

-----:
ORDIN DE PLATA NR.: 1837 TIP.DOC. 1 :
DATA EMITERII:7 februarie 2023 :
=====:
PLATITI: 2000-00 LEI: Doua Mii lei 00 bani :
:
:
=====:
PLATITOR: (R) "BIOSISTEM CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L. MD95ML000000002251429243 :
CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau :MOLDMD2X329:
=====:
BENEFICIAR (R)Dispensarul CONTUL DE PLATI/CODUL IBAN :
Republican de Narcologie MD23ML000000002251102291 :
CODUL FISCAL :1003600150509 / :
:
:
=====:
PRESTATORUL BENEFICIAR CODUL BANCII:
BC"Moldindconbank"S.A. :MOLDMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1675163655217 din 0: :
9.02.2023 : :
: :
: L.S. :
=====:
CODUL TRANZACTIEI:001: :
DATA PRIMIRII:07/02/2023 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
-----:
CONDUCTATOR:Web Poiata Vitalie :
MIIGYwYJKoZIHvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSq:
SIB3DQEBCwUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTIxMDEyODExMzgwNVVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaG1zaW5hdTEWMBQGA1UEChMNQml :
:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIHvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIB3DQEBCwUAMCIXIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAW:
YDVQQIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaG1zaW5hdTEWMBQGA1UEChMNQmlv :
:
L.S. (semnatura electronica) :
CONDUCTATOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
-----:

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2301422**

din
от **01.02.2023**

1. Destinația / Назначение

Pentru participare la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
BIOSISTEM MLD S.R.L.	1010600028048
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /
Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:
0,00 lei/лей.

4. Valabil pînă la / Действителен до 16.02.2023

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef interimar DDF Rîșcani
Funcția/Должность

Digitally signed by Stoicov Ana
Date: 2023.02.01 09:22:56 EET
Reason: MoldSign Signature
Location: Moldova



STOICOV Ana
Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: **SLONOVSCAIA Svetlana**
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 01.02.2023 ora 8:09:11
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,28)



BC "MOLDINDCONBANK" S.A. Filiala "Invest"

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

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

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

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

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

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

L. Svirepova
semnătura

MD 0101250





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

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

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2021 - 31.12.2021

Entitatea: BIOSISTEM MLD S.R.L.

Cod CUIŢO: 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, Comerț 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: zmi13@mail.ru

Numele și coordonatele al contabilului-șef: DI (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 3 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	Sfârșitul 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:	021		
	2.1. concesiuni, licențe și mărci			
	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	2793637	3559998
	din care:	081		
	3.1. clădiri			
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	2791637	3533108
	3.4. mijloace de transport	084		

A.

3.5. inventar și mobilier	085		26890
3.6. alte mijloace fixe	086	2000	
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120		1162136
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2793637	4722134
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	2793637	4722134

B.

ACTIVE CIRCULANTE			
I. Stocuri			
1. Materiale și obiecte de mică valoare și scurtă durată	240	51978	5346
2. Active biologice circulante	250		
3. Producția în curs de execuție	260		
4. Produse și mărfuri	270	7221203	9147976
5. Avansuri acordate pentru stocuri	280		
Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	7273181	9153322
II. Creanțe curente și alte active circulante			
1. Creanțe comerciale curente	300	3912218	2182471
2. Creanțe ale părților afiliate curente	310		
inclusiv: creanțe aferente intereselor de participare	311		
3. Creanțe ale bugetului	320	74631	208171
4. Creanțele ale personalului	330		
5. Alte creanțe curente	340		
6. Cheltuieli anticipate curente	350	2	
7. Alte active circulante	360	5756117	1608597
Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	9742968	3999239
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	3942779	9861933
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	20958928	23014494
	TOTAL ACTIVE (rd.230 + rd.420)	430	23752565	27736628
	P A S I V			
C.	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		
	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	20060126	16230339
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	10403995
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	20060126	26634334
	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	20065526	26639734	
D.	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:	641		
	2.1. împrumuturi din emisiunea de obligațiuni	642		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	643		
	2.2. alte împrumuturi pe termen lung	643		
	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:	721		
	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	3252667	343711
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	188105	355528
	6. Datorii față de personal	760	50	350
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	187676	150263
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
11. Alte datorii curente	810	58541	247042	
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	3687039	1096894	
F.	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	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	23752565	27736628

SITUAȚIA DE PROFIT ȘI PIERDERE

de la pînă la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	25963175	38680547
din care:			
venituri din vânzarea produselor și mărfurilor	011	25044358	37724557
venituri din prestarea serviciilor și executarea lucrărilor	012	918817	951393
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016		4597
Costul vânzărilor, total	020	15186814	24434231
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	15186814	24433364
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026		867
Profit brut (pierdere brută) (rd.010 - rd.020)	030	10776361	14246316
Alte venituri din activitatea operațională	040	247603	5189
Cheltuieli de distribuire	050	19740	6076
Cheltuieli administrative	060	1259776	1788732
Alte cheltuieli din activitatea operațională	070	640169	1870642
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	9104279	10586055

Venituri financiare, total	090	519239	1517765
din care:	091		
venituri din interese de participare			
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	25612	30619
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	493627	1487146
Cheltuieli financiare, total	100	597528	249562
din care:	101		
cheltuieli privind dobânzile			
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	597528	249562
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-78289	1268203
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	-78289	1268203
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	9025990	11854258
Cheltuieli privind impozitul pe venit	170	1051159	1450263
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	7974831	10403995

SITUAȚIA 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			

SITUAȚIA 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 vânzări	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 vânzarea 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)

Расписка 2

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2021

Дата предоставления: 29.03.2022

Временная метка отчёта зарегистрированного в Информационной Системе НБС : 29.03.2022
17:25:45

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

Расписка

Респондент

Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.

Предоставил отчёт: RSF1_21

На фискальный период: A/2021

Дата предоставления: 29.03.2022

Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 29.03.2022 14:51:06



BioSystems

PRODUCT LIST



From Barcelona to your lab

Argentina · Brazil · Chile · France · India · Italy · Mexico · Philippines ·
Portugal · Romania · Russia · South Korea · Spain · Turkey · Thailand · USA



After almost 40 years, BioSystems - a group of 15 companies - is a reliable partner for laboratories over the 5 continents in the fields of **In-vitro Human and Veterinary Clinical Diagnostic, Food & Beverage Analysis and Monitoring of Bioprocesses.**

Today, the scientific advances in Biotech and Digital technologies drive BioSystems to focus on better understanding your needs and expectations and so provide **Analytical Solutions** to deliver the best **User Experience.**

BioSystems worldwide team of **Scientists, Engineers and Expert Professionals** devote their best efforts to continuously design and develop new solutions and improve existing ones.

I'm convinced that **working together**, we will **design** the best solutions to your future needs.

I invite you to explore [BioSystems Product List](#)



A handwritten signature in black ink that reads "P. Vila." with a horizontal line underneath.

Pau Vila Cases Ph.D
CEO
BioSystems

Summary

Clinical Chemistry	3
Biochemistry Reagents	4
Microcolumn Chromatography	13
Calibrators & Standards	14
Internal Controls	15
PREVECAL Clinical Chemistry	17
Instruments	18
Hematology	24
Analyzers	25
Coagulation	27
Reagents & Instruments	28
Autoimmunity	29
Immunofluorescence	30
ELISA	33
PREVECAL Autoimmunity	35
Instruments	36
Rapid Tests	39
Alphabetical Index	41

BioSystems S.A. reserves the right to change specifications without prior notice.

Icon guide, by profile

(Guide icons of most relevant profiles for clinical chemistry tests)



Cardiac



Renal



Liver



Pancreatic



Diabetes



Fertility



Hemostasis



Anemia



Lipids



Ions



Immune



Inflammatory



















Infectious

Clinical Chemistry



















Biochemistry reagents

Test	Code	RA	RB	mL/Kit	
α1-ACID GLYCOPROTEIN					
Immunoturbidimetric assay					
Multipurpose	31928	1 x 50 mL	-	50	
BA Dedicated	23107	1 x 60 mL	1 x 15 mL	75	
α-AMYLASE DIRECT					
Direct Substrate					
Multipurpose	11583	5 x 5 mL	-	25	
	11550	6 x 25 mL	-	150	
A15/A25 Dedicated	12550	5 x 20 mL	-	100	
BA Dedicated	21550	8 x 20 mL	-	160	
	23550	4 x 20 mL	-	80	
α-AMYLASE-EPS					
IFCC					
Multipurpose	11534	1 x 32 mL	1 x 8 mL	40	WR
BA Dedicated	21534	2 x 60 mL	2 x 15 mL	150	
A15/A25 Dedicated	12535	1 x 32 mL	1 x 8 mL	40	WR
α-AMYLASE PANCREATIC					
IFCC					
Multipurpose	11799	1 x 20 mL	1 x 5 mL	25	
A15/A25 Dedicated	12799	1 x 40 mL	1 x 10 mL	50	
BA Dedicated	21799	2 x 60 mL	2 x 15 mL	150	
ACID PHOSPHATASE (ACP)					
SFBC					
Multipurpose (Total)	11548	4 x 10 mL	lyophilized	40	WR
Multipurpose (Non Prostatic)	11548	2 x 10 mL	lyophilized	20	WR
ADENOSINE DEAMINASE (ADA)					
Adenosine-Glutamate Dehydrogenase					
A15/A25 Dedicated	12754	4 x 8 mL	1 x 10 mL	40	WR
BA Dedicated	23754	2 x 16 mL	1 x 10 mL	40	WR
ALANINE AMINOTRANSFERASE (ALT/GPT)					
IFCC					
Multipurpose	11832	1 x 40 mL	1 x 10 mL	50	WR
	11533	1 x 160 mL	1 x 40 mL	200	WR
	11568	1 x 400 mL	1 x 100 mL	500	WR
	11562	1 x 800 mL	1 x 200 mL	1000	WR
A15/A25 Dedicated	12533	5 x 40 mL	5 x 10 mL	250	WR
BA Dedicated	21533	8 x 60 mL	8 x 15 mL	600	
	23533	4 x 60 mL	4 x 15 mL	300	
Pyridoxal Phosphate (AUX)	11666	1 x 5 mL			
ALBUMIN					
Bromocresol Green					
Multipurpose	11573	1 x 250 mL	-	250	Std Inc
	11547	2 x 250 mL	-	500	Std Inc
A15/A25 Dedicated	12547	5 x 50 mL	-	250	
BA Dedicated	21547	10 x 60 mL	-	600	
	23547	4 x 60 mL	-	240	
ALBUMIN (MICROALBUMINURIA)					
Immunoturbidimetric latex assay					
Multipurpose	31324	1 x 16 mL	1 x 4 mL	20	WR
	31924	1 x 40 mL	1 x 10 mL	50	WR
A15/A25 Dedicated	13324	1 x 40 mL	1 x 10 mL	50	WR
BA Dedicated	22324	4 x 60 mL	4 x 15 mL	300	
	23324	1 x 60 mL	1 x 15 mL	75	

Test	Code	RA	RB	mL/Kit	
ALKALINE PHOSPHATASE (ALP)-AMP AMP Buffer (IFCC)	 				
Multipurpose	11592	1 x 40 mL	1 x 10 mL	50	WR
	11593	1 x 160 mL	1 x 40 mL	200	WR
	11598	4 x 100 mL	2 x 50 mL	500	WR
A15/A25 Dedicated	12518	5 x 16 mL	2 x 10 mL	100	WR
BA Dedicated	21592	4 x 60 mL	4 x 15 mL	300	
	23592	1 x 60 mL	1 x 15 mL	75	
ALKALINE PHOSPHATASE (ALP)-DEA DEA Buffer	 				
Multipurpose	11590	1 x 40 mL	1 x 10 mL	50	WR
	11591	4 x 40 mL	4 x 10 mL	200	WR
	11597	4 x 100 mL	2 x 50 mL	500	WR
A15/A25 Dedicated	12514	5 x 16 mL	2 x 10 mL	100	WR
BA Dedicated	21590	4 x 60 mL	4 x 15 mL	300	
	23590	1 x 60 mL	1 x 15 mL	75	
AMMONIA Glutamate Dehydrogenase	  				
A15/A25 Dedicated	12532	1 x 20 mL	1 x 7 mL	27	RA
BA Dedicated	23532	1 x 20 mL	1 x 7 mL	27	RA
ANGIOTENSIN CONVERTING ENZYME (ACE) FAPGG					
A15/A25 Dedicated	12796	1 x 50 mL	-	50	
BA Dedicated	21796	2 x 60 mL	-	120	
ANTI-STREPTOLYSIN O (ASO) Immunoturbidimetric latex assay	 				
Multipurpose	31323	1 x 16 mL	1 x 4 mL	20	WR
	31923	1 x 40 mL	1 x 10 mL	50	WR
	31031	2 x 160 mL	2 x 40 mL	400	WR
A15/A25 Dedicated	13923	1 x 40 mL	1 x 10 mL	50	WR
BA Dedicated	22923	2 x 60 mL	2 x 15 mL	150	
	23923	1 x 60 mL	1 x 15 mL	75	
ANTITHROMBIN III Immunoturbidimetric assay					
Multipurpose	31936	1 x 40 mL	1 x 10 mL	50	
A15/A25 Dedicated	13936	1 x 40 mL	1 x 10 mL	50	
BA Dedicated	22936	2 x 60 mL	2 x 15 mL	150	
	23936	1 x 60 mL	1 x 15 mL	75	
APOLIPOPROTEIN A-1 (APO A-1) Immunoturbidimetric assay	 				
Multipurpose	31095	1 x 40 mL	1 x 10 mL	50	
BA Dedicated	23095	1 x 60 mL	1 x 15 mL	75	
APOLIPOPROTEIN B (APO B) Immunoturbidimetric assay	 				
Multipurpose	31098	1 x 40 mL	1 x 10 mL	50	
BA Dedicated	23098	1 x 60 mL	1 x 15 mL	75	
ASPARTATE AMINOTRANSFERASE (AST/GOT) IFCC					
Multipurpose	11830	1 x 40 mL	1 x 10 mL	50	WR
	11531	1 x 160 mL	1 x 40 mL	200	WR
	11567	1 x 400 mL	1 x 100 mL	500	WR
	11561	1 x 800 mL	1 x 200 mL	1000	WR
A15/A25 Dedicated	12531	5 x 40 mL	5 x 10 mL	250	WR
BA Dedicated	21531	8 x 60 mL	8 x 15 mL	600	
	23531	4 x 60 mL	4 x 15 mL	300	
Pyridoxal Phosphate (AUX)	11666	1 x 5 mL			

