ORDIN DE PLATA NR.: 2598 TIP.DOC. 1

DATA EMITERII:miercuri, 31 ianua

PLATITI: 13300-00 LEI: Treisprezece Mii Trei Sute lei 00 bani

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

CONTUL DE PLATI/CODUL IBAN
MD95ML0000000022514292 43
CODUL FISCAL :1010600028048 /

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

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) Institultul de Medicina Urgenta IMSP

CONTUL DE PLATI/CODUL IBAN
MD55VI022510300000002MDL
CODUL FISCAL :1003600152606 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A.

CODUL BANCII:
:VICBMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr. ocds-b3wdp1-MD-1703250206451 din 31.01.2024

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:31/01/2024
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAAEDi65avx+fXSldAAAAAQOLMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTI0MDEyNTExMzM1NloXDTI3MDEyNTExNDM1NlowgZ8xCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAAEDijjVd7aJ5r0rAAAAAQOKMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTI0MDEyNTExMzMzNVoXDTI3MDEyNTExNDMzNVowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

(semnatura electronica)

L.S.

CONDUCATOR: _____

(semnatura manuala)

CONTABIL-SEF: _____

(semnatura manuala)

SEMNATURA PRESTATORUL

L.S.

MOTIVUL REFUZULUI

L.S.

Digitally signed by Poiata Vitalie
Date: 2024.01.30 18:13:57 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. № **1814048**

Din От **16.01.2024 18:14**

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 **31.01.2024 18:14**

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 **16.01.2024 18:14**

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)

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.

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

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Lansion Biotechnology Co., Ltd.
Address: No.2,Qiande Road,Science Park,Jiangning District,210000 Nanjing,Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive: **Reference to Attachment I**

Risk Class: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.
We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: Binghuazhuo

Place: Nanjing,China

Name of authorized signatory:
Position held in the company: General Manager
Date: Apr. 13, 2022
Seal/Stamp:

Lansion Biotechnology Co., Ltd.

Attachment I

In Vitro Diagnostic Directive:

No.	Product
1	HbAlc Test Kit (Dry Fluorescence Immunoassay)
2	TSH Test Kit (Dry Fluorescence Immunoassay)
3	TT3 Test Kit (Dry Fluorescence Immunoassay)
4	TT4Test Kit (Dry Fluorescence Immunoassay)
5	D-Dimer Test Kit (Dry Fluorescence Immunoassay)
6	PSA Test Kit (Dry Fluorescence Immunoassay)
7	cTnl Test Kit (Dry Fluorescence Immunoassay)
8	NT-proBNP Test Kit (Dry Fluorescence Immunoassay)
9	cTnl/CK-MB/Myo Test Kit (Dry Fluorescence Immunoassay)
10	AMH Test Kit (Dry Fluorescence Immunoassay)
11	SAA Test Kit (Dry Fluorescence Immunoassay)
12	Myo Test Kit (Dry Fluorescence Immunoassay)
13	CK-MB Test Kit (Dry Fluorescence Immunoassay)
14	LH Test Kit (Dry Fluorescence Immunoassay)
15	FSH Test Kit (Dry Fluorescence Immunoassay)
16	PRLTest Kit (Dry Fluorescence Immunoassay)
17	β-HCG Test Kit (Dry Fluorescence Immunoassay)
18	Progesterone Test Kit (Dry Fluorescence Immunoassay)
19	PCT Test Kit (Dry Fluorescence Immunoassay)
20	SAA/CRP Test Kit (Dry Fluorescence Immunoassay)
21	CRP Test Kit (Dry Fluorescence Immunoassay)

22	H-FABP Test kit (Dry Fluorescence Immunoassay)
23	IL-6 Test Kit (Dry Fluorescence Immunoassay)
24	PGI/PGII Test Kit (Dry Fluorescence Immunoassay)
25	Ferritin Test Kit (Dry Fluorescence Immunoassay)
26	PCT/CRP Test Kit (Dry Fluorescence Immunoassay)
27	25-OH-VD Test Kit(Dry Fluorescence Immunoassay)
28	BNP Test Kit(Dry Fluorescence Immunoassay)
29	CCP Test Kit(Dry Fluorescence Immunoassay)
30	G-17 Test Kit(Dry Fluorescence Immunoassay)
31	FDP Test Kit (Dry Fluorescence Immunoassay)
32	S100-β test Kit (Dry Fluorescence Immunoassay)
33	ST2 test Kit (Dry Fluorescence Immunoassay)
34	HCY test Kit (Dry Fluorescence Immunoassay)
35	lgG4 test Kit (Dry Fluorescence Immunoassay)
36	(COVID-19)lgM/lgG Test Kit (Dry Fluorescence Immunoassay)
37	COVID-19 Antigen Test Kit (Dry Fluorescence Immunoassay)
38	SARS-CoV-2 Neutralizing Antibodies Test Kit(Dry Fluorescence Immunoassay)
39	fPSA Test Kit (Dry Fluorescence Immunoassay)
43	NGALTest Kit (Dry Fluorescence Immunoassay)
44	mAlb Test Kit (Dry Fluorescence Immunoassay)
45	ASO Test Kit (Dry Fluorescence Immunoassay)

