples in a timely manner. This in turn helps to avoid missed diagnosis of blood disease and false reports.



Beyond your expectations

Limitations of traditional PLT counting

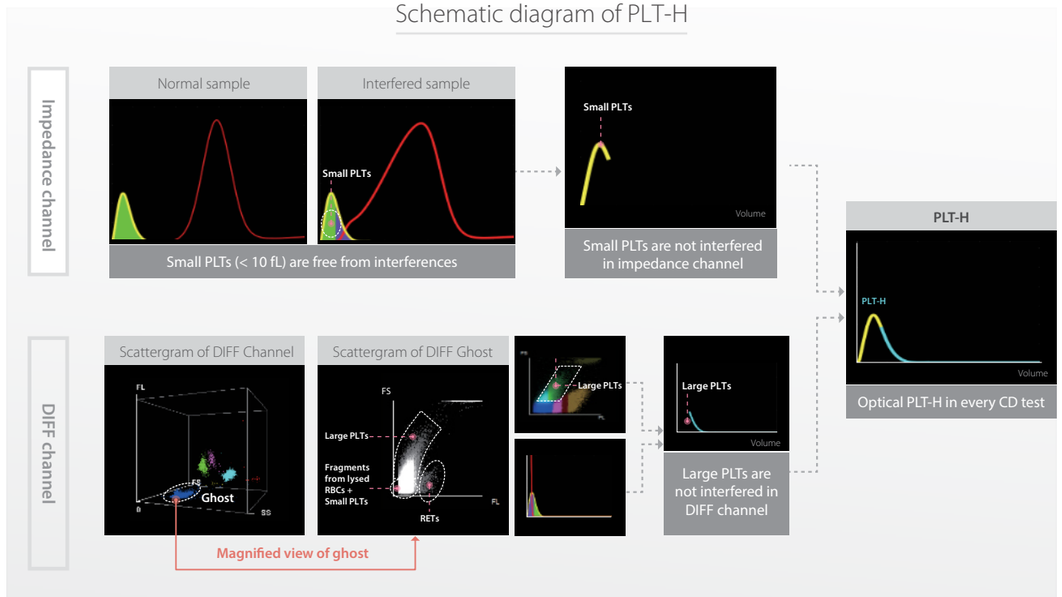
In the traditional impedance method, PLTs are subject to interferences that may lead to falsely high or falsely low results (as shown in the figure). Once an error report is generated, it will directly affect the judgment and decision-making of clinicians. The results reported at the clinical decision level are related to patient safety. Therefore, accurate PLT results are critical in clinical practice.



Optical PLT-H in every CD test

In order to solve the above problem, we have developed a brand new parameter PLT-H.
It combines small PLTs from the conventional impedance method and large PLTs from the optical method. The solution can resist the interferences in conventional PLT detection without requiring extra reagents.

Schematic diagram of PLT-H



CD + ESR in one test provide reliable ESR results with greater ease

The BC-700 series integrates an automatic ESR module in a hematology analyzer. It can also generate both CBC & ESR results in one test within 1.5 min. In addition, it saves the costs that would otherwise be incurred for the purchase, maintenance, consumables, and storage space of a separate ESR analyzer. Compared with the traditional Westergren method, this method performs better in quality traceability, repeatability, speed, safety, and level of automation.

Accurate

- Great correlation with the Westergren method
- Same QC and calibrator as in the BC-6000 series
- Combined examination helps to avoid the interferences of dehydration, polycythemia vera and anemia on ESR results

Cost-effective

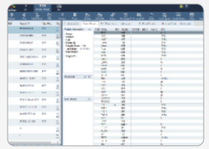
- The integrated instrument is capable of both CBC and ESR detection;
- Takes up the space of only one analyzer.

Automatic

- Report CBC + ESR results together within 1.5 min;
- The measurement results are protected against the influence of subjective factors;
- Automation can reduce the biosafety hazards that may otherwise be introduced by a manual method.