Biochemistry reagents












Test	Code	RA	RB	mL/Kit	
β2-MICROGLOBULIN					
Immunoturbidimetric latex assay					
Multipurpose	31920	1 x 800 mL	1 x 200 mL	1000	WR
	31925	1 x 40 mL	1 x 10 mL	50	WR
BA Dedicated	22925	2 x 60 mL	2 x 15 mL	150	
	23925	1 x 60 mL	1 x 15 mL	75	
β-HYDROXYBUTYRATE					
Hydroxybutyrate Dehydrogenase/Diaphorase					
A15/A25 Dedicated	12525	1 x 40 mL	1 x 10 mL	50	
BA Dedicated	21525	1 x 60 mL	1 x 15 mL	75	
BILIRUBIN (DIRECT)					
Diazotized Sulfanilic					
Multipurpose	11511	4 x 40 mL	4 x 10 mL	200	WR
	11545	2 x 400 mL	2 x 100 mL	1000	WR
BILIRUBIN (DIRECT) DPD					
Dichlorophenyl Diazonium					
A15/A25 Dedicated	12504	5 x 40 mL	5 x 10 mL	250	
BA Dedicated	21504	4 x 60 mL	4 x 15 mL	300	
	23504	1 x 60 mL	1 x 15 mL	75	
BILIRUBIN (TOTAL)					
Diazotized Sulfanilic					
Multipurpose	11510	4 x 40 mL	4 x 10 mL	200	WR
	11544	2 x 400 mL	2 x 100 mL	1000	WR
BILIRUBIN (TOTAL) DPD					
Dichlorophenyl Diazonium					
A15/A25 Dedicated	12506	5 x 40 mL	5 x 10 mL	250	
BA Dedicated	21506	8 x 60 mL	8 x 15 mL	600	
	23506	4 x 60 mL	4 x 15 mL	300	
BILIRUBIN (TOTAL AND DIRECT)					
Diazotized Sulfanilic					
Multipurpose	11515	2 x 50 mL	2 x 50 mL	200	WR
	11555	1 x 500 mL	1 x 500 mL	1000	WR
CALCIUM-ARSENAZO					
Arsenazo III					
Multipurpose	11570	1 x 200 mL	-	200	Std Inc
	11571	1 x 500 mL	-	500	Std Inc
A15/A25 Dedicated	12570	10 x 50 mL	-	500	
BA Dedicated	21570	10 x 60 mL	-	600	
	23570	4 x 60 mL	-	240	
CALCIUM-CRESOLPHTHALEIN					
O-Cresolphthalein Complexone					
Multipurpose	11811	1 x 160 mL	1 x 40 mL	200	Std Inc, WR
	11812	1 x 400 mL	2 x 50 mL	500	Std Inc, WR
A15/A25 Dedicated	12513	5 x 40 mL	5 x 10 mL	250	
BA Dedicated	21511	8 x 60 mL	8 x 15 mL	600	
	23511	2 x 60 mL	2 x 15 mL	150	
CALCIUM-MTB					
Metihylthymol Blue					
Multipurpose	11527	2 x 50 mL	2 x 50 mL	200	Std Inc, WR
	11507	1 x 250 mL	1 x 250 mL	500	Std Inc, WR
CARBON DIOXIDE (CO2)					
Phosphoenolpyruvate Carboxylase/ Malate Dehydrogenase					
Multipurpose	11827	1 x 200 mL	-	200	
A15/A25 Dedicated	11558	1 x 50 mL	-	50	
BA Dedicated	21558	2 x 60 mL	-	120	

Test	Code	RA	RB	mL/Kit	
CHOLESTEROL					
Cholesterol Oxidase/Peroxidase					
 					
Multipurpose	11805	1 x 50 mL	-	50	Std Inc
	11505	1 x 200 mL	-	200	Std Inc
	11506	1 x 500 mL	-	500	Std Inc
	11539	1 x 1000 mL	-	1000	Std Inc
A15/A25 Dedicated	12505	10 x 50 mL	-	500	
BA Dedicated	21505	10 x 60 mL	-	600	
	23505	4 x 60 mL	-	240	
CHOLESTEROL LDL DIRECT					
Detergent					
 					
Multipurpose	11585	1 x 60 mL	1 x 20 mL	80	
A15/A25 Dedicated	12585	3 x 20 mL	1 x 20 mL	80	
BA Dedicated	21585	2 x 60 mL	2 x 20 mL	160	
	23585	1 x 60 mL	1 x 20 mL	80	
CHOLESTEROL HDL DIRECT					
Detergent					
 					
Multipurpose	11557	1 x 60 mL	1 x 20 mL	80	
A15/A25 Dedicated	12557	3 x 20 mL	1 x 20 mL	80	
BA Dedicated	21557	2 x 60 mL	2 x 20 mL	160	
	23557	1 x 60 mL	1 x 20 mL	80	
CHOLESTEROL HDL					
Phosphotungstate/ Mg+2-Cholesterol Oxidase/ Peroxidase Reagent + Precipitant					
 					
Multipurpose	11523	2 x 50 mL	2 x 50 mL	200	Std Inc
CHOLESTEROL HDL PRECIPITATING REAGENT					
Phosphotungstate/ Mg+2 Precipitant					
 					
Multipurpose	11648	1 x 50 mL	-	50	Std Inc
CHOLESTEROL LDL PRECIPITATING REAGENT					
Polyvinyl Sulphate/ Polyethyleneglycol Precipitant					
 					
Multipurpose	11579	1 x 20 mL	-	20	
CHOLINESTERASE (CHE)					
Butyrylthiocholine					
					
Multipurpose	11588	1 x 40 mL	1 x 10 mL	50	WR
	11589	4 x 40 mL	4 x 10 mL	200	WR
A15/A25 Dedicated	12588	1 x 40 mL	1 x 10 mL	50	WR
BA Dedicated	21588	2 x 60 mL	2 x 15 mL	150	
CITRATE					
Citrate Lyase/ Malate Dehydrogenase					
					
A15/A25 Dedicated	11895	1 x 20 mL	1 x 5 mL	25	RB + Std Inc
	11795	2 x 20 mL	2 x 5 mL	50	RB + Std Inc
BA Dedicated	23795	2 x 20 mL	2 x 5 mL	50	RB + Std Inc
COMPLEMENT COMPONENT C3					
Immunoturbidimetric assay					
					
Multipurpose	31084	1 x 20 mL	-	20	
	31073	1 x 50 mL	-	50	
	31079	1 x 250 mL	-	250	
A15/A25 Dedicated	13084	1 x 50 mL	-	50	
BA Dedicated	23103	1 x 60 mL	1 x 15 mL	75	
COMPLEMENT COMPONENT C4					
Immunoturbidimetric assay					
					
Multipurpose	31085	1 x 20 mL	-	20	
	31074	1 x 50 mL	-	50	
	31080	1 x 250 mL	-	250	
A15/A25 Dedicated	13085	1 x 50 mL	-	50	
BA Dedicated	23104	1 x 60 mL	1 x 15 mL	75	

Biochemistry reagents



















Test	Code	RA	RB	mL/Kit	
C-REACTIVE PROTEIN (CRP)					
Immunoturbidimetric latex assay					
Multipurpose	31321	1 x 16 mL	1 x 4 mL	20	WR
	31921	1 x 40 mL	1 x 10 mL	50	WR
	31029	2 x 160 mL	2 x 40 mL	400	WR
A15/A25 Dedicated	13921	2 x 40 mL	2 x 10 mL	100	WR
BA Dedicated	22921	4 x 60 mL	4 x 15 mL	300	
	23921	1 x 60 mL	1 x 15 mL	75	
C-REACTIVE PROTEIN hs (CRP-hs)					
Immunoturbidimetric latex assay, High Sensitivity					
Multipurpose	31927	1 x 40 mL	1 x 10 mL	50	WR
A15/A25 Dedicated	13927	1 x 40 mL	1 x 10 mL	50	WR
BA Dedicated	22927	2 x 60 mL	2 x 15 mL	150	
	23927	1 x 60 mL	1 x 15 mL	75	
C-REACTIVE PROTEIN-er (CRP-er)					
Immunoturbidimetric latex assay, Extended Range					
BA Dedicated	22942	2 x 60 mL	2 x 15 mL	150	
	23942	1 x 60 mL	1 x 15 mL	75	
CREATINE KINASE (CK)					
IFCC					
Multipurpose	11790	1 x 40 mL	1 x 10 mL	50	WR
	11791	4 x 40 mL	4 x 10 mL	200	WR
A15/A25 Dedicated	12524	3 x 12 mL	1 x 10 mL	45	WR
BA Dedicated	21790	2 x 60 mL	2 x 15 mL	150	
	23790	1 x 60 mL	1 x 15 mL	75	
CREATINE KINASE-MB (CK-MB)					
Immunoinhibition					
Multipurpose	11792	1 x 40 mL	1 x 10 mL	50	WR
A15/A25 Dedicated	12566	3 x 12 mL	1 x 10 mL	45	WR
BA Dedicated	21792	2 x 60 mL	2 x 15 mL	150	
	23792	1 x 60 mL	1 x 15 mL	75	
CREATININE					
Jaffé-compensated					
Multipurpose	11802	1 x 50 mL	1 x 50 mL	100	Std Inc, WR
	11502	2 x 50 mL	2 x 50 mL	200	Std Inc, WR
	11542	1 x 500 mL	1 x 500 mL	1000	Std Inc, WR
A15/A25 Dedicated	12502	5 x 50 mL	5 x 50 mL	500	WR
BA Dedicated	21502	5 x 60 mL	5 x 60 mL	600	
	23502	5 x 20 mL	5 x 20 mL	200	
CREATININE ENZYMATIC					
Enzymatic					
Multipurpose	11734	1 x 60 mL	1 x 20 mL	80	Std Inc
A15/A25 Dedicated	12734	1 x 45 mL	1 x 15 mL	60	
BA Dedicated	21734	2 x 60 mL	2 x 20 mL	160	
D-DIMER					
Phosphoenolpyruvate Carboxylase/Malate					
BA Dedicated	21519	1 x 40 mL	1 x 10 mL	50	
ETHANOL					
Alcohol Dehydrogenase					
A15/A25 Dedicated	12789	1 x 20 mL	1 x 7 mL	27	
BA Dedicated	21789	2 x 20 mL	2 x 7 mL	54	
FERRITIN					
Immunoturbidimetric latex assay					
Multipurpose	31934	1 x 10 mL	1 x 5 mL	15	WR
	31935	1 x 30 mL	1 x 15 mL	45	WR
A15/A25 Dedicated	13934	1 x 30 mL	1 x 15 mL	45	WR
BA Dedicated	22934	2 x 40 mL	2 x 20 mL	120	
	23934	1 x 40 mL	1 x 20 mL	60	

NEW

Test	Code	RA	RB	mL/Kit	
FIBRINOGEN					
Immunoturbidimetric assay 					
Multipurpose	31600	1 x 40 mL	1 x 10 mL	50	
A15/A25 Dedicated	13600	1 x 40 mL	1 x 10 mL	50	
BA Dedicated	22804	2 x 60 mL	2 x 15 mL	150	
	23804	1 x 60 mL	1 x 15 mL	75	
FRUCTOSAMINE					
NBT 					
Multipurpose	11046	2 x 50 mL	-	100	Std Inc
FRUCTOSE					
Hexokinase/ Phosphoglucose Isomerase 					
A15/A25 Dedicated	11794	1 x 40 mL	1 x 10 mL	50	Std Inc, WR
BA Dedicated	23794	1 x 60 mL	1 x 15 mL	75	Std Inc
γ-GLUTAMYL TRANSFERASE (γ-GT)					
IFCC 					
Multipurpose	11584	1 x 40 mL	1 x 10 mL	50	WR
	11520	1 x 160 mL	1 x 40 mL	200	WR
A15/A25 Dedicated	12520	5 x 40 mL	5 x 10 mL	250	WR
BA Dedicated	21520	4 x 60 mL	4 x 15 mL	300	
	23520	2 x 60 mL	2 x 15 mL	150	
GLUCOSE					
Glucose Oxidase/ Peroxidase  					
Multipurpose	11803	1 x 50 mL	-	50	Std Inc
	11503	1 x 200 mL	-	200	Std Inc
	11504	1 x 500 mL	-	500	Std Inc
	11538	1 x 1000 mL	-	1000	Std Inc
A15/A25 Dedicated	12503	10 x 50 mL	-	500	
BA Dedicated	21503	10 x 60 mL	-	600	
	23503	4 x 60 mL	-	240	
GLUCOSE-HEXOKINASE					
Hexokinase  					
Multipurpose	11656	1 x 160 mL	1 x 40 mL	200	Std Inc, WR
A15/A25 Dedicated	12756	2 x 40 mL	2 x 10 mL	100	
BA Dedicated	21656	4 x 60 mL	4 x 15 mL	300	
	23656	1 x 60 mL	1 x 15 mL	75	
HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)					
Immunoturbidimetric latex assay 					
Multipurpose	31047	1 x 50 mL	1 x 10 mL	60	
A15/A25 Dedicated	13047	1 x 50 mL	1 x 10 mL	60	
BA Dedicated	22047	2 x 60 mL	2 x 12 mL	144	
	22147	1 x 60 mL	1 x 12 mL	72	
HOMOCYSTEINE					
Enzymatic Cycling 					
A15/A25 Dedicated	12737	1 x 40 mL	1 x 10.8 mL	50.8	
BA Dedicated	21737	1 x 60 mL	1 x 16.2 mL	76.2	
	23737	1 x 20 mL	1 x 5.4 mL	25.4	
IMMUNOGLOBULIN A (IgA)					
Immunoturbidimetric assay 					
Multipurpose	31082	1 x 20 mL	-	30	
	31071	1 x 50 mL	-	50	
	31077	1 x 250 mL	-	250	
A15/A25 Dedicated	13082	1 x 50 mL	-	50	
BA Dedicated	23101	1 x 60 mL	1 x 15 mL	75	









NGSP
Certified Method

Biochemistry reagents

Test	Code	RA	RB	mL/Kit	
IMMUNOGLOBULIN G (IgG) Immunoturbidimetric assay					
Multipurpose	31081	1 x 20 mL	-	20	
	31070	1 x 50 mL	-	50	
	31076	1 x 250 mL	-	250	
A15/A25 Dedicated	13081	1 x 50 mL	-	50	
BA Dedicated	23100	1 x 60 mL	1 x 15 mL	75	
IMMUNOGLOBULIN M (IgM) Immunoturbidimetric assay					
Multipurpose	31083	1 x 20 mL	-	20	
	31072	1 x 50 mL	-	50	
	31078	1 x 250 mL	-	250	
A15/A25 Dedicated	13083	1 x 50 mL	-	50	
BA Dedicated	23102	1 x 60 mL	1 x 15 mL	75	
IRON-CHROMAZUROL Chromazurol B	 				
Multipurpose	11546	4 x 50 mL	-	200	Std Inc
IRON-FERROZINE Ferrozine	 				
Multipurpose	11509	4 x 40 mL	4 x 10 mL	200	Std Inc, WR
A15/A25 Dedicated	12509	5 x 40 mL	5 x 10 mL	250	
BA Dedicated	21509	4 x 60 mL	4 x 15 mL	300	
	23509	2 x 60 mL	2 x 15 mL	150	
KAPPA Immunoturbidimetric assay	 				
Multipurpose	31216	1x16mL	1x4mL	20mL	
A15/A25 Dedicated	13216	1x40mL	1x10mL	50mL	
BA Dedicated	22216	1x10mL	1x10mL	50mL	
LAMBDA Immunoturbidimetric assay	 				
Multipurpose	31217	1x16mL	1x4mL	20mL	
A15/A25 Dedicated	13217	1x40mL	1x10mL	50mL	
BA Dedicated	22217	1x10mL	1x10mL	50mL	
LACTATE Lactate Oxidase/ Peroxidase					
Multipurpose	11736	1 x 40 mL	1 x 10 mL	50	WR
A15/A25 Dedicated	12736	2 x 40 mL	2 x 10 mL	100	
BA Dedicated	21736	4 x 60 mL	4 x 15 mL	300	
	23736	1 x 60 mL	1 x 15 mL	75	
LACTATE DEHYDROGENASE (LDH) Pyruvate	  				
Multipurpose	11580	1 x 40 mL	1 x 10 mL	50	WR
	11581	1 x 160 mL	1 x 40 mL	200	WR
A15/A25 Dedicated	12580	5 x 40 mL	5 x 10 mL	250	WR
BA Dedicated	21580	8 x 60 mL	8 x 15 mL	600	
	23580	4 x 60 mL	4 x 15 mL	300	
LACTATE DEHYDROGENASE (LDH)-IFCC IFCC	  				
Multipurpose	11587	1 x 160 mL	1 x 40 mL	200	WR
A15/A25 Dedicated	11586	1 x 40 mL	1 x 10 mL	50	WR
BA Dedicated	21586	8 x 60 mL	8 x 15 mL	600	
	23586	2 x 60 mL	2 x 15 mL	150	
LIPASE Color					
Multipurpose	11793	1 x 50 mL	1 x 10 mL	60	Std Inc
A15/A25 Dedicated	12793	2 x 20 mL	1 x 8 mL	48	
BA Dedicated	23793	1 x 50 mL	1 x 10 mL	60	