—Continued on the next page—

—Continued from previous page—

Attachment II

References to other union legislations, standards and common specification (if applicable) applied:

1)EN ISO13485:2016 Medical devices - Quality management systems- Requirements for regulatory purposes

2)EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer . Part 1: General requirements

3)EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

4)ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

5)ISTA-2A:2011: Series Partial Simulation Performance Test Procedure (Packaged - Products 1501b(68kg) or less)

ISO 20417:2021 Medical devices -- Information to be supplied by the manufacturer Information6supplied by the manufacturer with medical devices

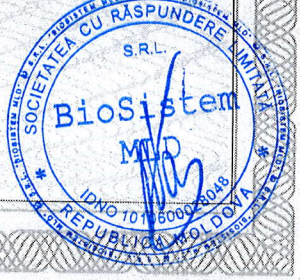
7)IEC 62366-1:2015+A1:2020 Medical Device Part 1 Application of usability engineering to medical devices

8) EN ISO 18113-1:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements

9)EN ISO 13612:2002 Performance evaluation of in vitro diagnostic medical devices

10) EN ISO14155-2020 Clinical investigation of medical devices for human subjects -- Good clinical practice

11) MEDDEV2.7.1 REV GUIDELINES ON MEDICAL DEVICES12) ASTM D4169 DC13 Standard Practice for Performance Testing of Shipping Containers and Systems



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

DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th 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**

Chuanbin Tan

Signatory name: Chuanbin Tan
signatory title: Technical Regulation Manager
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

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

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ATTACHMENT I

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

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

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		Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300、 BC-3300CT、 BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5800、 BC-5600	M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-6600、 BC-6800	M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator BR60 Hemalology 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
α-Amylase（α-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)	/	/
α-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)	/	/
Microalbuimn (MALB) Kit	/	/
Ferritin (FER) Kit	/	/
Transferrin (TRF) Kit	/	/
TRF Calibrator	/	/
TRF Control	/	/
FER Calibrator	/	/
Multimmun Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
α-L-Fucosidase Kit (CNPF method)	/	/
5′-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/
Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
β2-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	/	/
β2-Microglobulin（β2-MG） Kit (Latex Immunoturbidimetric Method)	/	/
β2-Microglobulin Control	/	/
β2-Microglobulin Calibrator (for Serum)	/	/
β2-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)	/	/
Immunoglobubin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
β-Hydroxybutyrate (β-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	/	/
β-HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
β-HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I(CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide(CLIA)	/	/
BNP Calibrators	/	/
Myoglobin(CLIA)	/	/
MYO Calibrators	/	/

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

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

NT-proBNP Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

NT-proBNP Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

NT-proBNP Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of NT-proBNP (N-terminal Brain Natriuretic Peptide Precursor) in human serum and plasma.

NT-proBNP can be used to evaluate heart contractile, diastolic dysfunction, and ventricular segment wall motion coordination. NT-proBNP is used to indicate heart failure patient at the early stage, determine HF risk levels, monitor medical efficiency of HF drug, evaluate prognosis of HF patient and to distinguish dyspnea that caused by HF from other diseases. Furthermore, NT-proBNP is a risk assessment indicator for Acute Coronary Syndrome (ACS).

[TEST PRINCIPLE]

NT-proBNP Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the NT-proBNP of the sample will combine with antibody which is attached to fluorescence microspheres. The marked complex is attached to the detection area of the immobilized antibody, and the other fluorescence microspheres are attached to the control area.

When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. NT-proBNP test strip in a sealed pouch with desiccant.....25 tests
2. QR code card for calibration.....1 piece
3. User Manual.....1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. FIC-S100 Dry Fluorescence Immunoassay Analyzer
2. LS-1000 Dry Fluorescence Immunoassay Analyzer
3. LS-2000 Dry Fluorescence Immunoassay Analyzer
4. LS-1100 Dry Fluorescence Immunoassay Analyzer
5. LS-2100 Dry Fluorescence Immunoassay Analyzer
6. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
7. LS-7000 Microfluidic and Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum and plasma**. Other bodily fluids and samples may not get the accurate result.
2. Plasma can be anticoagulant with heparin and sodium citrate under aseptic conditions.
3. At room temperature, the test should be performed within 4 hours after the sample collection.
4. Serum or plasma sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
5. The sample before testing should be recovered to room temperature (15°C-30°C).
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100:

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual).
4. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to drop 100μL sample into the sample port in the test strip.
7. **Reaction Time: 15 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".

For panel outside: After reaction time 15 minutes is elapsed, insert the test strip into the analyzer and then click "Test".

8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Cut-Off Value:

<75 years old: 125pg/mL

≥75 years old: 531pg/mL

The cut-off value for NT-proBNP was determined by testing samples from 300 apparently healthy individuals. The 95th percentile of the concentration for NT-proBNP is 125pg/mL, and the 97.5th percentile of the concentration for NT-proBNP is 531pg/mL.