RFID

Encryption key management



labXpert

Coming as standard configuration
Same software as BC-6 series

Floating screen

Switching between different analysis modes with a single touch

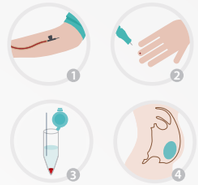
Excellent performance, high reliability, and ease of use

Continuous autoloading

5 positions x 6 racks

Cap piercing STAT

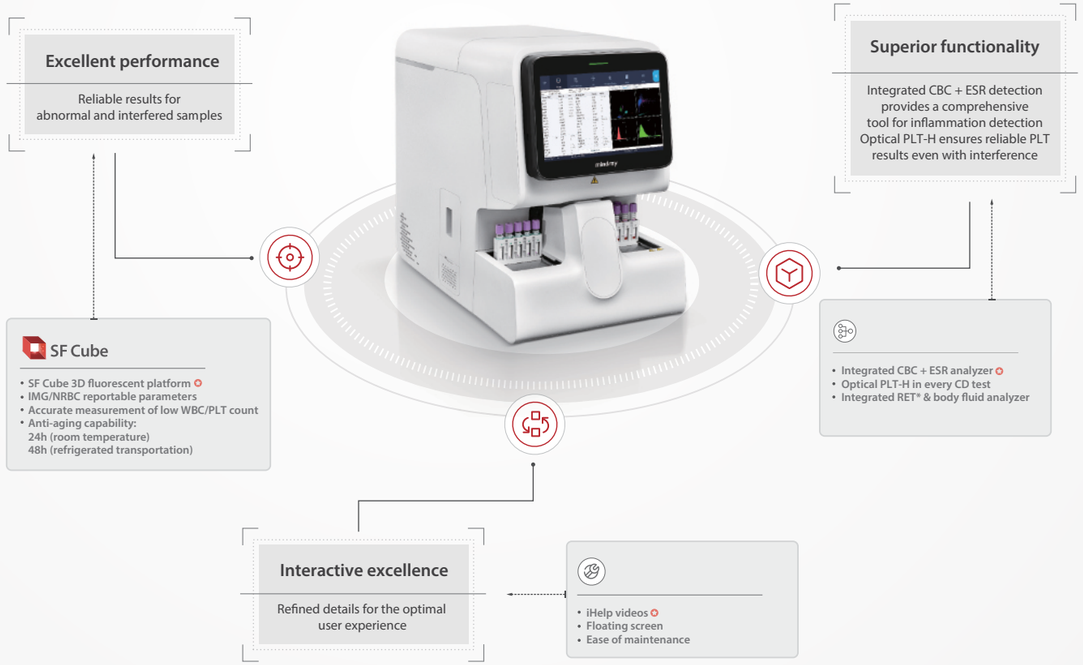
Supports STAT samples and capillary blood samples; minimizes bio-safety hazards



Applicable to different sample types

Peripheral blood/Capillary blood Pre-diluted blood/Body fluid

An all-in-one solution that goes above and beyond your expectations



MNCHIP

EC - Declaration of conformity

Manufacturer	**Tianjin MNCHIP Technologies Co., Ltd.** No.2 Building, Tianjin Teda Industrial Park No.19 Xinhuan Road West, TEDA, Tianjin, 300457, P.R. China
EC-Representative	**Lotus Global Co., Ltd** 1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom

Product

- **Chemistry Analyzer Pointcare M3**
- **Electrolyte Panel Lyophilized Kit [7]**
- **Liver and Renal Function Lyophilized Kit [9]**
- **Liver Function Panel Lyophilized Kit [8]**
- **Clinical Emergency Lyophilized Kit**
- **Renal Function Panel Lyophilized Kit [7]**
- **Glucose and Lipid Panel Lyophilized Kit [5]**
- **Myocardial Enzyme Panel Lyophilized Kit [5]**
- **General Chemistry I Lyophilized Kit [13]**
- **General Chemistry II Lyophilized Kit [8]**

We, the manufacturer, herewith declare that the products mentioned above meet the provisions of Directive 98/79/EC on In Vitro Diagnostic Medical Devices which apply to them.

The product concerned has been designed and manufactured under a quality management system according to Annex III of Directive 98/79/EC.

The above mentioned declaration of conformity is exclusively under the responsibility of Tianjin MNCHIP Technologies Co., Ltd.