Test	Code	RA	RB	mL/Kit	
MAGNESIUM					
Xylidyl Blue					
Multipurpose	11797	4 x 40 mL	4 x 10 mL	200	Std Inc, WR
A15/A25 Dedicated	12797	5 x 16 mL	2 x 10 mL	100	WR
BA Dedicated	21797	2 x 60 mL	2 x 15 mL	150	
	23797	1 x 60 mL	1 x 15 mL	75	
OXALATE					
Oxalate Oxidase/ Peroxidase					
A15/A25 Dedicated	12539	1 x 20 mL	1 x 5 mL	25 (20 tubes)	Std Inc, RB
Pretreatment Reagents	11839	-	-	100 tubes	
BA Dedicated (w/o tubes)	23539	1 x 20 mL	1 x 5 mL	25	Std Inc, RB
PHOSPHORUS					
Phosphomolybdate/ UV					
Multipurpose	11508	3 x 40 mL	1 x 50 mL	170	Std Inc, WR
A15/A25 Dedicated	12508	3 x 24 mL	2 x 15 mL	100	
BA Dedicated	21518	4 x 50 mL	4 x 20 mL	280	
	23518	1 x 50 mL	1 x 20 mL	70	
PREALBUMIN					
Immunoturbidimetric assay					
Multipurpose	31929	1 x 50 mL	-	50	
BA Dedicated	23106	1 x 60 mL	1 x 15 mL	75	
PROTEIN (TOTAL)					
Biuret					
Multipurpose	11800	1 x 50 mL	-	50	Std Inc
	11572	1 x 250 mL	-	250	Std Inc
	11500	2 x 250 mL	-	500	Std Inc
	11553	1 x 1000 mL	-	1000	Std Inc
A15/A25 Dedicated	12500	10 x 50 mL	-	500	
BA Dedicated	21513	2 x 60 mL	2 x 20 mL	160	
	23513	1 x 60 mL	1 x 20 mL	80	
PROTEIN (URINE+CSF)					
Pyrogallol Red					
Multipurpose	11501	4 x 50 mL	-	200	Std Inc
	11559	2 x 250 mL	-	500	Std Inc
A15/A25 Dedicated	12501	5 x 50 mL	-	250	Std Inc
BA Dedicated	21512	8 x 20 mL	-	160	
	23512	4 x 20 mL	-	80	
RHEUMATOID FACTORS (RF)					
Immunoturbidimetric latex assay					
Multipurpose	31322	1 x 16 mL	1 x 4 mL	20	
	31922	1 x 40 mL	1 x 10 mL	50	
	31030	2 x 160 mL	2 x 40 mL	400	
A15/A25 Dedicated	13922	1 x 40 mL	1 x 10 mL	50	
BA Dedicated	22922	4 x 60 mL	4 x 15 mL	300	
	23922	1 x 60 mL	1 x 15 mL	75	
TOTAL BILE ACIDS					
Enzymatic Cycling					
A15/A25 Dedicated	12551	1 x 18 mL	1 x 6 mL	24	Std Inc
BA Dedicated	21551	2 x 60 mL	2 x 20 mL	160	
	23551	1 x 60 mL	1 x 20 mL	80	
TOTAL IRON BINDING CAPACITY (TIBC)					
Fe3+ / Magnesium Hydroxide Carbonate Precipitating					
Multipurpose	11554	50 mL	3 g	50	

Biochemistry reagents

Test	Code	RA	RB	mL/Kit	
TRANSFERRIN					
Immunoturbidimetric assay					
Multipurpose	 31091	1 x 20 mL	-	20	
	31092	1 x 50 mL	-	50	
	31093	1 x 250 mL	-	250	
A15/A25 Dedicated	13091	1 x 50 mL	-	50	
BA Dedicated	22105	2 x 60 mL	2 x 15 mL	150	
	23105	1 x 60 mL	1 x 15 mL	75	
TRIGLYCERIDES					
Glycerol Phosphate Oxidase/ Peroxidase					
Multipurpose	  11828	1 x 50 mL	-	50	Std Inc
	11528	4 x 50 mL	-	200	Std Inc
	11529	2 x 250 mL	-	500	Std Inc
A15/A25 Dedicated	12528	10 x 50 mL	-	500	
BA Dedicated	21528	10 x 60 mL	-	600	
	23528	4 x 60 mL	-	240	
UNSATURATED IRON BINDING CAPACITY (UIBC)					
Ferrozine					
Multipurpose	11835	1 x 40 mL	1 x 10 mL	50	
A15/A25 Dedicated	12835	1 x 40 mL	1 x 10 mL	50	
BA Dedicated	21835	2 x 60 mL	2 x 15 mL	150	
UREA/ BUN-COLOR					
Urease/ Salicylate					
Multipurpose	 11536	2 x 50 mL	2 x 50 mL	200	Std Inc, RA
	11537	1 x 250 mL	1 x 250 mL	500	Std Inc, RA
UREA/ BUN-UV					
Urease/ Glutamate Dehydrogenase					
Multipurpose	 11516	4 x 40 mL	4 x 10 mL	200	Std Inc, WR
	11517	2 x 200 mL	2 x 50 mL	500	Std Inc, WR
	11541	1 x 800 mL	1 x 200 mL	1000	Std Inc, WR
A15/A25 Dedicated	12516	5 x 40 mL	5 x 10 mL	250	WR
BA Dedicated	21516	8 x 60 mL	8 x 15 mL	600	
	23516	4 x 60 mL	4 x 15 mL	300	
URIC ACID					
Uricase/Peroxidase					
Multipurpose	 11821	1 x 50 mL	-	50	Std Inc
	11521	1 x 200 mL	-	200	Std Inc
	11522	1 x 500 mL	-	500	Std Inc
	11540	1 x 1000 mL	-	1000	Std Inc
A15/A25 Dedicated	12521	10 x 50 mL	-	500	
BA Dedicated	21521	10 x 60 mL	-	600	
	23521	4 x 60 mL	-	240	
ZINC					
Bromo-PAPS					
A15/A25 Dedicated	  12526	2 x 20 mL	1 x 10 mL	50	Std Inc, RA

Microcolumn Chromatography

Code	Quantity	Comments
5-AMINOLEVULINIC ACID (ALA)/ PORPHOBILINOGEN (PBG) 11017	40 tests	EHRlich REAGENT ALA Standard included
HEMOGLOBIN A2 11077	20 tests	ION EXCHANGE
5-HYDROXYINDOLEACETIC ACID (5-HIAA) 11010	40 tests	NITROSE NAFTOL Standard included
17-HYDROXYCORTICOSTEROIDS (17-OH) 11006	40 tests	PORTER-SILBER Standard included
17-KETOSTEROIDS 11002	40 tests	ZIMMERMANN Standard included
METANEPHRINES 11022	40 tests	PISANO Standard included
VANILMANDELIC ACID 11003	20 tests	PERIODATE Standard included



Calibrators & Standards

Code	Quantity	Components
ADENOSINE DEAMINASE (ADA) 18052	1 x 1 mL	Adenosine Deaminase (ADA)
ALBUMIN (MICROALBUMINURIA) 31130	1 x 1 mL	Albumin (Microalbuminuria)
AMMONIA, ETHANOL, CO2 18065	2 x 5 mL	Ammonia, Ethanol, Carbon Dioxide
ANTI-STREPTOLYSIN O (ASO) 31119	1 x 1 mL	Anti-Streptolysin O (ASO)
APOLIPOPROTEIN A-I 31100	1 x 1 mL	Apolipoprotein A-I
APOLIPOPROTEIN B 31200	1 x 1 mL	Apolipoprotein B
β2-MICROGLOBULIN 31122	1 x 1 mL	β2-Microglobulin
BIOCHEMISTRY (BOVINE) 18011	5 x 5 mL	ACE, ACP, Albumin, ALP, ALT/GPT, AST/GOT, α-Amylase, β-hydroxybutyrate, Total Bilirubin, Calcium, Cholesterol, Chloride, CK, Creatinine, Direct Bilirubin, Iron, Lactate, LDH, Lipase, Glucose, γ-GT, Magnesium, Phosphorus, Potassium, Sodium, Total Bile Acids, Total Protein, Triglycerides, UIBC, Urea, Uric acid, and Zinc.
BIOCHEMISTRY (HUMAN) 18044	5 x 5 mL	ACE, ACP, Albumin, ALP, ALT/GPT, AST/GOT, α-Amylase, α-Amylase Pancreatic, β-hydroxybutyrate, Direct Bilirubin, Direct HDL-Cholesterol, Direct LDL-Cholesterol, Total Bilirubin, Creatinine, Calcium, Chloride, CK, γ-GT, Cholesterol, Lactate, LDH, Lipase, Cholinesterase, Glucose, Iron, Triglycerides, Magnesium, Phosphorus, Potassium, Total Protein, Sodium, UIBC, Urea, Uric acid, and Zinc.
BILIRUBIN 11513	1 x 5 mL	Bilirubin
CHOLESTEROL HDL/LDL 11693	1 x 1 mL	HDL Cholesterol Direct/ LDL Cholesterol Direct
CREATININE KINASE-MB (CK-MB) 11824	1 x 1 mL	CK-MB
C-REACTIVE PROTEIN (CRP/CRP-hs) 31113	1 x 1 mL 1 x 5 mL	CRP CRP-hs
C-REACTIVE PROTEIN (CRP-er) 31182	1 x 3 mL	CRP-er
D-DIMER 18077	1 x 3 mL	D-Dimer
FERRITIN 31127	1 x 3 mL	Ferritin
FIBRINOGEN 31601	1 x 1 mL	Fibrinogen

NEW

Code	Quantity	Components
HbA1C-DIRECT 31048	4 x 0.5 mL	HbA1C
HOMOCYSTEINE 11750	5 x 1 mL	Homocysteine
KAPPA/LAMBDA CALIBRATOR 18070	5 x 1 mL	Kappa Light Chains and Lamda Light Chains
PROTEIN 31075	5 x 1 mL	Set of five Levels. α1-Acid Glycoprotein, Antithrombin III, IgA, IgG, IgM, Complement C3 and C4, Prealbumin and Transferrin.
PROTEIN (URINE) 11603	1 x 5 mL	Protein (Urine)
RHEUMATOID FACTORS (RF) 31116	1 x 3 mL	Rheumatoid Factor (RF)

Internal Controls

Code	Quantity	Components
ADA 18048	2 x 1 mL	LEVEL I and II Adenosine Deaminase
AMMONIA, ETHANOL, CO2 18063	3 x 5 mL	LEVEL I Ammonia, Ethanol, Carbon Dioxide
18064	3 x 5 mL	LEVEL II
BIOCHEMISTRY SERUM 18009	5 x 5 mL	LEVEL I ACE, ACP, Albumin, ALP, ALT/GPT, AST/GOT,
18005	20 x 5 mL	α-Amylase, β-hydroxybutyrate, Direct and Total
18010	5 x 5 mL	LEVEL II Bilirubin, Calcium, Chloride, Cholesterol, HDL-
18007	20 x 5 mL	Cholesterol, CK, Creatinine, Glucose, γ-GT, Iron, LDH, Lactate, Lipase, Magnesium, Phosphorus, Potassium, Protein Total, Sodium, Total Bile Acids, Triglycerides, UIBC, Urea, Uric acid and Zinc.
BIOCHEMISTRY SERUM (HUMAN) 18042	5 x 5 mL	LEVEL I ACE, ACP, Albumin, ALP, ALT/GPT, AST/GOT,
18043	5 x 5 mL	LEVEL II α-Amylase, α-Amylase Pancreatic, β-hydroxybutyrate, Direct and Total Bilirubin, Calcium, Chloride, Cholesterol, Direct Cholesterol-HDL, Direct Cholesterol-LDL, Cholinesterase, CK, Creatinine, Glucose, γ-GT, Iron, Lactate, LDH, Lipase, Magnesium, Phosphorus, Potassium, Protein total, Sodium, Triglycerides, UIBC, Urea, Uric acid and Zinc.
BIOCHEMISTRY URINE 18054	1 x 5 mL	LEVEL I Albumin, α-Amylase, α-Amylase Pancreatic,
18066	1 x 5 mL	LEVEL II Calcium, Chloride, Citrate, Creatinine, Glucose, Magnesium, Phosphorus, Potassium, Protein urine, Sodium, Urea and Uric acid.

Controls

Code	Quantity	Components	
β2-MICROGLOBULIN			
31592	2 x 1 mL	LEVEL I and II	β2-Microglobulin
β2-MICROGLOBULIN URINE			
31215	1 x 3 mL		β2-Microglobulin
CREATININE KINASE-MB			
18024	1 x 1 mL	LEVEL I	CK, and CK-MB
18061	1 x 1 mL	LEVEL II	
CONTROL URINE			
18036	1 x 20 mL		Albumin, 5-Aminolevulinic Acid
18037	10 x 20 mL		(ALA), 5-Hydroxyindolacetic acid, 17-Hydroxycorticosteroids, 17-Ketosteroids, Metanephrines, Protein and Vanilmandelic acid.
D-DIMER			
18078	2 x 1 mL	LEVEL I and II	D-Dimer
FERTILITY BIOCHEMISTRY			
18053	1 x 1 mL		Citrate, Fructose and Zinc
FIBRINOGEN			
31602	1 x 1 mL		Fibrinogen
FRUCTOSAMINE			
18057	1 x 1 mL		Fructosamine
HEMOGLOBIN A1C			
18001	1 x 0.5 mL	NORMAL	HbA1c Direct turbidimetry
18002	1 x 0.5 mL	ELEVATED	
HEMOGLOBIN A2			
10011	1 x 0.5 mL	ELEVATED	HbA2 Chromatography
HOMOCYSTEINE			
18058	1 x 1 mL	LEVEL I	Homocysteine
18059	1 x 1 mL	LEVEL II	
LIPID SERUM			
18040	3 x 1 mL	LEVEL I	Apolipoprotein A-I, Apolipoprotein B, Cholesterol, Cholesterol-HDL, Cholesterol-LDL and Triglycerides
18041	3 x 1 mL	LEVEL II	
OXALATE URINE			
18080	1 x 5 mL	LEVEL I	Oxalate
18041	1 x 5 mL	LEVEL II	
PROTEIN SERUM			
31211	3 x 1 mL	LEVEL I	α1-Acid Glycoprotein, Antithrombin III, Complement C3 and C4, C-Reactive Protein-hs, Ferritin, IgA, IgG, IgM, Prealbumin, Transferrin, Kappa Light Chains and Lambda Light Chains
31212	3 x 1 mL	LEVEL II	
RHEUMATOID SERUM			
31213	3 x 1 mL	LEVEL I	Anti-Streptolysin O, C-Reactive Protein, Rheumatoid Factors, CRPer
31214	3 x 1 mL	LEVEL II	

External Quality Control

PREVECAL

www.prevecal.net

International External Quality Assessment Scheme

- ▶ Yearly program for the comparison of results between laboratories.
- ▶ Monthly measurements of different control materials
- ▶ The final report summarises all monthly reports and shows additional data on performance and capability
- ▶ 6-sigma quality management for the assessment for each measurement procedure of the laboratory
- ▶ On-line participation through www.prevecal.net
- ▶ Accredited by ISO 17043

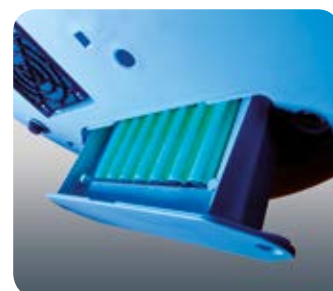
Clinical Chemistry

Code	Quantity	Components
PREVECAL BIOCHEMISTRY (BOVINE)		
18027	12 x 5 mL	ACP, Albumin, ALP, ALT/GPT, AST/GOT, α-Amylase, Total Bilirubin, Calcium, Chloride, Cholesterol, HDL-Cholesterol, Cholinesterase, CK, Creatinine, Glucose, γ-GT, Iron, Lactate LDH, Lipase, Magnesium, Phosphorus, Potassium, Proteins, Sodium, Triglycerides, Urea and Uric acid.
PREVECAL BIOCHEMISTRY HUMAN		
18045	12 x 5 mL	ALT, Albumin, α-Amylase, α-Amylase Pancreatic, AST, Direct and Total Bilirubin, Calcium, (human sera) Chloride, Cholesterol, Cholinesterase, HDL-Cholesterol, CK, Creatinine, ACP, ALP, Phosphorus, Glucose, γ-GT, Iron, Lactate LDH, LDL-Cholesterol, Lipase, Magnesium, Potassium, Proteins, Sodium, Triglycerides, Uric Acid and Urea.
PREVECAL RHEUMA		
31009	12 x 1 mL	Anti-streptolysin O, C-reactive Protein and Rheumatoid Factors (human sera).
PREVECAL PROTEINS		
31010	12 x 1 mL	α1-Acid Glycoprotein, CRP-hs, Immunoglobulins (A, G and M), Complements C3 (human sera) and C4, Ferritin, Prealbumin and Transferrin.
PREVECAL URINE		
18067	12 x 5 mL	Albumin, α-Amylase, α-Amylase Pancreatic, Calcium, Chloride, Citrate, Creatinine, Glucose, Magnesium, Phosphorus, Potassium, Protein Urine, Sodium, Urea and Uric Acid.