It is recommended that each laboratory establish its own reference

range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 25000pg/mL, the analyzer displays ">25000pg/mL", and if the result is less than 50pg/ml, the analyzer displays "<50pg/mL". Specific data can be exported through related software as needed.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. This kit is only for the serum and plasma test.
2. The test result of this kit is only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[PRODUCT PERFORMANCE]

1. Measuring Range: 50-25000pg/mL.
2. Lower Detection Limit: ≤50pg/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.
6. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of linear range, and the detection result was greater than the upper limit of detection.

[PRECAUTIONS]

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

1. Jame LI, Carlos AC, Saif A, et al. The N-terminal pro-BNP investigation of dyspnea in the emergency department(PRIDE) study. Am J Cardiol, 2005, 95:948-954.
2. Charlotte K, Bjorn G, Lars K, et al. N-Terminal pro-B-typenatriuretic peptide and long-term mortality in stable coronary heart disease. N Engl J Med, 2005, 352:666-675.
3. Paulo B, Ana A, Joana P, et al. N-terminal-Pro-brain natriuretic peptide predicts outcome after hospital discharge in heart failure patients. Circulations, 2004, 110:2168-2174.
4. Lene SN, Jens S, Niels AK, et al. N-terminal pro-brain natriuretic peptide for discriminating between cardiac and non-cardiac dyspnoea. Eur J Heart Failure, 2004, 6:63-70.

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Revision Date: May 24, 2019
Version Number: 0.1
Production date and expiration see the label.

D-Dimer Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

D-Dimer Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

D-Dimer Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of D-Dimer in human plasma. This test is used as an aid in the assessment and evaluation of patients suspected of deep vein thrombosis (DVT) and pulmonary embolism (PE), diagnosis of disseminated intravascular coagulation (DIC), effective evaluation and monitoring the effect of thrombolytic therapy, diagnosis and assessment of myocardial infarction and cerebral infarction.

[TEST PRINCIPLE]

D-Dimer Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the D-Dimer of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area.

When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. D-Dimer test strip in a sealed pouch with desiccant.....25 tests
2. Sample diluent.....25 pieces
3. QR code card for calibration.....1 piece
4. User Manual.....1 piece
5. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. FIC-S100 Dry Fluorescence Immunoassay Analyzer
2. LS-1000 Dry Fluorescence Immunoassay Analyzer
3. LS-2000 Dry Fluorescence Immunoassay Analyzer
4. LS-1100 Dry Fluorescence Immunoassay Analyzer
5. LS-2100 Dry Fluorescence Immunoassay Analyzer
6. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
7. LS-7000 Microfluidic and Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **plasma**. Other bodily fluids and samples may not get the accurate result.
2. Plasma sample can be anticoagulant with heparin and sodium citrate under aseptic conditions.
3. At room temperature, the test should be performed within 4 hours after the sample collection.
4. Plasma sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
5. The sample before testing should be recovered to room temperature (15°C-30°C).
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press “Test” icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to deliver 100μL sample into one tube of sample diluent. Mix gently and thoroughly. And then drop 100μL of mixed fluid into the sample port in the test strip.
7. **Reaction Time: 10 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click “Test”.

For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click “Test”.

8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Cut-Off Value: 0.5μg/mL

D-Dimer concentration is determined using samples obtained from 200 apparently healthy individuals.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 10μg/mL, the analyzer displays ">10μg/mL", and if the result is less than 0.1μg/mL, the analyzer displays "<0.1μg/mL". Specific data can be exported through related software as needed.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. This kit is only for plasma.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[PRODUCT PERFORMANCE]

1. Measuring Range: 0.1-10μg/mL.
2. Lower Detection Limit: ≤0.1μg/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.
6. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of linear range, and the detection result was greater than the upper limit of detection.

[PRECAUTIONS]

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

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2. Chen jiuyan. Detection of d-dimer and its application in the diagnosis and treatment of thrombotic diseases. Shanxi Journal of Medicine. 2008, 37(24): 1123-1125.

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Revision Date: May 31, 2019

Version Number: 0.1

Production date and expiration see the label.

PCT Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

PCT Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

PCT Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of PCT (Procalcitonin) in serum and plasma. This test is used as an aid in the differential diagnosis of bacterial infection and viral infection, early diagnosis and death assessment of sepsis, monitoring of therapeutic effect of bacterial infection.

[TEST PRINCIPLE]

PCT Test Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the PCT of the sample will combine with antibody which is attached to fluorescence microspheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence microspheres are attached to the control area.

When the test strip is inserted into the analyzer, the analyzer automatically scans two ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. PCT test strip in a sealed pouch with desiccant.....25 tests
2. QR code card for calibration.....1 piece
3. User Manual.....1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. FIC-S100 Dry Fluorescence Immunoassay Analyzer
2. LS-1000 Dry Fluorescence Immunoassay Analyzer
3. LS-2000 Dry Fluorescence Immunoassay Analyzer
4. LS-1100 Dry Fluorescence Immunoassay Analyzer
5. LS-2100 Dry Fluorescence Immunoassay Analyzer
6. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
7. LS-7000 Microfluidic and Dry Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum and plasma**. Other bodily fluids and samples may not get the accurate result.
2. Plasma can be anticoagulant with heparin and sodium citrate under aseptic conditions.
3. At room temperature, the test should be performed within 4 hours after the sample collection.
4. Serum or plasma sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.
5. The sample before testing should be recovered to room temperature (15°C-30°C).
6. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to drop 100μL sample into the sample port in the test strip.
7. **Reaction Time: 10 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".