Tianjin, 18 Aug 2018

Tianjin MNCHIP Technologies Co., Ltd. CONPORATE SEAL 2010

Zhanhui Wang

Zhanhui WANG, Dr.
Management Representative

Xenon light source

Microfluidic Reagent Rotor

7 minutes

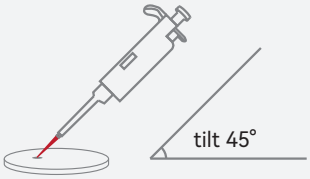
Sample-to-answer in 3 simple steps and approximately 7 -12 minutes

Clinical Chemistry⁺ - Pointcare® M4
On-site Blood Chemistry Analyzer

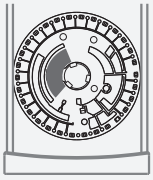
EASY TO USE
Fully automatic system - no special operating skills required

- 4.3 inch capacitive touch screen
- 100µL whole blood, serum or plasma.
- Barcoded prefabricated calibration information
- LIS compatible, no need to manually enter patient information.
- Results could be printed through a thermal printer (optional) , an office printer or through data management platform (MDMP).
- Ability to print reports with your practice logo by installing the MNCHIP medical data management platform.

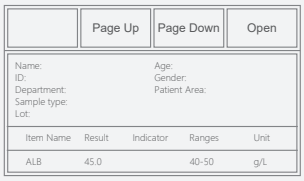
QUICK RESULTS
From sample to complete results in 3 simple steps in approximately 7-12 minutes



1. Add sample



2. Insert disc



3. Read results

PRECISE MEASUREMENTS
Advanced technology ensures precise results

- Microfluidic discs with pre-installed reagent beads ensure accurate analysis of blood samples and reagents.
- Stable measurement optics include a troboscopic xenon lamp, a wavelength selection system, and a multiple-wavelength detector.
- Integrated quality control software monitors the entire process in real time (ensuring consistent analysis of blood samples, reagents, microfluidic discs and chemistry analyzer).

Specifications

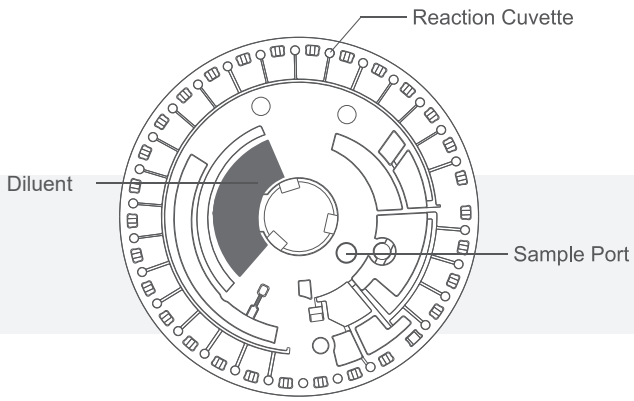
Sample Type	Whole blood, Plasma, Serum
Sample Size	100µL
Time to Results	About 7-12 minutes
User Interface	4.3 Inch touch screen
Reaction Temperature	37℃±0.2℃
Power Requirement	120VA
Dimensions	210(L)×125(W)×175(H)mm
Net weight	About 2.5kg

Parameters	Up to 19 parameters in one test, 33 parameters configured into 10 profiles
Reagent Disc	Disposable, prepackaged with self-contained lyophilized reagent
Calibration	Automatic self-calibration by scanning QR Code on the aluminium foil pouch
Quality Control	Built-in Realtime Quality Control (RQC) system
Connection Interfaces	WLAN, USB, Ethernet interface, compatible with LIS
Print Mode	Optional external thermal printer, office printer (optional), MDMP, LIS
Data Capacity	50,000 test results and quality control date
Operation Environment	Temperature 10-30℃, Humidity 40-85%