ISO 17043 — ACCREDITED

All kits include general instructions and cards for results.

Instruments



BTS 350 SEMI-AUTOMATIC ANALYZER

Code 80175

Semi-Automatic Analyzer LED Technology

- ▶ LED configuration: 340, 405, 505, 535, 560, 600, 635, 670 nm, (optional: 450 nm).
- ▶ Durable, humidity proof Hard Coated Filters.
- ▶ Battery Power Pack (2hrs)-OPTIONAL (AC14773).
- ▶ Photometric Range 0.0-3.5A for all wavelengths.
- ▶ Flow Cuvette 18 μ L (macro, semi-micro and microcuvette).
- ▶ Levy-Jennings QC chart (based on Westgard's Rules).
- ▶ Calibration by Factor, single calibrator or calibration curve.
- ▶ Maximum power of 30 W. (minimal energy consumption).
- ▶ USB Port to export data (results and graphs).
- ▶ The lowest maintenance.



Instruments



A15

Random Access Analyzer

- ▶ Continuous loading of samples during working session (STAT samples).
- ▶ Innovative design and functional robustness.
- ▶ Low water consumption, less than 0.5 L/ hour.
- ▶ Throughput of 150 tests/hour.
- ▶ Real prozone detection function.
- ▶ Primary tubes and pediatric vials in any position.
- ▶ Maximum flexibility in the positioning of samples and reagents.
- ▶ Minimum reading volume of 180 mL.
- ▶ Clinical Chemistry and Turbidimetry dedicated reagents.
- ▶ Filter configuration 340, 405, 505, 535, 560, 600, 635, 670 nm (adaptable).

Code 83105

Optional configurations

A15 with cooling system for 20 refrigerated reagents positions

Code 83105 C

Instruments



Code 83101-V2

Random Access Analyzer

- ▶ Throughput of 240 tests/hour.
- ▶ Clinical Chemistry and Turbidimetry dedicated reagents.
- ▶ 30 refrigerated positions by 20 and 50 mL reagents bottles.
- ▶ Flexibility in positioning with polyvalent (sample and reagent) racks.
- ▶ Real prozone detection function non lot dependent.
- ▶ Unlimited STAT capabilities. Run at any time.
- ▶ Minimum reading volume of 180 mL.
- ▶ Filter configuration 340, 405, 505, 535, 560, 600, 635, 670 nm (adaptable).
- ▶ Automatic conditioning of fluid system.

Consumables A15/A25

Code	Quantity	Description
BO11524	1000 mL	Concentrated system liquid
BO13416	100 mL	Concentrated washing solution
AC11485	10 uds.	Reaction rotor
A1K110	1 unit	Power Supply Unit, 110V
A1K220	1 unit	Power Supply Unit, 220V
AC17200	4 x 20 mL	Acid Washing Solution (WS1)
AC10770	1000 units	Sample wells (pediatric cups)
BO11493	10 units	Reagent bottles 50 mL + caps
BO11494	10 units	Reagent bottles 20 mL + caps
BO13442	10 units	Amber reagent bottles 50 mL + caps
LA10418	5 units	Halogen lamp A25 12V/20W
LA10429	5 units	Halogen lamp A15 6V/10W
AC14681	1 unit	External barcode reader



BA200

LED TECHNOLOGY

Random Access Analyzer

Code 83200

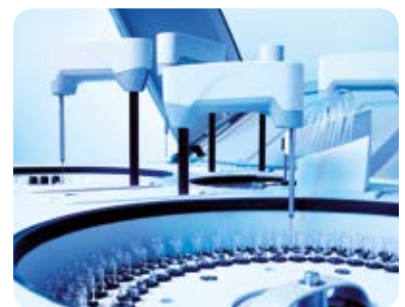
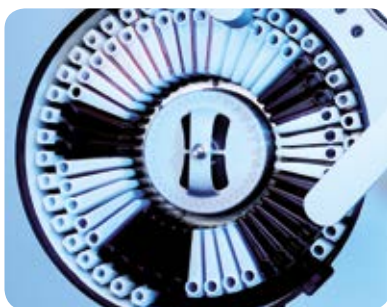
- ▶ STAT and Routine Laboratories Benchtop Random Clinical Chemistry Analyzer.
- ▶ Dynamic Baseline with SMART LED Technology.
- ▶ High reagent and sample capacity (88 positions), the highest grade in flexibility.
- ▶ Barcoded dedicated reagents.
- ▶ Highly accurate dispensing.
- ▶ 120 - cuvette rotor with washing station.
- ▶ Compact system with low maintenance.
- ▶ Real 200 t/h, even with bi reagent reactions.



Accessories BA200

Code	Quantity	Description
AC17346	1 unit	Wheeled table + computer support
AC17345	1 unit	Wheeled table

Instruments



Random Access Analyzer

- ▶ Throughput of 400 test/hour (Clinical Chemistry and Turbidimetry).
- ▶ Optical system based on LED technology that assures unlimited lifetime avoiding lamp replacement and improving sensitivity.
- ▶ Photometric range up to 3.5 Abs and optical resolution of 0.0001 Abs.
- ▶ Capacity up to 135 sample positions (90 samples with barcode).
- ▶ 88 Cooling reagents on board (5 - 8°C) by 20 and 60 mL dedicated reagent bottles.
- ▶ Easy STAT samples positioning.
- ▶ Non fixed positions for samples, control, calibrator nor STAT.
- ▶ Barcode readers for sample and reagents.
- ▶ ISE module, Na⁺, K⁺, Cl⁻, Li⁺ (optional).
- ▶ Minimum user maintenance.
- ▶ Less than 14 L/h water consumption and energy-efficient management (500 VA).
- ▶ Capacity to fully integrate into LIS (ASTM, HL7).
- ▶ Compact system with no peripherals (external bottles, pumps/ compressors, weighing scales, additional tubes, etc.).



**reddot award 2014
winner**

Red Dot Award for high design quality

Consumables and accessories BA200/BA400

Code	Presentation	Description
AC11485	10 units	Reaction rotors
AC16434	500 mL	Concentrated washing solution
A1K1500	1 unit	Power Supply Unit 1500 VA
AC10770	1000 units	Sample wells (Pediatric cups)
AC16362	10 units	Reagent bottles 60 mL + caps
AC16363	10 units	Reagent bottles 20 mL + caps
AC16364	10 units	Amber reagent bottles 60 mL + caps
AC16365	10 units	Amber reagent bottles 20 mL + caps
AC17201	4 x 20 mL	Acid washing solution (WS1)
AC17205	4 x 15 mL	Alkaline washing solution (WS2)
AC14681	1 unit	External barcode reader

ISE Module	Presentation	Description
5201	1 unit	Sodium Electrode (Na ⁺)
5202	1 unit	Potassium Electrode (K ⁺)
5207	1 unit	Chloride Electrode (Cl ⁻)
5204	1 unit	Reference Electrode
5205	1 unit	Lithium Electrode (Li ⁺)
5420	1 unit	Reagent pack Na ⁺ /K ⁺ /Cl ⁻ /Li ⁺
5412	125 mL	Urine diluent 125 ml
5408	500 mL	Urine diluent 500 ml
5421	1 unit	ISE Cleaning solution Kit
2814	1 unit	Bi-level quality control kit (Na ⁺ /K ⁺ /Cl ⁻ /Li ⁺)
2815	1 unit	Tri-level quality control kit (Na ⁺ /K ⁺ /Cl ⁻ /Li ⁺)

Hematology



Analyzer systems

Microfluidic technology

Hematology Analyzers

- ▶ Low consumption: Only 3 reagents
- ▶ Compact design
- ▶ Full-color touch screen
- ▶ Connectivity: LIS connection; results sent by email



HA5

Code 86103

HA5^{OP}

Code 86203

Complete Hematology system 5-DIFF uses laser based flow cytometry with forward-scattered light detection for WBC, volumetric impedance method for RBC and photometric method for HGB.

- ▶ Sampling mode: closed
- ▶ Processed sample volume : 2x1.4µL
- ▶ Throughput: 60 test/hour
- ▶ 26 parameters, 1 scattergram, 3 histograms

Consumables

Product	Code	Quantity
Reagent pack 5 DIFF 100 test	60126	4.3L
Reagent pack 5 DIFF 400 test	60128	6.3L
Control blood 5 DIFF (level: high, normal,low)	60122	3x3mL

- ▶ Sampling mode: open
- ▶ Processed sample volume : 2x1.4µL
- ▶ Throughput: 57 test/hour
- ▶ 26 parameters, 1 scattergram, 3 histograms

Consumables

Product	Code	Quantity
Reagent pack 5 DIFF OP 100 test	60140	3.78L
Reagent pack 5 DIFF OP 250 test	60141	5.55L
Control blood 5 DIFF (level: high, normal,low)	60122	3x3mL

Analyzer systems

Microfluidic technology



HA3

Code 86003

Complete hematology system 3-DIFF based on the volumetric impedance method.

- ▶ Two operating modes: open/closed
- ▶ Processed sample volume : 2.5µL
- ▶ Throughput: 60t/h in closed mode
- ▶ 22 parameter, 3 histograms

Consumables

Product	Code	Quantity
Reagent pack 3 DIFF 100 test	60110	1.85L
Reagent pack 3 DIFF 500 test	60112	5.45L
Control blood 3 diff (level: high, normal,low)	60109	3x2.5mL
Cleaning solution	60108	100mL

Accessories



HALOADER

Code HA86000

The HALoader is an automatic sample vial loading device. The Autoloader is compatible with HA5 hematology analyzer and it supports the different vial types: **Greiner Vacuette, BD vacutainer y BD MAP.**

- ▶ 60t/h — Throughput
- ▶ 50 samples/tray — Capacity
- ▶ Random access mode
- ▶ Built in sample mixer and barcode reader
- ▶ All operations can be paused at any time

Net weight – 8.5Kg

Coagulation



Reagents & Instruments

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



COA X

Semi-automated coagulometers

- ▶ Three models: 1, 2 or 4 optical channels.
- ▶ Prepared for the daily routine and the upcoming requirements.
- ▶ High quality results.

Specifications

Code	85001	85002	85004
Optic channels	1	2	4
Wavelength (mm)	620 (red)	405 (UV)	405 (UV)
Global Coag. Tests	PT, APTT, TT, FIB	PT, APTT, TT, FIB	PT, APTT, TT, FIB
Specific Coag. Tests	-	individual factors	
Latex Tests	D-Dimer	D-Dimer	
Chromogenic Coag. Tests	-	AT,PC	
Display	Color Touch screen display		
Dimensions	230 x 140 x 90 mm (l,b,h)		
Interfaces	RS 232 (2x) Printer, barcode reader USB (2x) Network, Firmware update		



Consumables

Product

1 box 500 cuvettes	85020
--------------------	-------

Autoimmunity



Immunofluorescence

Code	Quantity	Description
ANTI-NUCLEAR ANTIBODIES HEp-2 (ANA-HEp-2)		
<i>HEp-2 cells</i>		
44108	24 tests	Complete kit, 6 wells
44508	60 tests	Complete kit, 6 wells
44509	120 tests	Complete kit, 12 wells
44546	10 slides	Slide box, 6 wells
44547	10 slides	Slide box, 12 wells
ANTI-nDNA ANTIBODIES (nDNA)		
<i>Crithidia luciliae</i>		
44825	24 tests	Complete kit, 6 wells
44818	60 tests	Complete kit, 6 wells
44817	120 tests	Complete kit, 12 wells
44820	10 slides	Slide box, 6 wells
44819	10 slides	Slide box, 12 wells
ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)		
<i>Ethanol fixed ANCA</i>		
44850	24 tests	Complete kit, 6 wells
44851	60 tests	Complete kit, 6 wells
44852	10 slides	Slide box, 6 wells
44911	10 slides	Slide box, 12 wells
<i>Formalin fixed ANCA</i>		
44878	10 slides	Slide box, 6 wells
44898	60 tests	Complete kit, 6 wells
<i>Methanol fixed ANCA</i>		
44895	10 slides	Slide box, 6 wells
ANTI-ENDOMYSIUM ANTIBODIES (AEA)		
<i>Monkey Esophagus (Endomysium)</i>		
44548	48 tests	Complete kit, 4 wells
44715	96 tests	Complete kit, 8 wells
44557	12 slides	Slide box, 4 wells
44710	12 slides	Slide box, 8 wells
AUTOANTIBODIES RL/RK/RS (ANA-AMA-ASMA-APCA-LKM)		
<i>Rat Liver/Kidney/Stomach</i>		
44558	48 tests	Complete kit, 4 wells
44648	96 tests	Complete kit, 8 wells
44570	12 slides	Slide box, 4 wells
44639	12 slides	Slide box, 8 wells
AUTOANTIBODIES MsL/MsK/MsS (ANA-AMA-ASMA-APCA-LKM)		
<i>Mouse Liver/Kidney/Stomach</i>		
44826	12 slides	Slide box, 4 wells
44827	12 slides	Slide box, 8 wells
ANTI-MITOCHONDRIAL ANTIBODIES (AMA)		
<i>Rat Kidney</i>		
44510	48 tests	Complete kit, 4 wells
44514	96 tests	Complete kit, 8 wells
44511	12 slides	Slide box, 4 wells
44515	12 slides	Slide box, 8 wells
ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA)		
<i>Rat Stomach</i>		
44520	48 tests	Complete kit, 4 wells
44524	96 tests	Complete kit, 8 wells
44521	12 slides	Slide box, 4 wells
44525	12 slides	Slide box, 8 wells

Code	Quantity	Description
GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)		
		<i>Monkey Kidney</i>
44588	12 slides	Slide box, 4 wells
ANTI-ADRENAL CORTEX ANTIBODIES (AACA)		
		<i>Monkey Adrenal</i>
44574	48 slides	Slide box, 4 wells
44575	12 slides	Slide box, 4 wells
ANTI-STRIATED MUSCLE ANTIBODIES (AStMA)		
		<i>Rat Striated Muscle</i>
44649	12 slides	Slide box, 4 wells
ANTI-ISLET CELL ANTIBODIES (AICA)		
		<i>Monkey Pancreas</i>
44609	48 tests	Complete kit, 4 wells*
44572	12 slides	Slide box, 4 wells
ANTI-THYROID ANTIBODIES (ATA)		
		<i>Monkey Thyroid</i>
44550	48 tests	Complete kit 4 wells
44551	12 slides	Slide box, 4 wells
ANTI-SKIN ANTIBODIES (ASA)		
		<i>Monkey Esophagus</i>
44560	48 tests	Complete kit, 4 wells*
44561	12 slides	Slide box, 4 wells
ANTI-KERATIN ANTIBODIES (AKA)		
		<i>Rat Esophagus</i>
44618	48 tests	Complete kit, 4 wells*
44517	12 slides	Slide box, 4 wells
AUTOANTIBODIES DUO		
44874	60 tests	HEp2/ML. Slide box, 6 wells
TISSUE SLIDES FOR RESEARCH USE ONLY (RUO)		
44571		Monkey Heart
44679		Monkey Stomach
44573		Monkey Ovary
44685		Monkey Sciatic Nerve
44687		Monkey Brain
44684		Monkey Cerebellum
44589		Monkey Hypophysis
44688		Monkey Jejunum
44638		Monkey Submaxillary
44566		Monkey Testicle
44516		Rat Colon
44527		Rat Sciatic Nerve
Conjugates for Monkey tissues		
IgG FITC/Evans (M)		
44847	3.5 mL	Anti-(Monkey adsorbed) IgG FITC conjugate, contains Evans Blue.
44882	10 mL	For use with AEA, GBMA, AICA, ATA, ASA and AACA.
IgG FITC/Evans (M) hs		
44914	3.5 mL	High sensitive Anti-(Monkey absorbed) IgG FITC conjugate, contains Evans Blue.
44915	10 mL	For use with AEA, GBMA, AICA, ATA, ASA and AACA

Immunofluorescence

Code	Quantity	Description
IgA FITC/Evans		
44692	3.5 mL	Anti-IgA FITC conjugate, contains Evans Blue.
44835	10 mL	For use with AEA.