For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click "Test".

8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Cut-Off Value: 0.5ng/mL

CRP concentration is determined using samples obtained from 200 apparently healthy individuals.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 50ng/mL, the analyzer displays ">50ng/mL", and if the result is less than 0.1ng/mL, the analyzer displays "<0.1ng/mL". Specific data can be exported through related software as needed.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf

serum or negative sample.

[LIMITATION]

1. This kit is only for serum and plasma test.
2. The test result of this kit are only one of the diagnostic aids for the clinicians.
3. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.

[PRODUCT PERFORMANCE]

1. Measuring Range: 0.1-50ng/mL.
2. Lower Detection Limit: ≤0.1ng/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.
6. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of linear range, and the detection result was greater than the upper limit of detection.

[PRECAUTIONS]

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

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4. Yukioka H, Yoshida G, Kurita S. Plasma procalcitonin in sepsis and organ failure. Ann Acad Med Singapore, 2001, 30(5): 528-531.

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Production date and expiration see the label.

cTnI /CK-MB/Myo Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

cTnI /CK-MB/Myo Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

cTnI /CK-MB/Myo Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of cTnI /CK-MB/Myo (Cardiac Troponin I/ Creatine Kinase Isozyme/Myoglobin) in human serum .
cTnI is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI),Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).
CK-MB is an important indicator for the diagnosis of acute myocardial infarction (AMI), which is secreted into the blood in large quantities during the attack.CK-MB began to rise 3-6h when AMI symptoms occur, and reached the peak value after 12-24h. If there were no complications, the level of CK-MB in the blood would be restored to the normal level after 3d; if there were complications, the level of CK-MB in the blood would remain high and not decrease. If AMI occurs again, the CK-MB that has declined will rise again. CK-MB measurement can also be used as a non-invasive evaluation index for myocardial reperfusion after thrombolytic therapy.
Myo can be used as the most sensitive index in the early diagnosis of acute myocardial infarction (AMI).

[TEST PRINCIPLE]

cTnI/CK-MB/Myo Kit (Dry Fluorescence Immunoassay) uses the principle of antigen-antibody reaction. The testing sample will migrate forward due to capillary action, then the sample will combine with antibody which is attached to fluorescence micro-spheres. This marked complex is attached to the detection area of immobilized antibody and the other fluorescence micro-spheres are attached to the control area. When the test strip is inserted into the analyzer, the analyzer automatically scans ribbons and detected the fluorescence intensity of the composite emission from the testing area and the control area. The ratio of the two fluorescence values was used to calculate the content of the detected substances.

[MAIN COMPONENTS]

1. cTnI/CK-MB/Myo test strip in a sealed pouch with desiccant.....25 tests
2. QR code card for calibration.....1 piece
3. User Manual.....1 piece
4. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.
Test strip should be used within 60 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-3000 Automatic Fluorescence Immunoassay Analyzer
9. LS-3100 Automatic Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum** . Other bodily fluids and samples may not get the accurate result.
2. At room temperature(15°C-30°C), the test should be performed within 4 hours after the sample collection.
3. Serum sample can be stored at 2°C-8°C for 24 hours, can be stored at -20°C for 6 months. It is suggested to use fresh sample to test. Microbial contamination samples can not be used.
4. Frozen samples should be completely melted, rewarmed and mixed completely before use. Avoid repeated freeze-thaw. It is suggested freeze - thaw of sample should not more than 1 time.
5. **Sample Volume: 100μL**

[TEST PROCEDURE]

1. Collect samples according to user manual.
Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100:

1. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
2. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
3. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
4. Using pipette to drop 100μL sample into the sample port in the test strip.
5. **Reaction Time: 10 minutes**
   For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".
   For panel outside: After reaction time 10 minutes is elapsed, insert the test strip into the analyzer and then click "Test".
6. The result will be shown on the screen and printed automatically.
   Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Reference Range:

cTnI ≤0.5ng/mL

CK-MB ≤5ng/mL

Myo ≤70ng/mL

cTnI/CK-MB/Myo concentration is determined using samples obtained from 180 apparently healthy individuals.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of cTnI is more than 40ng/mL, the analyzer displays ">40ng/mL", and if the result is less than 0.1ng/mL, the analyzer displays "<0.1ng/mL". If the test result of CK-MB is more than 80ng/mL, the analyzer displays ">80ng/mL", and if the result is less than 2ng/mL, the analyzer displays "<2ng/mL". If the test result of Myo is more than 500ng/mL, the analyzer displays ">500ng/mL", and if the result is less than 20ng/mL, the analyzer displays "<20ng/mL". Specific data can be exported through related software as needed(Optional) .
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 3 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. The test result of this kit are only one of the diagnostic aids for the clinicians.
2. Samples containing interfering substances may affect the test results, and the maximum allowable concentrations are: hemoglobin 3mg/mL, bilirubin 2mg/mL, and triglyceride 10mg/mL.