MNCHIP

CE ISO 13485 Self-testing

Pointcare® M4
Reagent Discs



	General Chemistry I Lyophilized Kit	Clinical Emergency Lyophilized Kit	Renal Function Panel Lyophilized Kit	Liver Function Panel Lyophilized Kit	Electrolyte Panel Lyophilized Kit	Glucose and Lipid Panel Lyophilized Kit	General Chemistry II Lyophilized Kit	Liver and Renal Function Lyophilized Kit	Ammonia Panel Lyophilized Kit	General Chemistry IV Lyophilized Kit
TP	TP			TP				TP		TP
ALB	ALB		ALB	ALB				ALB		ALB
GLO*	GLO*			GLO*				GLO*		GLO*
A/G*	A/G*			A/G*				A/G*		A/G*
ALT	ALT			ALT				ALT		ALT
AST	AST	AST		AST				AST		AST
GGT				GGT				GGT		GGT
ALP				ALP						ALP
TBIL	TBIL			TBIL				TBIL		TBIL
DBIL	DBIL			DBIL						DBIL
IBIL*	IBIL*			IBIL*						IBIL*
UA	UA	UA	UA							UA
CRE	CRE	CRE	CRE				CRE	CRE		CRE
UREA	UREA		UREA				UREA	UREA		UREA
CK		CK								
CK-MB		CK-MB								
LDH		LDH								
α-HBDH		α-HBDH								
AMY		AMY					AMY			
GLU	GLU	GLU				GLU	GLU	GLU		GLU
GSP						GSP				
TG	TG					TG				TG
CHOL	CHOL					CHOL				CHOL
HDL-C	HDL-C					HDL-C				HDL-C
LDL-C*	LDL-C*					LDL-C*				LDL-C*
K^+		K^+			K^+		K^+			
Na^+		Na^+			Na^+		Na^+			
Cl^-		Cl^-			Cl^-		Cl^-			
Ca^{2+}			Ca^{2+}		Ca^{2+}					
P			P		P					
Mg^{2+}					Mg^{2+}					
CO_2		CO_2	CO_2		CO_2		CO_2			
NH_3									NH_3	

* Calculated test value

Corporate Headquarters
MNCHIP Technologies Co.,Ltd
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Development Zone,300457 Tianjin P.R.China

Contact Us
sales@mnchip.com
service@mnchip.com
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Ver 5.4
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Test Items:

Category	Test Item
COVID-19	COVID-19 Antigen
	(COVID-19) IgM/IgG
	SARS-CoV-2 Neutralizing Antibodies
	COVID-19 Antigen (Self-test)
Diabetes	HbA1c
Inflammation	CRP
	PCT
	SAA
	SAA/CRP
	PCT/CRP
	IL-6
Cardiac	cTnI
	CK-MB
	Myo
	cTnI /CK-MB/Myo
	NT-proBNP
	D-Dimer
	H-FABP

Category	Test Item
Thyroid	TSH
	TT3
	TT4
Hormone	β-HCG
	AMH
	LH
	FSH
	PRL
	Progesterone
Gastric Function	PG Ⅰ /PG Ⅱ
Tumor	PSA
Bone metabolism	25-OH-VD
Anemia	Ferritin

Category	Test Item
Analyzer	LS-1100
	LS-2100
	LS-4000

New items are available soon!

Category	Test Item
Coming soon	IgG4
	BNP
	Lp-PLA2
	HCY
	Coagulation products
	LA-100 Handheld Coagulation Analyzer

New items are available soon!

Lansion Biotechnology Co., Ltd.

Add: No.2 Qiande Road, Jiangning District, Nanjing, China
E-mail: biz@lansionbio.com
Web: en.lansionbio.com
Tel: +86-25-5857 7600
Fax: +86-25-5875 8600

CE IVD

LS-1100

Dry Fluorescence Immunoassay Analyzer (Portable)

Quantitative

Rapid

Sensitive

Reliable

Accurate, Anytime and Anywhere

Lansion Biotechnology Co., Ltd.

LS-1100 Dry Fluorescence Immunoassay Analyzer (Portable)

Analyzer Introduction:

LS-1100 uses the advanced method of Time-resolved Fluorescence Immunoassay (TRFIA), for the in-vitro quantitative detection of bio-markers for diabetes, infectious diseases, cardiovascular diseases, sex hormones, gastric diseases, thyroid function, tumors, COVID-19 and other diseases.

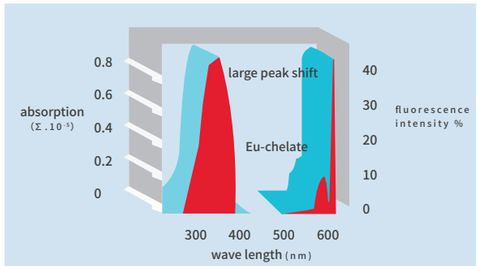
Application: laboratory, emergency , ICU, clinical laboratory, clinic, ambulance, field rescue and other clinical departments, etc.