Conjugates for Rat and Mouse tissues

FITC/Evans (R)		
44590	3.5 mL	(Rat adsorbed) Anti-IgG, IgA, IgM FITC conjugate, contains Evans Blue.
44836	10 mL	For use with Autoantibodies Screening, AMA and ASMA.

Conjugates for HEp-2, nDNA and ANCA

IgG FITC/Evans		
44697	3 mL	Anti-IgG FITC conjugate, contains Evans Blue.
44834	10 mL	For use with HEp-2, nDNA, ANCA AStMA and AKA.

Auxiliary Reagents

Miscellaneous

44846	10 mL	Glycin (for GBMA)
44592	100 mL	PBS (10x)
44694	3 mL	Mounting medium
44897	100 u.	Coverslips (24 x 60 mm)

Immunofluorescence Controls*

44696	0.3 mL	Negative Control
44889	2.0 mL	Negative Control
44502	0.3 mL	Anti-Nuclear Antibodies-Homogeneous Positive Control
44890	2.0 mL	Anti-Nuclear Antibodies-Homogeneous Positive Control
44585	0.3 mL	Anti-Nuclear Antibodies-Centromere Positive Control
44504	0.3 mL	Anti-Nuclear Antibodies-Nucleolar Positive Control
44503	0.3 mL	Anti-Nuclear Antibodies-Speckled Positive Control
44549	0.3 mL	Anti-Endomysium Antibodies IgA Positive Control
44893	2.0 mL	Anti-Endomysium Antibodies IgA Positive Control
44732	0.3 mL	Anti-Endomysium Antibodies IgG Positive Control
44512	0.3 mL	Anti-Mitochondrial Antibodies Positive Control
44891	2.0 mL	Anti-Mitochondrial Antibodies Positive Control
44522	0.3 mL	Anti-Smooth Muscle Antibodies Positive Control
44892	2.0 mL	Anti-Smooth Muscle Antibodies Positive Control
44553	0.3 mL	Anti-Thyroid Antibodies Positive Control
44542	0.3 mL	Anti-nDNA Antibodies Positive Control
44894	2.0 mL	Anti-nDNA Antibodies Positive Control
44854	0.3 mL	C-ANCA Positive Control
44912	2.0 mL	C-ANCA Positive Control
44855	0.3 mL	P-ANCA Positive Control
44913	2.0 mL	P-ANCA Positive Control
44896	0.3 mL	X-ANCA Positive Control

ELISA

Code	Quantity	Description
ANA-SCREENING 44785	96 tests	Purified SSA(Ro), SSB(La), Sm/RNP, RNP (70, A and C), Sm, Scl70, Jo1, dsDNA, ssDNA, nucleosomes, total histones, PMScl 100, Centromere B
ENA 6-SCREENING 44740	96 tests	SSA (Ro), SSB (La), Sm, Sm/RNP, Jo1, Scl70
ENA 4-PROFILE 44775	96 tests	Highly purified SSA, SSB, Sm, Sm/RNP
ENA 6-PROFILE 44910	96 tests	Highly purified SSA (Ro), SSB (La), Sm, Sm/RNP, Jo1, Scl70
ANTI-Sm ANTIBODIES 44755	96 tests	Highly purified human antigen
ANTI-Sm/RNP ANTIBODIES 44770	96 tests	Highly purified human antigen
ANTI-SSA (Ro) ANTIBODIES 44765	96 tests	Highly purified antigen
ANTI-SSB (La) ANTIBODIES 44750	96 tests	Highly purified antigen
ANTI-CENTROMERE B ANTIBODIES (CENP-B) 44865	96 tests	Recombinant antigen
ANTI-Jo1 ANTIBODIES 44864	96 tests	Highly purified antigen
ANTI-Scl70 ANTIBODIES 44863	96 tests	Highly purified antigen
ANTI-HISTONES ANTIBODIES (HIST) 44862	96 tests	Highly purified antigen
ANTI-NUCLEOSOME ANTIBODIES (NCL) 44861	96 tests	Purified antigen
ANTI-dsDNA ANTIBODIES 44705	96 tests	Calf thymus antigen
ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA) 44860	96 tests	Highly purified antigen
ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM) 44780	96 tests	Highly purified antigen
ANTI-PHOSPHOLIPID ANTIBODIES IgG/IgM (APLA) 44867	96 tests	Mixture of cardiolipin, phosphatidyl serine, phosphatidyl inositol, phosphatidic acid and human b2-Glycoprotein 1

ELISA

Code	Quantity	Description
ANTI- β 2-GLYCOPROTEIN 1 ANTIBODIES IgG/IgM (β 2-GP1) 44868	96 tests	Highly purified antigen
ANTI-ANNEXIN V ANTIBODIES IgG/IgM (ANX) 44869	96 tests	Highly purified antigen
ANTI-PR3 ANTIBODIES (C-ANCA) 44791	96 tests	Purified human antigen
ANTI-MPO ANTIBODIES (P-ANCA) 44790	96 tests	Purified human antigen
ANTI-BPI ANTIBODIES 44905	96 tests	Purified human antigen
ANTI-CATHEPSIN G ANTIBODIES 44906	96 tests	Purified human antigen
ANTI-ELASTASE ANTIBODIES 44907	96 tests	Purified human antigen
ANTI-LACTOFERRIN ANTIBODIES 44908	96 tests	Purified human antigen
ANTI-LYSOZYME ANTIBODIES 44909	96 tests	Purified human antigen
ANTI-GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBM) 44870	96 tests	Highly purified antigen
ANTI-tTRANSGLUTAMINASE IgA ANTIBODIES (Anti-tTG IgA)* 44754	96 tests	Recombinant human antigen activated by calcium and gliadin
ANTI-tTRANSGLUTAMINASE IgG ANTIBODIES (Anti-tTG IgG)* 44798	96 tests	Recombinant human antigen activated by calcium and gliadin
ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA) 44704	96 tests	Gliadin
ANTI-DEAMIDATED GLIADIN (DGP-IgG) 44884	96 tests	Synthetic deamidated gliadin
ANTI-DEAMIDATED GLIADIN (DGP-IgA) 44885	96 tests	Synthetic deamidated gliadin

Code	Quantity	Description
ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES IgG/IgA (ASCA) 44872	96 tests	Highly purified mannan from Saccharomyces cerevisiae
ANTI-THYROID PEROXIDASE ANTIBODIES (anti-TPO) 44795	96 tests	Recombinant human thyroid Peroxidase
ANTI-THYROGLOBULIN ANTIBODIES (anti-TG) 44796	96 tests	Highly purified human antigen
ANTI-INSULIN ANTIBODIES 44873	96 tests	Mixture of recombinant and purified insulin
ANTI-M2 ANTIBODIES (M2) 44871	96 tests	Highly purified mitochondrial M2 subtype antigen

External Quality Control



International External Quality
Assessment Scheme

- ▶ Yearly program for the comparison of results between laboratories
- ▶ Monthly measurements of different control materials
- ▶ The final report summarises all monthly reports and shows additional data on performance
- ▶ On-line participation through www.prevecal.net

Autoimmunity

Code	Quantity	Description
Prevecal ANA 18046	12 x 0.3 mL	Antinuclear antibodies
Prevecal ANCA 18056	4 x 0.3 mL	ANCA
Prevecal nDNA 18047	12 x 0.3 mL	Anti-nDNA antibodies
Prevecal CELIAC 18051	4 x 0.3 mL	Anti-endomysium, anti-tTG, anti-Gliadin, and DGP antibodies.

All kits include general instructions and cards for results.

Instruments



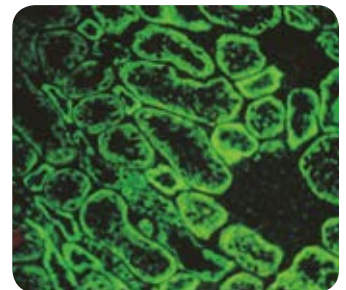
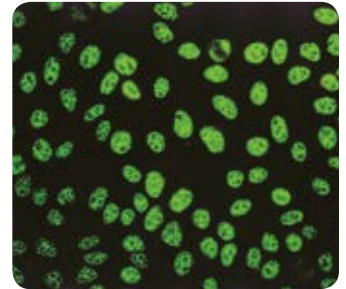
Code 84101

Immunofluorescence Processor

- ▶ Sample volume 3 μ L.
- ▶ Sample tray interchangeable racks (13mm x 100 mm, 15 mm x 100 mm or 2 mL).
- ▶ Dilution tray 96 vials (1.2 mL).
- ▶ Slides (plates) 16 (2).
- ▶ Reagent tray 8 conjugates (15 mL), 15 controls (2 mL), 1 additional diluent (50 mL).
- ▶ Reagents reservoirs 1 L bottle of washing solution, 1 L waste bottle, 1 L buffer bottle.
- ▶ Level sensor probe conductive.
- ▶ Slide washing flux system utilizing simultaneous dispensing and aspirating probes.
- ▶ Barcode reader hand-held barcode reader.

Consumables

Code	Quantity	Description
44592	100 mL	PBS (10x)
BO13416	100 mL	Concentrated Washing Solution
AC14682	120 strips	iPro Dilution Tubes (1,1 mL)



Code 84201

Fluorescence Microscope (LED Technology)

- ▶ Optical system Infinity corrected plan objectives, (10x, 20x and 40x).
- ▶ Head & Eyepieces WF10x paired eyepiece.
- ▶ Bright Field Illumination 12V, 20W halogen light source with precentred light condenser bulb coupled with a collector lens system provides optimum brightness along the optical path.
- ▶ Fluorescence Light Source High power blue LED (470-480nm).
- ▶ Fluorescence Filters FITC.
- ▶ Power Supply 110 - 240V AC. 50/60Hz. Single phase.

Consumables

Code	Description
ME15035	4x objective
ME15039	100x objective
AC15045	Trinocular head
AC15277	Digital Camera

Instruments



Immunofluorescence Laboratory Software: Total Integration

Code 84301

- ▶ LIMS Communication.
- ▶ Bidirectional communication with iPro: import sessions and request new test.
- ▶ Patterns, titers and images of controls configurable by test.
- ▶ Patient results management in association with images from the camera (TWAIN compatible).
- ▶ Patient historical of results and images: SQL Server Database.
- ▶ Possibility to print results report with images.
- ▶ Image reference Atlas.

Rapid tests



Rapid tests

Code	Quantity	Method
Latex Seroagglutination		
ANTI-STREPTOLYSIN O (ASO) - SLIDE		
31448	1 x 3 mL	Agglutination
31019	50 tests	LATEX
31086	150 tests	
C-REACTIVE PROTEIN (CRP) - SLIDE		
31107	1 x 3 mL	Agglutination
31011	50 tests	LATEX
31012	150 tests	
RHEUMATOID FACTORS (RF) - SLIDE		
31108	1 x 3 mL	Agglutination
31013	50 tests	LATEX
31014	150 tests	
Syphilis Serodiagnostics		
RPR-CARBON		
36001	100 tests	Agglutination
36002	500 tests	
TPHA		
36005	200 tests	Hemagglutination
Febril Serodiagnostics		
MULTISCREENING		
33001	6 x 100 tests	Agglutination SLIDE AND TUBE TESTS Salmonella paratyphi AH, Salmonella paratyphi BH, Salmonella typhi H, Salmonella typhi O, B. abortus (Rose Bengal), Proteus Ox19. Positive (Salmonella, Brucella and Proteus) and negative controls included.
SALMONELLA		
33080	8 x 100 tests	Agglutination SLIDE AND TUBE TEST Salmonella paratyphi AO, Salmonella paratyphi AH, Salmonella paratyphi BO, Salmonella paratyphi BH, Salmonella paratyphi CO, Salmonella paratyphi CH, Salmonella typhi H, Salmonella typhi O.
FEBRILE ANTIGENS		
33309	5 mL	Brucella abortus
33315	5 mL	Brucella abortus (Rose Bengal)
33301	5 mL	Salmonella paratyphi AH
33302	5 mL	Salmonella paratyphi AO
33303	5 mL	Salmonella paratyphi BH
33304	5 mL	Salmonella paratyphi BO
33305	5 mL	Salmonella paratyphi CH
33306	5 mL	Salmonella paratyphi CO
33307	5 mL	Salmonella typhi H
33308	5 mL	Salmonella typhi O
33311	5 mL	Proteus Ox19

Alphabetical Index

	Pg.		Pg.
α-AMYLASE DIRECT	4	ANTI-MPO ANTIBODIES (P-ANCA)	34
α-AMYLASE PANCREATIC	4	ANTI-nDNA ANTIBODIES (nDNA)	30
α-AMYLASE-EPS	4	ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)	30
α1-ACID GLYCOPROTEIN	4	ANTI-NUCLEAR ANTIBODIES HEp-2 (ANA-HEp-2)	30
A15	19	ANTI-NUCLEOSOME ANTIBODIES (NCL)	33
A25	20	ANTI-PHOSPHOLIPID ANTIBODIES IgG/IgM (APLA)	33
Accesories BA200	21	ANTI-PR3 ANTIBODIES (C-ANCA)	34
ACID PHOSPHATASE (ACP)	4	ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES IgG/IgA (ASCA)	35
ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)	28	ANTI-Sc170 ANTIBODIES	33
ADA	15	ANTI-SKIN ANTIBODIES (ASA)	31
ADENOSINE DEAMINASE (ADA)	4	ANTI-Sm ANTIBODIES	33
ADENOSINE DEAMINASE (ADA)	14	ANTI-Sm/RNP ANTIBODIES	33
ALANINE AMINOTRANSFERASE (ALT/GPT)	4	ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA)	30
ALBUMIN	4	ANTI-SSA (Ro) ANTIBODIES	33
ALBUMIN (MICROALBUMINURIA)	4	ANTI-SSB (La) ANTIBODIES	33
ALBUMIN (MICROALBUMINURIA)	14	ANTI-STREPTOLYSIN O (ASO)	5
ALKALINE PHOSPHATASE (ALP)-AMP	5	ANTI-STREPTOLYSIN O (ASO)	14
ALKALINE PHOSPHATASE (ALP)-DEA	5	ANTI-STREPTOLYSIN O (ASO) - SLIDE	40
AMMONIA	5	ANTI-STRIATED MUSCLE ANTIBODIES (ASiMA)	31
AMMONIA, ETHANOL, CO2	14	ANTI-THYROGLOBULIN ANTIBODIES (anti-TG)	35
AMMONIA, ETHANOL, CO2	15	ANTI-THYROID ANTIBODIES (ATA)	31
5-AMINOLEVULINIC ACID (ALA)/ PORPHOBILINOGEN (PBG)	13	ANTI-THYROID PEROXIDASE ANTIBODIES (anti-TPO)	35
ANA-SCREENING	33	ANTI-t TRANSGLUTAMINASE IgA ANTIBODIES (Anti-tTG IgA)*	34
ANGIOTENSIN CONVERTING ENZYME (ACE)	5	ANTI-t TRANSGLUTAMINASE IgG ANTIBODIES (Anti-tTG IgG)*	34
ANTI-ADRENAL CORTEX ANTIBODIES (AACA)	31	ANTI-β2-GLYCOPROTEIN 1 ANTIBODIES IgG/IgM (β2-GP1)	34
ANTI-ANNEXIN V ANTIBODIES IgG/IgM (ANX)	34	ANTITHROMBIN III	5
ANTI-BPI ANTIBODIES	34	APOLIPOPROTEIN A-1 (APO A-1)	5
ANTI-CARDIOLIPIN ANTIBODIES (ACA-IgG/IgM)	33	APOLIPOPROTEIN A-I	14
ANTI-CATHEPSIN G ANTIBODIES	34	APOLIPOPROTEIN B	14
ANTI-CENTROMERE B ANTIBODIES (CENP-B)	33	APOLIPOPROTEIN B (APO B)	5
ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)	33	ASPARTATE AMINOTRANSFERASE (AST/GOT)	5
ANTI-DEAMIDATED GLIADIN (DGP-IgA)	34	AUTOANTIBODIES DUO	31
ANTI-DEAMIDATED GLIADIN (DGP-IgG)	34	AUTOANTIBODIES MsL/MsK/MsS (ANA-AMA-ASMA-APCA-LKM)	30
ANTI-dsDNA ANTIBODIES	33	AUTOANTIBODIES RL/RK/RS (ANA-AMA-ASMA-APCA-LKM)	30
ANTI-ELASTASE ANTIBODIES	34		
ANTI-ENDOMYSIUM ANTIBODIES (AEA)	30	β-HYDROXYBUTYRATE	6
ANTI-GLIADIN ANTIBODIES (AGA-IgG/IgA)	34	β2-MICROGLOBULIN	6
ANTI-GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBM)	34	β2-MICROGLOBULIN	14
ANTI-HISTONES ANTIBODIES (HIST)	33	β2-MICROGLOBULIN	16
ANTI-INSULIN ANTIBODIES	35	β2-MICROGLOBULIN URINE	16
ANTI-ISLET CELL ANTIBODIES (AICA)	31	β-HYDROXYBUTYRATE	6
ANTI-Jo1 ANTIBODIES	33	β2-MICROGLOBULIN	6
ANTI-KERATIN ANTIBODIES (AKA)	31	β2-MICROGLOBULIN	14
ANTI-LACTOFERRIN ANTIBODIES	34	β2-MICROGLOBULIN	16
ANTI-LYSOZYME ANTIBODIES	34	β2-MICROGLOBULIN URINE	16
ANTI-M2 ANTIBODIES (M2)	35	BA200	21
ANTI-MITOCHONDRIAL ANTIBODIES (AMA)	30	BA400	23