[PRODUCT PERFORMANCE]

1. Measuring Range: cTnI: 0.1ng/mL～40ng/mL
   CK-MB: 2ng/mL～80ng/mL
   Myo: 20ng/mL～500ng/mL
2. Accuracy: Verify with comparison experiments, the relative deviation ≤15%, the correlation coefficient r≥0.990.
3. Within-Run Precision: ≤15%.
4. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. Only used for in vitro diagnostics.
2. Do not use the kit beyond the expiration date.
3. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
4. Do not reuse the test strip.
5. The damaged test strip or package cannot be used.
6. Do not mix the components of different kits.

[REFERENCES]

1. Yang Zhenhua, Pan Bozhong, Xu Juntang. Chinese Medical Association Test Document: Guidelines for the Application of Markers of Myocardial Injury. Chinese Journal of Laboratory Medicine,2002,25(3):185-189.
2. Jin Caining ,Xu Guobin,Zhu Lihua,etc. Determination of Human Myocardial TnI and its application in clinical diagnosis. Journal of Clinical Laboratory,2002,20(2):118-120.
3. Department of Medical Administration, Ministry of Health. National Clinical Laboratory Operating Procedures. Southeast University Press, 2015 4th edition.

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Revision Date: August 20, 2020

Version Number: 0.0

Production date and expiration see the label.

CRP Test Kit User Manual

(Dry Fluorescence Immunoassay)

[PRODUCT NAME]

CRP Test Kit (Dry Fluorescence Immunoassay)

[PACKAGE SPECIFICATION]

1 test/kit
5 tests/kit
25 tests/kit
50 tests/kit
100 tests/kit

[INTENDED USE]

CRP Test Kit (Dry Fluorescence Immunoassay) is intended for in-vitro quantitative measurement of CRP in human serum,plasma and whole blood.

Creactive protein (CRP) is a typical acute-phase reactive protein synthesized by the liver,named for its ability to bind to the capsular C polysaccharide of Streptococcus pneumoniae.Under normal conditions, CRP molecules exist in the form of pentamers,which can also be decomposed into monomers in acidic or alkaline environments,which can cause certain immune reactions.However,because CRP monomers exist in cell membranes instead of serum,it is difficult Detection. In inflammation,infection, tissue damage,CRP is rapidly synthesized in the liver under the stimulation of cytokines (such as interleukin-6,tumor necrosis factor),and 20% of the liver's ability to synthesize protein at the peak of the acute phase reaction is directly It points to the synthesis of CRP,which can be used for routine verification and the detection of cardiovascular inflammation.

Full-scale CRP includes conventional hypersensitive CRP (hs-CRP) and regular CRP.The common use of hs-CRP can be used as an auxiliary means of cardiovascular disease risk identification.Used in conjunction with traditional clinical diagnosis of acute coronary syndrome,it can be used as an early warning indicator for recurrence of coronary artery disease or acute coronary syndrome. Common uses of regular CRP can be used to evaluate infection, tissue damage and inflammatory diseases.Commonly used clinical and laboratory testing methods include immunoturbidimetric method, immunofluorescence method, latex enhanced immunoturbidimetric method and so on.

[TEST PRINCIPLE]

CRP Test Kit (Dry Fluorescence Immunoassay) uses immunofluorescence double antibody sandwich method quantitatively detect the content of CRP.Two highly specific and sensitive monoclonal antibodies, of which CRP mouse monoclonal antibody 1 is a capture antibody, are coated on the test area on a nitrocellulose membrane, and CRP mouse monoclonal antibody 2 is labeled as fluorescent microspheres and fixed on the binding pad. The detection buffer is mixed with the sample, the antigen in the sample is combined with the CRP mouse monoclonal antibody 2 labeled fluorescent microspheres in the binding pad, and the complex is then captured by the CRP mouse monoclonal antibody 1 immobilized on the test area to form fluorescent microspheres Sandwich structure; the chicken IgY-labeled fluorescent particle complex in the binding pad combines with the goat anti-chicken IgY immobilized on the quality control area of the nitrocellulose membrane to form a quality control area. The compound can be measured and analyzed by supporting equipment, which can quantitatively detect the content of CRP in human blood.

[MAIN COMPONENTS]

1. CRP test strip in a sealed pouch with desiccant.....25 tests
2. Sample diluent.....25 pieces
3. QR code card for calibration.....1 piece
4. User Manual.....1 piece
5. Quantitative suction and dropping tube (Optional).

Note: Do not mix or interchange different batches of kit.

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip should be used within 30 minutes once the foil pouch is opened.