Features:

“Quantitative, Sensitive, Reliable”

Method	Time-resolved Fluorescence Immunoassay (TRFIA)
Specimen	Serum/Plasma/Whole Blood/Nasal swabs
Weight	1.3kg
Dimensions	225mm×152mm×105mm (L×W×H)
Screen	7 inch touch screen
Data Storage	10000
Printer	Built-in thermal printer
Battery	Built-in lithium battery (standby time: 10hrs)
Communication	RS232(LIS/HIS), USB

Time-resolved Fluorescence Immunoassay (TRFIA) Method:



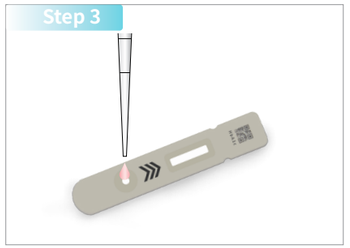
Basic principle of TRFIA

TRFIA is super-sensitive detection technique characterized by specific fluorescence of rare earth ions. It is not only highly sensitive, but also overcomes the instability of enzyme marker and is the better choice for immunological detection. The high fluorescence intensity and long life of labeled ionic chelates are beneficial to eliminate the influence of fluorescent substances in samples and environment on the test results.

Easy Operation:

QR Code Calibration

Information Input



Sample Dispense

Automatic Detection

Result Output

CE CE

Declaration of Conformity

Manufacturer:	Lansion Biotechnology Co., Ltd. Add: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA Tel: 025-58577660
Authorized Representative:	Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124, Heidelberg, Germany

We declare under our sole responsibility that:

Product Name:	Dry Fluorescence Immunoassay Analyzer
Type/Model:	LS-1100
Classification:	Others
Conformity Assessment Peocedure:	Directive 98/79/EC Annex III

We herewith declare that the product meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning medical devices (IVDD 98/79/EC) and its transpositions in national laws which apply to it.

Nanjing, China March, 12,2020
Place, Date

Signature

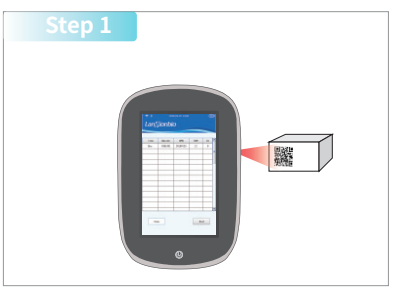
LS-1100

Dry Fluorescence Immunoassay Analyzer (Portable)

Features:

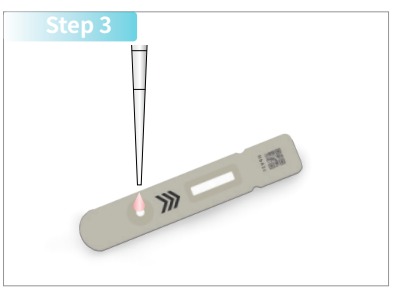
Method	Time-resolved Fluorescence Immunoassay (TRFIA)
Specimen	Serum/Plasma/Whole Blood/Urine
Weight	1.3kg
Dimensions	225mm×152mm×105mm (L×W×H)
Screen	7 inch touch screen
Data Storage	10000
Printer	Built-in thermal printer
Battery	Built-in lithium battery (standby time: 10hrs)
Communication	RS232(LIS/HIS), RJ45, USB, WIFI, Bluetooth

Easy Operation:



QR Code Calibration

Information Input



Sample Dispense

Automatic Detection

Result Output

Lansion Biotechnology Co., Ltd.

LS-1100 Quick Operation Guide

Preparation

1.Scan QR code to read item information.
Menu-Item Management-"Scan"

2.Input information as needed.

Adding the Sample

For detailed information on adding the sample, please refer to test procedure of the test kit.

Testing

For panel inside:

1.Insert the test strip into the slot right after adding sample mixture to the sample well.

2.Press "Test" to start testing.

3.Read the test result or print the result.

For panel outside:

1.Leave the test strip with sample mixture at room temperature for reaction (reaction time refer to the test kit).

2.Insert the test strip into the slot when reaction finish.

3.Press "Test" to start testing.

4.Read the test result or print the result.