Alphabetical Index

	Pg.		Pg.
BILIRUBIN	14	CREATININE ENZYMATIC	8
BILIRUBIN (DIRECT)	6	CREATININE KINASE-MB	16
BILIRUBIN (DIRECT) DPD	6	CREATININE KINASE-MB (CK-MB)	14
BILIRUBIN (TOTAL AND DIRECT)	6		
BILIRUBIN (TOTAL)	6	D-DIMER	
BILIRUBIN (TOTAL) DPD	6	D-DIMER	14
BIOCHEMISTRY (BOVINE)	14	D-DIMER	16
BIOCHEMISTRY (HUMAN)	14		
BIOCHEMISTRY SERUM	15	ENA 4-PROFILE	33
BIOCHEMISTRY SERUM (HUMAN)	15	ENA 6-PROFILE	33
BIOCHEMISTRY URINE	15	ENA 6-SCREENING	33
BTS 350	24	ETHANOL	9
C-REACTIVE PROTEIN (CRP-er)	14	FEBRILE ANTIGENS	40
C-REACTIVE PROTEIN (CRP)	8	FERRITIN	8
C-REACTIVE PROTEIN (CRP) - SLIDE	40	FERRITIN	14
C-REACTIVE PROTEIN (CRP/CRP-hs)	14	FERTILITY BIOCHEMISTRY	16
C-REACTIVE PROTEIN hs (CRP-hs)	8	FIBRINOGEN	9
C-REACTIVE PROTEIN-er (CRP-er)	8	FIBRINOGEN	15
CALCIUM-ARSENAZO	6	FIBRINOGEN	16
CALCIUM-CRESOLPHTHALEIN	6	FIBRINOGEN CLAUSS	28
CALCIUM-MTB	6	FITC/Evans(R)	32
CARBON DIOXIDE (CO2)	6	FRUCTOSAMINE	9
CHOLESTEROL	7	FRUCTOSAMINE	16
CHOLESTEROL HDL	7	FRUCTOSE	9
CHOLESTEROL HDL DIRECT	7		
CHOLESTEROL HDL PRECIPITATING REAGENT	7	GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)	31
CHOLESTEROL HDL/LDL	14	GLUCOSE	9
CHOLESTEROL LDL DIRECT	7	GLUCOSE-HEXOKINASE	9
CHOLESTEROL LDL PRECIPITATING REAGENT	7	γ-GLUTAMYL TRANSFERASE (γ-GT)	9
CHOLINESTERASE (CHE)	7		
CITRATE	7	HA3	26
COAGULATION CALIBRATOR	28	HA5	26
COAGULATION CONTROL	28	HbA1C-DIRECT	15
COAX	28	HEMOGLOBIN A1C	16
COMPLEMENT COMPONENT C3	7	HEMOGLOBIN A1C-DIRECT (HbA1C-DIR)	9
COMPLEMENT COMPONENT C4	7	HEMOGLOBIN A2	13
CONSUMABLES A15/A25	20	HEMOGLOBIN A2	16
CONSUMABLES AND ACCESSORIES BA200/BA400	23	HOMOCYSTEINE	10
CONSUMABLES COAX	28	HOMOCYSTEINE	15
CONSUMABLES HA3/HA5	26	HOMOCYSTEINE	16
CONSUMABLES IMLD	37	17-HYDROXYCORTICOSTEROIDS (17-OH)	13
CONSUMABLES IPRO	36	5-HYDROXYINDOLEACETIC ACID (5-HIAA)	13
CONTROL URINE	16		
CREATINE KINASE (CK)	8	IgA FITC/Evans	32
CREATINE KINASE-MB (CK-MB)	8	IgG FITC/Evans	32
CREATININE	8	IgG FITC/Evans (M)	32

	Pg.		Pg.
IMLD	37	RPR-CARBON	40
IMLS	38		
Immunofluorescence Controls*	32	SALMONELLA	40
IMMUNOGLOBULIN A (IgA)	9		
IMMUNOGLOBULIN G (IgG)	10	THROMBIN TIME (TT)	28
IMMUNOGLOBULIN M (IgM)	10	TISSUE SLIDES FOR RESEARCH USE ONLY (RUO)	31
I PRO	36	TOTAL BILE ACIDS	11
IRON-CHROMAZUROL	10	TOTAL IRON BINDING CAPACITY (TIBC)	11
IRON-FERROZINE	10	TRANSFERRIN	12
		TRIGLYCERIDES	12
17-KETOSTEROIDS	13		
		UNSATURATED IRON BINDING CAPACITY (UIBC)	12
LACTATE	10	UREA/ BUN-COLOR	12
LACTATE DEHYDROGENASE (LDH)	10	UREA/ BUN-UV	12
LACTATE DEHYDROGENASE (LDH)-IFCC	10	URIC ACID	12
LIPASE	10		
LIPID SERUM	16	VANILMANDELIC ACID	13
MAGNESIUM	11	ZINC	12
METANEPHRINES	13		
MISCELLANEOUS	32		
MULTISCREENING	40		
OXALATE	11		
OXALATE URINE	16		
PHOSPHORUS	11		
PREALBUMIN	11		
PREVECAL ANA	17		
PREVECAL ANCA	17		
PREVECAL BIOCHEMISTRY (BOVINE)	17		
PREVECAL BIOCHEMISTRY HUMAN	17		
PREVECAL CELIAC	17		
PREVECAL nDNA	17		
PREVECAL PROTEINS	17		
PREVECAL RHEUMA	17		
PREVECAL URINE	17		
PROTEIN	15		
PROTEIN (TOTAL)	11		
PROTEIN (URINE)	15		
PROTEIN (URINE+CSF)	11		
PROTEIN SERUM	16		
PROTHROMBIN TIME (PT)	28		
RHEUMATOID FACTORS (RF)	11		
RHEUMATOID FACTORS (RF)	15		
RHEUMATOID FACTORS (RF) - SLIDE	40		
RHEUMATOID SERUM	16		



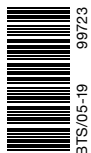




Ginger Group



BioSystems



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



- Certified Management System
- EN ISO 9001
- EN ISO 13485

EC DECLARATION OF CONFORMITY

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

Hereby DECLARES

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

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

under the specifications declared by BioSystems S.A.

It means that the products:

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

Barcelona, November 6th, 2012




Dr. Antonio Elduque
Managing director
BioSystems S.A.



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



CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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



AUTOIMMUNITY – ELISA:

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

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

AUTOINMUNIDAD – INSTRUMENTOS:

AUTOIMMUNITY – INSTRUMENTS:

iPRO



RAPID TESTS – LATEX AGGLUTINATION:

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

Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon

TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening

Febrile Serodiagnostics Salmonella

Brucella abortus

Brucella abortus, Rose Bengal

Proteus Ox19

Salmonella paratyphi AH

Salmonella paratyphi AO

Salmonella paratyphi BH

Salmonella paratyphi BO

Salmonella paratyphi CH

Salmonella paratyphi CO

Salmonella typhi H

Salmonella typhi O

Brucella Positive Control

Proteus Positive Control

Salmonella Positive Control

Serology Negative Control

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

No.	Location	Scope
/01	BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain	Design, development, manufacture, distribution, installation and service of instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics.
/02	BIOSYSTEMS, S.A. Pol. Ind. Can Tapiolas Naves 12, 13, 21 y 22 08110 Montcada i Reixac (Barcelona) Spain	Reagent labelling and assembly. Storage of raw materials for instruments, instruments and reagents for: - Clinical diagnostics. - Agri-food analysis. - Veterinary diagnostics. Dispatched of stored product.

2022-12-15



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

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

including the locations according to annex

Scope: Design, development, manufacture, distribution, installation and service of instruments and reagents for:

- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Reagent labelling and assembly.
Storage of raw materials for instruments, instruments and reagents for:

- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Dispatched or stored product.

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

Validity: The certificate is valid from 2022-12-19 until 2025-12-18.
First certification 1996

2022-12-15



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

证书附件

标准 **ISO 9001:2015**
证书登记号码 **01 100 1832306**

号码	场地	认证范围
/01	(分证书) 迪瑞医疗科技股份有限 公司 统一社会信用代码： 91220101605902656F 注册地址：中华人民共和国 吉林省长春市高新技术产业开发区 云河街 95 号 邮编：130012 经营地址：同上述地址	体外诊断医疗器械的设计开发、生产和销售
/02	(分证书) 迪瑞医疗科技股份有限 公司 统一社会信用代码： 91220101605902656F 注册地址：中华人民共和国吉林 省长春市高新技术产业开发区 云河街 95 号 邮编：130012 经营地址：中华人民共和国吉林 省长春市高新技术产业开发区 宜居路 3333 号 邮编：130103	体外诊断医疗器械的设计开发、生产和销售

2021-04-19


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

认证证书

标准 **ISO 9001:2015**
证书登记号码 **01 100 1832306**

证书持有者: **迪瑞医疗科技股份有限公司**
统一社会信用代码: 91220101605902656F
注册地址: 中华人民共和国吉林省长春市
高新技术产业开发区云河街 95 号
邮编: 130012
经营地址: 同上述地址

所包括场地已列于证书附件上

认证范围: 体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期: 证书有效期从 2021-05-03 至 2024-05-02。
此证书须经过符合要求的监督审核保持有效。
初次发证始于 2018 年
本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306/01**

主证持有者: **迪瑞医疗科技股份有限公司**
中华人民共和国吉林省长春市高新技术产业开发区云河街 95 号
邮编: 130012

场地: **(分证书) 迪瑞医疗科技股份有限公司**
统一社会信用代码: 91220101605902656F
注册地址: 中华人民共和国吉林省长春市
高新技术产业开发区云河街 95 号
邮编: 130012
经营地址: 同上述地址

认证范围: 体外诊断医疗器械的设计开发、生产和销售

有效期: 证明完成了审核并满足了 ISO 9001:2015 标准的要求。
证书连同主证书 01 100 1832306 一起有效期从 2021-05-03 至 2024-05-02。
此证书须经过符合要求的监督审核保持有效。
本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306/02**

主证持有者: **迪瑞医疗科技股份有限公司**
中华人民共和国吉林省长春市高新技术产业开发区云河街 95 号
邮编: 130012

场地: **(分证书) 迪瑞医疗科技股份有限公司**
统一社会信用代码: 91220101605902656F
注册地址: 中华人民共和国吉林省长春市
高新技术产业开发区云河街 95 号
邮编: 130012
经营地址: 中华人民共和国吉林省长春市
高新技术产业开发区宜居路 3333 号
邮编: 130103

认证范围: 体外诊断医疗器械的设计开发、生产和销售

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期: 证书连同主证书 01 100 1832306 一起有效期从 2021-05-03 至 2024-05-02。

此证书须经过符合要求的监督审核保持有效。
本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2021-04-19

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306**

No.	Location	Scope
/01	c/o Dirui Industrial Co., Ltd. Unified Social Credit Code: 91220101605902656F Registration Address: 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P. R. China Operation Address: same as above	Design and Development, Manufacture and Sales of In Vitro Diagnostic Medical Test Systems
/02	c/o Dirui Industrial Co., Ltd. Unified Social Credit Code: 91220101605902656F Registration Address: 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P. R. China Operation Address: 3333 Yiju Street, New & High Tech. Development Zone, Changchun, 130103 Jilin, P. R. China	Design and Development, Manufacture and Sales of In Vitro Diagnostic Medical Test Systems

2021-04-19


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 1 of 1

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306**

Certificate Holder: **Dirui Industrial Co., Ltd.**
Unified Social Credit Code: 91220101605902656F
Registration Address: 95 Yunhe Street,
New & High Tech. Development Zone,
Changchun, 130012 Jilin, P. R. China
Operation Address: same as above

including the locations according to annex

Scope: Design and Development, Manufacture and Sales of in Vitro
Diagnostic Medical Test Systems

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

Validity: The certificate is valid from 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
First certification 2018
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2021-04-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306/01**

Organization: **Dirui Industrial Co., Ltd.**
95 Yunhe Street, New & High Tech. Development Zone,
Changchun, 130012 Jilin, P.R. China

Site: **c/o Dirui Industrial Co., Ltd.**
Unified Social Credit Code: 91220101605902656F
Registration Address: 95 Yunhe Street, New & High Tech.
Development Zone, Changchun, 130012 Jilin, P. R. China
Operation Address: same as above

Scope: Design and Development, Manufacture and Sales of In Vitro
Diagnostic Medical Test Systems

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

Validity: The certificate is valid in conjunction with the main certificate 01
100 1832306 from 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2021-04-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306/02**

Organization: **Dirui Industrial Co., Ltd.**
95 Yunhe Street, New & High Tech. Development Zone,
Changchun, 130012 Jilin, P. R. China

Site: **c/o Dirui Industrial Co., Ltd.**
Unified Social Credit Code: 91220101605902656F
Registration Address: 95 Yunhe Street,
New & High Tech. Development Zone,
Changchun, 130012 Jilin, P. R. China
Operation Address: 3333 Yiju Street,
New & High Tech. Development Zone,
Changchun, 130103 Jilin, P. R. China

Scope: Design and Development, Manufacture and Sales of In Vitro
Diagnostic Medical Test Systems

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

Validity: The certificate is valid in conjunction with the main certificate 01
100 1832306 from 2021-05-03 until 2024-05-02.
It remains valid subject to satisfactory surveillance audits.
This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2021-04-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope: Design and development, production, distribution and servicing
of instruments and reagents for clinical diagnostic.

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

Report No.: 92648791-40
Effective date: 2022-12-12
Expiry date: 2025-12-12
Issue date: 2022-12-12

J. Pyclik



Jaroslav Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1695779-1

Organization: BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	BIOSYSTEMS S.A. Costa Brava 30 08030 Barcelona Spain	Design and development, production, distribution and servicing of instruments and reagents for clinical diagnostic.
/02	BIOSYSTEMS S.A. Polígono Industrial Can Tapioles Naves 12, 13, 21, 22 08010, Montcada i Reixac – Barcelona, Spain	Labelling and assembling of reagents, warehousing and shipment of instruments and reagents for clinical diagnostic.

Report No.: 92648791-40
Effective date: 2022-12-12
Expiry date: 2025-12-12
Issue date: 2022-12-12



Jaroslav Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DIRUI



Product Catalogue»»

DIRUI



COMPANY PROFILE >>

Located in Changchun, the heart of North Eastern China, DIRUI Industrial Co., Ltd is a supplier of world class laboratory solutions for trusted medical facilities worldwide.