[APPLICABLE DEVICES]

1. LS-1000 Dry Fluorescence Immunoassay Analyzer
2. LS-2000 Dry Fluorescence Immunoassay Analyzer
3. LS-1100 Dry Fluorescence Immunoassay Analyzer
4. LS-2100 Dry Fluorescence Immunoassay Analyzer
5. LS-4000 Hand-Held Dry Fluorescence Immunoassay Analyzer
6. LS-7000 Dry Fluorescence Immunoassay Analyzer
7. LS-7100 Microfluidic and Dry Fluorescence Immunoassay Analyzer
8. LS-7800 Automatic Microfluidic and Dry Fluorescence Immunoassay Analyzer
9. LS-3000 Automatic Fluorescence Immunoassay Analyzer
10. LS-3100 Automatic Fluorescence Immunoassay Analyzer

[SAMPLE REQUIREMENT]

1. Used for human **serum, plasma and whole blood**. Other bodily fluids and samples may not get the accurate result.
2. Whole blood and plasma sample can be anticoagulant with EDTA ,heparin and sodium citrate under aseptic conditions.
3. At room temperature, the test should be performed within 4 hours after the sample collection. Serum or plasma sample can be stored at 2°C-8°C for 3 days at most. If more than 3 days, it should be stored at -20°C. It is suggested to use fresh sample to test. Stale blood sample may not get accurate result.Whole blood samples cannot be stored in freezing, only can be stored for 3 days under the conditions of 2℃ -8℃.
4. Avoid using microbial contamination samples.
5. Frozen samples must be completely melted, restored to room temperature, and mixed well before use. Avoid repeated freezing and thawing. It is recommended that the sample be frozen and thawed no more than once. If there is sediment in the thawed sample, the sample should be centrifuged before testing.

[TEST PROCEDURE]

1. Collect samples according to user manual.
2. Before the test, the sample and test strip should be recovered to room temperature (15°C-30°C).

For LS-1100

3. Perform QR code calibration when necessary. (Details refer to LS-1100 User Manual)
4. On the main interface of LS-1100, press "Test" icon to enter testing interface. Input patient information, sample information, doctor information when necessary. (Details refer to LS-1100 User Manual)
5. Remove test strip from sealed pouch and put it on a clean table, horizontally placed.
6. Using pipette to deliver 5μL of sample into one tube of sample diluent. Mix gently and thoroughly. And then drop 100μL of mixed fluid into the sample port in the test strip.
7. **Reaction Time: 3 minutes**

For panel inside: Insert the test strip into the analyzer immediately after sample dispensing. Then click "Test".

For panel outside: After reaction time 3 minutes is elapsed, insert the test strip into the analyzer and then click "Test".

8. The result will be shown on the screen and printed automatically.

Notes: It is required to perform QR code calibration when starting to use one new batch of kit.

[EXPECTED VALUE]

Cut-Off Value: CRP≤10μg/mL；hs-CRP≤3μg/mL

CRP concentration is determined using samples obtained from 178 apparently healthy individuals. hs-CRP concentration was determined using samples obtained from 158 apparently healthy individuals.

It is recommended that each laboratory establish its own reference range for the population it serves.

[INTERPRETATION OF RESULT]

1. If the test result of the sample is more than 200μg/mL, the analyzer displays ">200μg/mL", and if the result is less than 0.5μg/mL, the analyzer displays "<0.5μg/mL". Specific data can be exported through related software as needed.The results of regular CRP and hs-CRP are shown separately. When the test result is greater than 10 mg/L, the specific value is displayed in the CRP; when the test result is less than 5 mg/L, the specific value is displayed in the hs-CRP.
2. When the sample concentration exceeds the detection limit, the maximum dilution ratio is 2 times when the sample is diluted with calf serum or negative sample.

[LIMITATION]

1. The test result of this kit are only one of the diagnostic aids for the clinicians.
2. Samples containing interfering substances can affect test results. The maximum allowable concentration is: hemoglobin 3 mg/ mL bilirubin 0.25 mg/ mL and triglyceride 10 mg/ mL.

[PRODUCT PERFORMANCE]

1. Measuring Range: 0.5-200μg/mL,r≥0.990.
2. Lower Detection Limit: ≤0.5μg/mL.
3. Accuracy: Verify with comparison experiments, the relative deviation ≤15%.
4. Within-Run Precision: ≤15%.
5. Between-Run Precision: ≤15%.

[PRECAUTIONS]

1. Only used for in vitro diagnostics,and it is for one-time use, please do not reuse it.
2. After the test strip is removed from the sealed pouch, it should be tested as soon as possible to avoid excessive time in the air, resulting in dampness.
3. The damaged test strip or package cannot be used.
4. Do not mix the components of different kits.
5. All samples from patients should be treated as potential sources of infection.
6. Used reagent cards should be properly disposed of in accordance with local regulations to avoid contamination.

[REFERENCES]

1. Zhao heping, xiao qunfeng. Quantitative determination of c-reactive protein. Journal of practical medicine, 2006, 13(21):3908.
2. Yang zhenxiu. Detection of c-reactive protein. Shanghai journal of medical examinations, 1999, 14(5):261-263.

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Revision Date: May 3, 2021
Version Number: 0.2
Production date and expiration see the label.