Since its establishment in 1992, DIRUI has been dedicated to the research & development, manufacturing and sales of high quality medical testing products (medical devices, diagnostic reagents, and immunoreagents). Dirui's collective product portfolio not only represents some of the most advanced medical testing technology in China but also the world. Furthermore DIRUI has obtained a multitude of national invention patents as well as the CE mark for all products manufactured. Pioneering the technologies of anti-VC urinalysis reagent strips and quality controls, DIRUI is also the first Chinese domestic manufacturer of automatic bio-chemical analyzers such as the acclaimed CS-800 clinical chemistry analyzer as well as the H-800 fully automatic urine analyzer. DIRUI's BF series hematology analyzers and FUS series urine sediment analyzers feature world class advanced technology to ensure the highest quality results on a stable, easy to use system.

Dirui is an ISO9001 and ISO13485 certified manufacturer. With quality at the forefront of our corporate ideology Dirui has successfully gained a foot hold in the international medical industry and shall tirelessly strive to provide our customers with ever improving products and service.



CATALOG >>

CHEMISTRY ANALYZER

.....	1
CS-6400 Auto-Chemistry System	01
CS-4000 Auto-Chemistry System	02
CS-1600 Auto-Chemistry Analyzer	03
CS-1300B Auto-Chemistry Analyzer	04
CS-1200 Auto-Chemistry Analyzer	05
CS-600B Auto-Chemistry Analyzer	06
CS-400 Auto-Chemistry Analyzer	07
CS-300B Auto-Chemistry Analyzer	08
CS-T240 Auto-Chemistry Analyzer	09
DR-7000D Semi-Automatic Chemistry Analyzer	10
Quality control & Calibrator	11
CS Series Auto-Chemistry Analyzer Reagent	12
CS-T240 CS-300B Auto-Chemistry Analyzer Reagent	13

HEMATOLOGY ANALYZER

.....	16
BF-6880 Automatic Hematology Analyzer	16
BF-6800 Automatic Hematology Analyzer	17
BF-6500 Automatic Hematology Analyzer	18
BF-5180 Automatic Hematology Analyzer	19
BCC-3600 Hematology Analyzer	20
BCC-3000B Hematology Analyzer	21

URINE ANALYZER

..... 22

Automatic Urinalysis System(FUS-200&H-800) 22

Automatic Urinalysis System(FUS-100&H-800) 23

FUS-2000 Urinalysis Hybrid 24

FUS-200 Urine Sediment Analyzer 25

FUS-100 Urine Sediment Analyzer 26

H-1000 Automatic Urine Analyzer 27

H-800 Automatic Urine Analyzer 28

H-500 Urine Analyzer 29

H-100 Urine Analyzer 30

Urinalysis Control 31

Dirui Urinalysis Strips Collection 32

FECAL OCCULT BLOOD ANALYZER

..... 33

FB-100 Fecal Occult Blood Analyzer 33

CS-6400

Auto-Chemistry System



CS-6400 Auto-Chemistry System, the most intelligent version of DIRUI CS series analyzers, offer an extreme efficient work style to achieve your turnaround time goals. Utilizing the advanced technology to improved laboratory efficiency, cost-effective and optimized productivity. Flexible combination design provides customers with multiple choices. The throughput of each photometric module is 1600 T/H, matching 1 to 4 modules and 1 ISE modules which could reach up to 7360 T/H.

Product Features:

- © Fully automatic, random access
- © 1600T/H each module, maximum matching 4 modules and 1 ISE module
- © 2 Refrigerated reagent compartments for each module, 134 reagent positions for each reagent compartment
- © Double circle reaction cuvettes, totally 330 reaction cuvettes
- © 8 stops 11 steps automatic rinsing system
- © LIS interface, supporting remote maintenance
- © Wavelength: 340nm, 380nm, 405nm, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm, 750nm and 800nm
- © Automatic clot detection and automatic checking of serum indices

Order Information:

Product Number	Description	Pack size
1520502005	DIRUI CS-6400-10 Auto-Chemistry System	1 module with PC
1520502009	DIRUI CS-6400-20 Auto-Chemistry System	2modules with PC
1520502011	DIRUI CS-6400-30 Auto-Chemistry System	3 modules with PC
1520502013	DIRUI CS-6400-40 Auto-Chemistry System	4 modules with PC
1520502018	DIRUI CS-6400 ISE module with single unit	1 module
1520502019	DIRUI CS-6400 ISE module with double unit	1 module

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901009	CS-Alkaline Detergent	5L/ barrel	1 barrel
2320901010	CS-Alkaline Detergent	500ml/ battle	1 bottle
2320903002	CS-Reference Liquid	2L/ barrel	1 barrel
2320904002	CS-Internal Standard Liquid	2L/ barrel	1 barrel
2320902002	CS-Diluent	2L/ barrel	1 barrel
2320910001	CS-ISE Detergent	100ml/ bottle	1 bottle

CS-4000

Auto-Chemistry System



CS-4000 Auto-Chemistry System, the new version of DIRUI CS series analyzers and applications offer fabulous efficiency to satisfy the turnaround time requirements. Utilizing the advanced technology to improve laboratories efficiency and optimize the labor costs. Flexible combination design provides customers with multiple choices, the excellent throughput of each photometric module is 1000 T/H, matching 1 to 4 modules and 1 ISE module could reach up to 4960 T/H.

Product Features:

- © Fully automatic, random access
- © 1000 T/H each module, maximum matching 4 modules and 1 ISE module
- © 2 Refrigerated reagent compartments for each module, 67 reagent positions for each reagent compartment
- © 8 steps 11 steps automatic rinsing system
- © LIS interface, supporting remote maintenance
- © Wavelength: 340nm, 380nm, 405nm, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm, 750nm and 800nm
- © Automatic clot detection and automatic checking of serum indices

Order Information:

Product Number	Description	Pack size
1520502027	DIRUI CS-4000-10 Auto-Chemistry System	1 module with PC
1520502028	DIRUI CS-4000-20 Auto-Chemistry System	2modules with PC
1520502029	DIRUI CS-4000-30 Auto-Chemistry System	3 modules with PC
1520502030	DIRUI CS-4000-40 Auto-Chemistry System	4 modules with PC
1520502033	DIRUI CS-4000 ISE module with single unit	1 module
1530504011	DIRUI CS-4000 ISE module with double unit	1 module

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901009	CS-Alkaline Detergent	5L/ barrel	1 barrel
2320901010	CS-Alkaline Detergent	500ml/ bottle	1 bottle
2320903002	CS-Reference Liquid	2L/ barrel	1 barrel
2320904002	CS-Internal Standard Liquid	2L/ barrel	1 barrel
2320902002	CS-Diluent	2L/ barrel	1 barrel
2320910001	CS-ISE Detergent	100ml/ bottle	1 bottle

CS-1600

Auto-Chemistry Analyzer



CS-1600 Auto Chemistry Analyzers a fast version of DIRUI CS series analyzers. It uses advanced technology to improve laboratory efficiency, cost-effective, increased detectable efficiency and stability. It can fit laboratory size form medium to large with an excellent throughput 1200 T/H.

Product Features:

- ◎Fully automatic, random access
- ◎Throughput is 1200T/H for photometry test, and the maximum throughput is 1350 T/H with a 450 T/H ISE
- ◎2 refrigerated reagent compartments, 134 reagent positions
- ◎Double circle reaction cuvettes, totally 330 reaction cuvettes
- ◎8 stops 11 steps automatic rinsing system
- ◎Support LIS connection, as well as remote maintenance operation
- ◎Wavelength: 340nm, 380nm, 405nm, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm, 750nm and 800nm
- ◎Automatic clot detection and automatic checking of serum indices

Order Information:

Product Number	Description	Pack size
1520502006	DIRUI CS-1600 Auto-Chemistry Analyzer	1 instrument with PC
1520502008	DIRUI CS-1600 Auto-Chemistry Analyzer with ISE unit	1 instrument with PC

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901009	CS-Alkaline Detergent	5L/ barrel	1 barrel
2320901010	CS-Alkaline Detergent	500ml/ battle	1 bottle
2320903002	CS-Reference Liquid	2L/ barrel	1 barrel
2320904002	CS-Internal Standard Liquid	2L/ barrel	1 barrel
2320902002	CS-Diluent	2L/ barrel	1 barrel
2320910001	CS-ISE Detergent	100ml/ bottle	1 bottle

CS-1300B

Auto-Chemistry Analyzer



CS-1300B Auto-Chemistry Analyzer is a member of DIRUI CS series analyzers. Features include detectable efficiency, stability, lowering the cost and saving the operation time. The throughput is 900 T/H which suit the laboratory size from medium to large.

Product Features:

- ◎Fully automatic, random access
- ◎Constant speed 900 T/H for photometry test, it can reach up to 1050 with a 450 T/H ISE
- ◎2 Refrigerated reagent compartments, 132 reagent position with extra 2 Anti-Bacteria PhosphorFree Detergent positions
- ◎8 stops 12 steps automatic rinsing system
- ◎Support LIS connection, as well as remote maintenance operation
- ◎Wavelength: 340nm, 380nm, 405m, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm and 800nm
- ◎Automatic clot detection and automatic checking of serum indices

Order Information:

Product Number	Description	Pack size
1520502024	DIRUI CS-1300B Auto-Chemistry Analyzer	1 module
1520502020	DIRUI CS-1300B Auto-Chemistry Analyzer with ISE unit	1 module

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901003	CS-Alkaline Detergent	2L/ barrel	1 barrel
2320903002	CS-Reference Liquid	2L/ barrel	1 barrel
2320904002	CS-Internal Standard Liquid	2L/ barrel	1 barrel
2320902002	CS-Diluent	2L/ barrel	1 barrel
2320910001	CS-ISE Detergent	100ml/ bottle	1 bottle

CS-1200

Auto-Chemistry Analyzer



CS-1200 Auto-Chemistry Analyzer provides high technology to lower the cost and reduce the operation time. Meanwhile, it also can provide a stable testing procedure and accurate test results. The throughput is 800 T/H which will fit requirements for the lab size from medium to large.

Product Features:

- ©Fully automatic, random access
- ©Throughput 800 T/H, and the maximum throughput can reach to 960 T/H with a 480 T/H ISE
- ©2 Refrigerated reagent compartments, 132 reagent positions
- ©8 stops 12 steps automatic rinsing system
- ©Support LIS connection, as well as remote maintenance operation
- ©Wavelength: 340nm, 380nm, 405m, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm and 800nm
- ©Automatic clot detection and automatic checking of serum indices

Order Information:

Product Number	Description	Pack size
1520502016	DIRUI CS-1200 Auto-Chemistry Analyzer	1 module
1520502025	DIRUI CS-1200 Auto-Chemistry Analyzer with ISE unit	1 module

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901003	CS-Alkaline Detergent	2L/ barrel	1 barrel
2320903002	CS-Reference Liquid	2L/ barrel	1 barrel
2320904002	CS-Internal Standard Liquid	2L/ barrel	1 barrel
2320902002	CS-Diluent	2L/ barrel	1 barrel
2320910001	CS-ISE Detergent	100ml/ bottle	1 bottle

CS-600B

Auto-Chemistry Analyzer



CS-600B Auto-Chemistry Analyzer is a high efficiency, medium-size analyzer with the throughput of 600 T/H, which is one of the most popular instruments in the global market. This model is built in some new functions which meet the demands of medium size laboratories.

Product Features:

- ◎Fully automatic, random access
- ◎Constant speed 600 T/H for photometry test, and the maximum throughput can reach to 1000 H/T with a 600 T/H ISE
- ◎2 Refrigerated reagent compartments and 1 sample compartment
- ◎90 reagent positions and 115 sample positions
- ◎7 stops 11 steps washing system
- ◎LIS interface, supporting remote maintenance
- ◎Wavelength: 340nm, 380nm, 405nm, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm and 800nm
- ◎Automatic clot detection and automatic checking of serum indices

Order Information:

Product Number	Description	Pack Size
1520501004	DIRUI CS-600B Auto-Chemistry Analyzer	1 instrument
1520501005	DIRUI CS-600B Auto-Chemistry Analyzer with ISE unit	1 instrument

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901003	CS-Alkaline Detergent	2L/ barrel	1 barrel
2320903001	Reference Liquid for Auto-Chemistry Analyzer	500ml/ bottle	1 bottle
2320904001	Internal Standard Liquid for Auto-Chemistry Analyzer	2L/ barrel	1 barrel
2320902001	Piluent for Auto-Chemistry Analyzer	2L/ barrel	1 barrel
2320910001	CS-ISE Detergent	100ml/ bottle	1 bottle

CS-400

Auto-Chemistry Analyzer



CS-400 Auto Chemistry analyzer is a high-performance analyzer of DIRUI CS series. It is an ideal instrument for medium size laboratories. The features include high efficiency, testing accuracy, safety and lower-cost for the maintenance.

Product Features:

- ◎ Fully automatic, random access
- ◎ Constant throughput 400T/H for photometry test, the maximum throughput is 800 T/H with a 600 T/H ISE
- ◎ 2 Refrigerated reagent compartments and 1 sample compartment
- ◎ 90 reagent positions and 115 sample positions
- ◎ 7 stops 11 steps rinsing system
- ◎ LIS interface, supporting remote maintenance
- ◎ Wavelength: 340nm, 380nm, 405m, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm and 800nm
- ◎ Automatic clot detection and automatic checking of serum indices

Order Information:

Product Number	Description	Pack Size
1520501001	DIRUI CS-400 Auto-Chemistry Analyzer	1 instrument
1520501002	DIRUI CS-400 Auto-Chemistry Analyzer with ISE unit	1 instrument

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901003	CS-Alkaline Detergent	2L/ barrel	1 barrel
2320903001	Reference Liquid for Auto-Chemistry Analyzer	500ml/ bottle	1 bottle
2320904001	Internal Standard Liquid for Auto-Chemistry Analyzer	2L/ barrel	1 barrel
2320902001	Piluent for Auto-Chemistry Analyzer	2L/ barrel	1 barrel
2320910001	CS-ISE Detergent	100ml/ bottle	1 bottle

CS-300B

Auto-Chemistry Analyzer



CS-300B Auto-Chemistry Analyzer is a small size and stand upright analyzer in DIRUI CS series. It is the ideal instrument for consolidating test in small or medium size laboratories. The throughput is 300 T/H, 66 test items conducted simultaneously, with a friendly software and easy operation system. Comparing with CS-T240, CS 300B is more efficient.

Product Features:

- ◎ Fully automatic, random access
- ◎ Constant throughput is 300T/H, and the maximum throughput is 450T/H with a 450 T/H ISE
- ◎ Refrigerated reagent and sample compartments
- ◎ 67 reagent positions and 115 sample positions
- ◎ 7 stops 11 steps rinsing system
- ◎ LIS interface, supporting remote maintenance
- ◎ Wavelength: 340nm, 380nm, 405m, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm,700nm and 800nm

Order Information:

Product Number	Description	Pack Size
1520503003	DIRUI CS-300B Auto-Chemistry Analyzer	1 instrument
1520503004	DIRUI CS-300B Auto-Chemistry Analyzer with ISE mode	1 instrument

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901003	CS-Alkaline Detergent	2L/ barrel	1 barrel
2320903001	Reference Liquid for Auto-Chemistry Analyzer	500ml/ bottle	1 bottle
2320904001	Internal Standard Liquid for Auto-Chemistry Analyzer	2L/ barrel	1 barrel
2320902001	Piluent for Auto-Chemistry Analyzer	2L/ barrel	1 barrel
2320910001	CS-ISE Detergent	100ml/ bottle	1 bottle

CS-T240

Auto-Chemistry Analyzer



CS-T240 Auto-Chemistry Analyzer is a random access clinical chemistry analyzer, which can be integrated in any type of laboratories for routine, emergency analysis. The throughput is 240 T/H with up to 57 test items conducted simultaneously. It is convenient, flexible, economic for small to medium size laboratories. This is a big step in automatic bench top analyzer.