IVD	For in vitro diagnostic use only
REF	Catalog number
	Manufacturer
LOT	Lot number
EC REP	European Authorized Representative
	Date of Manufacture
	Use by date
	Consult instructions for use
4℃ 30℃	Store between 4-30℃
Σ 25	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion

Better Usability

Minimum size with the footprint similar to that of a 17 inch laptop, with space saving design that allows internal storage of lyse giving small labs more space.
10.4 inch TFT touch screen together with our powerful software enhances user operations and experience.

New technology that eliminates the need for cleanser and rinse, reducing the number of reagents needed while at the same time lowering overall reagent consumption.
Flexible packaging of reagents, with normal and small sizes to better cater to the needs of different daily sample volumes.

Enhanced Performance

Higher throughput at 70 tests per hour.

Micro sample volume at 9.0uL for whole blood mode with capillary whole blood samples supported, perfect for pediatric samples.

Technical Specifications

Principles
Impedance method for WBC, RBC and PLT counting
Cyanide free reagent for hemoglobin test

Performance

Parameter	Linearity Range	Precision (CV %)	Carryover
WBC(10^9/L)	0-200	≤3.5% (4.0-6.9) ≤2.0% (7.0 -15.0)	≤0.5%
RBC(10^{12}/L)	0-8.00	≤1.5% (3.5-6.5)	≤0.5%
HGB(g/L)	0-280	≤1.5% (100 -180)	≤0.5%
MCV(fL)		≤1.0% (70 -110)	
PLT(109/L)	0-4000	≤5.0% (100 -149) ≤4.0% (150 -500)	≤1.0%

Parameters
21 parameters: WBC, Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR,P-LCC
3 histograms for WBC, RBC and PLT
2 research parameters: NLR, PLR

Reagent
M-30D DILUENT
M-30CFL LYSE
PROBE CLEANSER

Sample Volume
Prediluted mode 20μL
Whole blood mode 9 μL

Throughput
70 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 500,000 results including numeric and graphical information

Communication
LAN Port supports HL7 protocol
Support bi-directional LIS

Interface
4 USB port (for external printer, software upgrade, barcode reader, WIFI adapter,keyboard and mouse), LAN port (1)

Printout
Thermal recorder, 50 mm wide paper, various printouts formats
External printer optional

Operating Environment
Temperature: 10°C~40°C
Humidity: 10%~90%
Air pressure: 70kPa ~ 106kPa

Power Requirement
100V-240V
≤300VA
50Hz/60Hz

Dimension and Weight
Dimension: Depth(410 mm) x width(300 mm) x height(400 mm)
Weight: ≤20Kg

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P/N: ENG-BC-30s-210285x6P-20200616

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BC-30s

Auto Hematology Analyzer

Minimum Size, Maximum Capability

BC-30s

Auto Hematology Analyzer

What a 3-part should be

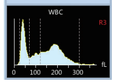
At Mindray we pride ourselves in our dedication and experience in developing better solutions for small labs. Our new line of 3-part hematology analyzers is the culmination of that effort. Compact yet powerful, full featured yet affordable, the BC-30s is what a 3-part analyzer should be.

Exclusive Feature

Detailed flag information never before seen on a 3-part analyzer. Provides information useful for diagnosis including WBC flag, RBC flag and PLT flag.

Different flag information provided according to parameter results together with histograms.

Parameter		Result	Unit
WBC	L	2.4	10^9/L
Lym#	L	0.7	10^9/L
Mid#	R	0.3	10^9/L
Gran#	RL	1.4	10^9/L
Lym%		0.305	
Mid%	R	0.130	
Gran%	R	0.565	

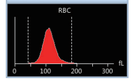


Leucopenia
Lymph decreased
Pancytopenia

Sample 1 : BC-30s shows flags "Leucopenia", "Lymph decreased", "Pancytopenia" which mean white blood cell decreased, the low number of Lymphocyte and decreased of leukocyte, erythrocyte and plate count. Meanwhile "R3" flag is also displayed. Two kinds of flag messages are both supported to ensure clinicians have better understanding of sample results.

Sample 2 : Flag "Anemia" means that the sample has the possibility of anemia.

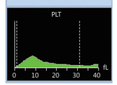
Parameter		Result	Unit
RBC	L	1.86	10^12/L
HGB	L	67	g/L
HCT	L	0.193	
MCV	H	103.5	fL
MCH	H	35.8	pg
MCHC		346	g/L
RDW-CV		0.157	
RDW-SD	H	60.7	fL



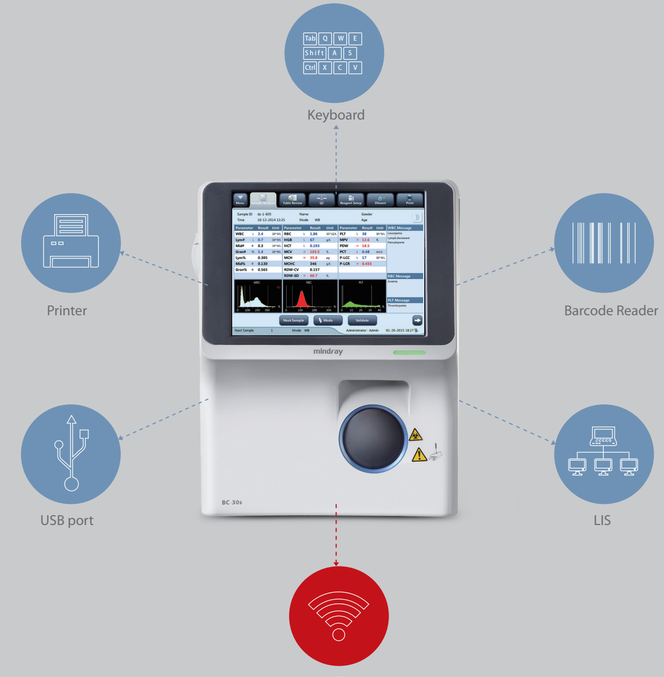
Anemia

Sample 3 : Flag "Thrombopenia" indicator is shown together with Platelets low flag.

Parameter		Result	Unit
PLT	L	38	10^9/L
MPV	H	12.6	fL
PDW	H	18.5	
PCT	L	0.48	mL/L
P-LCC	L	17	10^9/L
P-LCR	H	0.455	



Thrombopenia



WIFI capability provides you an added option for data communication together with bi-directional LIS, USB port and LAN port, barcode reader, printer and keyboard.

Test Items:

Category	Test Item	Specimen Type	Sample Volume	Reaction Time	Measuring Range
Diabetes	HbA1c	WB	5μL	15min	3.0-14.0%
Inflammation	CRP	S/P/WB	5μL	3min	0.5-200μg/mL
	PCT	S/P/WB	100μL	10min	0.1-50ng/mL
	SAA	S/P/WB	5μL	15min	2.0-300μg/mL
Cardiac	CK-MB	S/P/WB	100μL	10min	2.0-80ng/mL
	cTnI	S/P/WB	100μL	10min	0.05-40ng/mL
	Myo	S/P/WB	100μL	10min	20-500ng/mL
	NT-proBNP	S/P/WB	100μL	15min	50-25000pg/mL
	D-Dimer	P/WB	100μL	10min	0.1-10μg/mL
	H-FABP	S/P/WB	100μL	15min	1-120ng/mL
Hormone	T3	S/P/WB	100μL	15min	0.5-10nmol/L
	T4	S/P/WB	100μL	10min	10-350nmol/L
	TSH	S/P/WB	100μL	15min	0.1-60μIU/mL
	25-OH-VD	S/P	100μL	10min	5-70ng/mL
	β-HCG	S/P/WB	50μL	15min	2-20000mIU/mL
	LH	S/P/WB	100μL	15min	5-200mIU/mL
	FSH	S/P/WB	100μL	10min	1-150mIU/mL
	GH	S/P/WB	100μL	10min	0.05-100ng/mL
	PRL	S/P/WB	100μL	10min	1-100ng/mL
	AMH	S/P/WB	100μL	10min	0.1-50ng/mL
Gastric Function	PGI	S/P/WB	100μL	10min	10-60ng/mL
	PGII	S/P/WB	100μL	10min	5-100ng/mL
	G-17	S/P/WB	100μL	10min	5-300ng/mL
Renal Function	NGAL	S/P/WB/Urine	100μL	10min	50-5000ng/mL
	mAlb	Urine	100μL	5min	10-200mg/L
	β2-MG	S/P/WB	10μL	10min	0.5-20mg/L
	Cys-C	S/P/WB	10μL	5min	0.5-10ng/L
Tumor	PSA	S/P/WB	100μL	10min	0.1-100ng/mL

New items are available soon!

LS-1100

Dry Fluorescence Immunoassay Analyzer (Portable)

Quantitative

Rapid

Sensitive

Reliable

Accurate, Anytime and Anywhere

Lansion Biotechnology Co., Ltd.

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CE IVD

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 Mellitus, Inflammation, Cardiovascular Diseases, Hormone, Gastric Diseases, Renal Diseases, Tumor, etc.

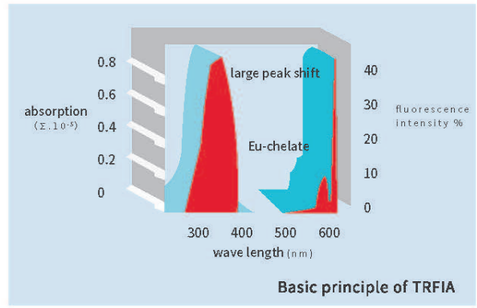
Application: Laboratory, ER, Cardiology, ICU, Respiratory, Pediatrics, etc.

Features:

Quantitative, Rapid and High Sensitive
Reliable Result (QC system, QR code calibration)

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	⩾5000
Printer	Built-in thermal printer
Battery	Built-in lithium battery (super standby time)
Communication	RS232(LIS/HIS), RJ45, USB, WIFI, Bluetooth

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 best 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