Product Features:

- ◎ Fully automatic, random access
- ◎ Constant speed 240T/H
- ◎ Refrigerated reagent sample compartment
- ◎ 8 stops 12 steps rinsing system
- ◎ LIS interface, supporting remote maintenance
- ◎ Reagent and sample share one disk(user defined position proportion), totally 67 position
- ◎ Wavelength: 340nm, 380nm, 405nm, 450nm, 480nm, 505nm, 546nm, 570nm, 600nm, 660nm, 700nm and 800nm

Order Information:

Product Number	Description	Pack Size
1520503011	DIRUI CS-T240 Auto-Chemistry Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2320901001	CS-Anti-Bacterial Phosphor-Free Detergent	500ml/ bottle	1 bottle
2320901003	CS-Alkaline Detergent	2L/ barrel	1 barrel

DR-7000D

Semi-Automatic Chemistry Analyzer



DR-7000D is a semi-automatic chemistry analyzer, and quite popular among small size laboratories. It is compact, low maintenance and easy to operate.

Product Features:

- © Wavelength: 340nm, 405m, 450nm, 492nm, 505nm, 546nm, 578nm, 630nm
- © Optical system using the improved interference filter
- © With high testing precision and system reliability
- © English operation interface, real time measurement and display of absorbance curve, and available curve amplification function
- © Built in thermal printer and external stylus printer interface

Order Information:

Product Number	Description	Pack Size
1520201001	DIRUI DR-7000D Semi-Automatic Chemistry Analyzer	1 instrument

Quality control & Calibrator

Product Code	Name	Package
2320908001	Clinical Chemical Calibration Serum Level 1	5ml
2320908002	Clinical Chemical Calibration Serum Level 2	5ml
2320906001	ISE Standard Solution HIGH	1x10ml
2320906002	ISE Standard Solution LOW	1x10ml
2320906003	ISE Standard Solution HIGH	3x10ml
2320906004	ISE Standard Solution LOW	3x10ml
2320907003	ISE Blood Sample Calibrator	freeze-dried powder 0.18gx1dissolved liquid 4mlx1
2320907004	ISE Blood Sample Calibrator	freeze-dried powder 0.18gx5dissolved liquid 4mlx5
2320909001	Clinical Chemical Quality Control SerumLevel 1	5ml
2320909002	Clinical Chemical Quality Control SerumLevel 2	5ml
2320905004	ISE Blood Quality Control HIGH	freeze-dried powder 0.18g*1dissolved liquid 4ml*1
2320905005	ISE Blood Quality Control LOW	freeze-dried powder 0.18g*1dissolved liquid 4ml*1
2320905006	ISE Blood Quality Control HIGH	freeze-dried powder 0.18g*5dissolved liquid 4ml*5
2320905007	ISE Blood Quality Control LOW	freeze-dried powder 0.18g*5dissolved liquid 4ml*5

CS series

Auto-Chemistry Analyzer Reagents

Diagnostics&Instrument

AUTO-CHEMISTRY ANALYZER

Product Code	Abbreviation	Full name	Test Method		Package	
			R1	R2	R1	R2
2321601002	ALT	Alanine Aminotransferase	IFCC Recommended Method	KINETIC	4x50ml	1x50ml
2321602007	AST	Aspartate Aminotransferase	IFCC Recommended Method	KINETIC	4x50ml	1x50ml
2321603006	ALP	Alkaline Phosphatase	IFCC Recommended Method	KINETIC	4x50ml	1x50ml
2321604007	GGT	γ -Glutamyl Transferase	IFCC Recommended Method	KINETIC	4x50ml	1x50ml
2321605005	CHE	Cholinsterase	Substrate hydrolysis method	KINETIC	4x50ml	1x50ml
2321606001	TB	Total Bilirubin	Diazonium Salt Method	END POINT	5x50ml	1x5ml
2321606019	TB-V	Total Bilirubin-Vanadate Oxidation	Vanadate Oxidation Method	END POINT	4x50ml	1x50ml
2321607002	DB	Direct Bilirubin	Diazonium Salt Method	END POINT	5x50ml	1x3ml
2321607016	DB-V	Direct Bilirubin-Vanadate Oxidation	Vanadate Oxidation Method	END POINT	4x50ml	1x50ml
2321608007	TBA	Bile Acid	Enzymatic Cycling Method	KINETIC	3x50ml	2x25ml
2321609001	TP	Total Protein	Biuret Method	END POINT		5x50ml
2321610007	ALB	Albumin	Bromoresol Green Method	END POINT		5x50ml
2321611008	GLDH	Glutamate Dehydrogenase	Improved DGKC Method	KINETIC	4x50ml	1x50ml
2321612008	ICDH	ISO-Citrate Dehydrogenase	Substrate Method	KINETIC	4x50ml	1x50ml
2321613009	LAP	Leucine Aminopeptidase	Substrate Hydrolysis Method	KINETIC	4x50ml	1x50ml
2321666002	ADA	Adenosine Deaminase	Enzyme Method	KINETIC	1x60ml	1x30ml
2321645007	PA	Prealbumin	Immune Transmission Turbidity Method	END POINT	1x 50ml	1x 10ml
2321658002	5'-NT	5'-Nucleotidase	Enzyme Method	KINETIC	1x50ml	1x25ml
2321646002	AFU	α -L-Fucosidase Assay	M-G-CNP Method	KINETIC		1x 50ml
2321630007	AMY	Amylase	IFCC Recommended Method	KINETIC	4x50ml	1x50ml
2321670003	P-AMY	Pancreatic Amylase	Enzymatic Colorimetric Method	KINETIC	4x50ml	1x50ml
2321615006	GLU-HK	Glucose - Hexokinase	Hexokinase Method	END POINT	4x50ml	1x50ml
2321616001	GLU-OX	Glucose - Oxidase	Oxidase Method	END POINT	4x50ml	1x50ml
2321648002	HbA1c	Glycohemoglobin A1C	Latex Agglutination Reaction Method	END POINT	R1: 2x15ml R2: 1x8.5ml	R1: 0.5mlx1 Lyse: 2x60ml
2321621008	FMN	Fructosamine	NBT Reduction Method	KINETIC		5x 50ml
2321617001	BUN	Urea	Enzyme Method	KINETIC	4x50ml	1x50ml
2321618008	UA	Uric Acid	Enzyme Method	END POINT	4x50ml	1x50ml
2321619004	CRE-ENZYME	Creatinine-Enzyme	Enzyme Method (540nm)	END POINT	4x50ml	1x50ml
2321620006	CRE	Creatinine	Picric Acid Method	KINETIC	2x50ml	2x50ml
2321657002	CYS-C	Cystatin C	Latex Agglutination Reaction Method	END POINT	1x60ml	1x20ml

Product Code	Abbreviation	Full name	Test Method		Package	
			R1	R2	R1	R2
2321650002	MALB	MicroAlbumin	Immune Transmission Turbidity Method	END POINT	1x40ml	1x10ml
2321651002	$\hat{\alpha}_2$ -MG	$\hat{\alpha}_2$ -Microglobulin	Latex Enhanced Immunoturbidimetric Method	END POINT	1x40ml	1x10ml
2321622008	TC	Total Cholesterol	Enzyme Method	END POINT	4x50ml	1x50ml
2321623008	TG	Triglycerides	Oxidase Method	END POINT	4x50ml	1x50ml
2321624007	HDL-C	High Density Lipoprotein-Cholesterol	Direct Method	END POINT	3x50ml	2x25ml
2321625007	LDL-C	Low Density Lipoprotein-Cholesterol	Direct Method	END POINT	3x50ml	2x25ml
2321664002	APO A1	Apolipoprotein A1	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321665002	APO B	Apolipoprotein B	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321637007	LP(a)	Lipoprotein (a)	Latex Agglutination Reaction Method	END POINT	1x 45ml	1x 15ml
2321626007	CK	Creatinine Kinase	IFCC Recommended Method	KINETIC	4x50ml	1x50ml
2321627006	CK-MB	Creatinine Kinase MB Isoenzyme	Immunosuppression	KINETIC	4x50ml	1x50ml
2321628006	LDH	Lactate Dehydrogenase	Substrate Method	KINETIC	4x50ml	1x50ml
2321629007	HBDH	α -Hydroxybutyrate Dehydrogenase	DGKC Recommended Method	KINETIC	4x50ml	1x50ml
2321662002	HCY	Homocysteine	Enzymatic Cycling Method	END POINT	1x60ml	1x17ml
2321631008	Ca-CPC	Calcium-CressolPhthalein Complex	Cresolphthalein Complexone Method	END POINT	2x50ml	2x50ml
2321632006	Ca-ARS	Calcium-Arsenazo	Arsenazo III Method	END POINT	5x50ml	5x50ml
2321633003	Cl	Chloride	Mercury Thiocyanate Method	END POINT	5x50ml	5x50ml
2321634007	Mg-XB	Magnesium	Magnesium Blue Method	END POINT	5x50ml	5x50ml
2321636007	PHOS	Inorganic Phosphorus	Direct UV Method	END POINT	5x50ml	5x50ml
2321663002	CO2	Carbon Dioxide	Enzyme Method	END POINT	1x50ml	1x50ml
2321656002	Zn	Zinc	Complex Chromotest Method	END POINT	1x60ml	1x15ml
2321638007	C3	Complement 3	Immune Transmission Turbidity Method	END POINT	1x 50ml	1x 10ml
2321639007	C4	Complement 4	Immune Transmission Turbidity Method	END POINT	1x 50ml	1x 10ml
2321640007	IgA	Immunoglobulin-A	Immune Transmission Turbidity Method	END POINT	1x 50ml	1x 10ml
2321641007	IgM	Immunoglobulin-M	Immune Transmission Turbidity Method	END POINT	1x 50ml	1x 10ml
2321642007	IgG	Immunoglobulin-G	Immune Transmission Turbidity Method	END POINT	1x 50ml	1x 10ml
2321643007	ASO	Anti Streptolysin O	Latex Enhanced Immunoturbidimetric Method	END POINT	1x 40ml	1x 10ml
2321644007	RF	Rheumatoid Factor	Latex Enhanced Immunoturbidimetric Method	END POINT	1x 40ml	1x 10ml
2321652002	CRP	C-Reactive Protein	Latex Enhanced Immunoturbidimetric Method	END POINT	2x70ml	2x8ml
2321647010	TRF	Transferrin	Immunoturbidimetric Method	END POINT	1x50ml	1x10ml

CS-T240、CS-300B
Auto-Chemistry Analyzer Reagents

Diagnosics&Instrument AUTO-CHEMISTRY ANALYZER

Product Code	Abbreviation	Full name	Test Method		Package	
			R1	R2	R1	R2
2321601003	ALT	Alanine Aminotransferase	IFCC Recommended Method	KINETIC	4x80ml	4x20ml
2321602002	AST	Aspartate Aminotransferase	IFCC Recommended Method	KINETIC	4x80ml	4x20ml
2321603001	ALP	Alkaline Phosphatase	IFCC Recommended Method	KINETIC	4x80ml	4x20ml
2321604001	GGT	γ -Glutamyl Transferase	IFCC Recommended Method	KINETIC	4x80ml	4x20ml
2321605001	CHE	Cholinesterase	Butyryl Thiocholine Substrate Method	KINETIC	4x80ml	4x20ml
2321606002	TB	Total Bilirubin	Diazonium Salt Method	END POINT	12x20ml	1x5ml
2321606022	TB-V	Total Bilirubin-Vanadate Oxidation	Vanadate Oxidation Method	END POINT	4x80ml	4x20ml
2321607001	DB	Direct Bilirubin	Diazonium Salt Method	END POINT	12x20ml	1x3ml
2321607020	DB-V	Direct Bilirubin-Vanadate Oxidation	Vanadate Oxidation Method	END POINT	4x80ml	4x20ml
2321608001	TBA	Bile Acid	Enzymatic Cycling Method	KINETIC	4x60ml	4x20ml
2321609002	TP	Total Protein	Biuret Method	END POINT	12x20ml	12x20ml
2321610001	ALB	Albumin	Bromocresol Green Method	END POINT	12x20ml	12x20ml
2321611001	GLDH	Glutamate Dehydrogenase	Improved DGKC Method	KINETIC	4x80ml	4x20ml
2321612001	ICDH	Iso-Citrate Dehydrogenase	Substrate Method	KINETIC	4x80ml	4x20ml
2321613001	LAP	Leucine Aminopeptidase	Substrate Hydrolysis	KINETIC	4x80ml	4x20ml
2321666001	ADA	Adenosine Deaminase	Enzyme Method	KINETIC	1x60ml	1x30ml
2321645008	PA	Prealbumn	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321658001	5'-NT	5'-Nucleotidase	Enzyme Method	KINETIC	1x50ml	1x25ml
2321646003	AFU	α -L-Fucosidase Assay	M-G-CNP	KINETIC	1 x 50ml	
2321630002	AMY	Amylase	IFCC Recommended Method	KINETIC	4x80ml	4x20ml
2321670002	P-AMY	Pancreatic Amylase	Enzymatic Colorimetric Method	KINETIC	4x 80ml	4x20ml
2321615001	GLU-HK	Glucose - Hexokinase	Hexokinase Method	END POINT	4x80ml	4x20ml
2321616002	GLU-OX	Glucose - Oxidase	Oxidase Method	END POINT	4x80ml	4x20ml
2321648001	HbA1c	Glycohemoglobin A1C	Latex Agglutination Reaction Method	END POINT	R1:15mlX2 , R2-A: 0.5mlX1, R2-B: 9.5mlX1 ,Lyse: 50mlX2	
2321621001	FMN	Fructosamine	NBT Reduction Method	KINETIC	12 x 20ml	
2321617002	BUN	Urea	Enzyme Method	KINETIC	4x80ml	4x20ml
2321618001	UA	Uric Acid	Enzyme Method	END POINT	4x80ml	4x20ml
2321619001	CRE-ENZYME	Creatinine-Enzyme	Enzyme Method (540nm)	END POINT	4x80ml	4x20ml
2321620001	CRE	Creatinine	Picric Acid Method	KINETIC	6x20ml	6x20ml
2321657001	CYS-C	Cystatin C	Latex Agglutination Reaction Method	END POINT	1x60ml	1x20ml

Product Code	Abbreviation	Full name	Test Method		Package	
			R1	R2	R1	R2
2321650001	MALB	MicroAlbumin	Immune Transmission Turbidity Method	END POINT	1x40ml	1x10ml
2321651001	â ₂ -MG	â ₂ -Microglobulin	Latex Enhanced Immunoturbidimetric Method	END POINT	1x40ml	1x10ml
2321622002	TC	Total Cholesterol	Enzyme Method	END POINT	4x80ml	4x20ml
2321623002	TG	Triglycerides	Oxidase Method	END POINT	4x80ml	4x20ml
2321624001	HDL-C	High Density Lipoprotein-Cholesterol	Direct Method	END POINT	4x60ml	4x20ml
2321625001	LDL-C	Low Density Lipoprotein-Cholesterol	Direct Method	END POINT	4x60ml	4x20ml
2321664001	APO A1	Apolipoprotein A1	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321665001	APO B	Apolipoprotein B	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321637008	LP(a)	Lipoprotein (a)	Latex Agglutination Reaction Method	END POINT	1x45ml	1x15ml
2321626001	CK	Creatinine Kinase	IFCC Recommended Method	KINETIC	4x80ml	4x20ml
2321627001	CK-MB	Creatinine Kinase MB Isoenzyme	Immunosuppression	KINETIC	4x80ml	4x20ml
2321628001	LDH	Lactate Dehydrogenase	Substrate Method	KINETIC	4x80ml	4x20ml
2321629001	HBDH	α -Hydroxybutyrate Dehydrogenase	DGKC Recommended Method	KINETIC	4x80ml	4x20ml
2321662001	HCY	Homocysteine	Enzymatic Cycling Method	END POINT	1x60ml	1x17ml
2321631001	Ca-CPC	Calcium-CressolPhtalein Complex	O-Cresolphthalein Complexone Method	END POINT	6x20ml	6x20ml
2321632001	Ca-ARS	Calcium-Arsenazo	Arsenazo III Method	END POINT	12x20ml	12x20ml
2321633001	Cl	Chloride	Mercury Thiocyanate Method	END POINT	12x20ml	12x20ml
2321634001	Mg-XB	Magnesium	Magnesium Blue Method	END POINT	12x20ml	12x20ml
2321636001	PHOS	Inorganic Phosphorus	Direct UV Method	END POINT	5x50ml	5x50ml
2321663001	CO2	Carbon Dioxide	Enzyme Method	END POINT	1x50ml	1x50ml
2321656001	Zn	Zinc	Complex Chromotest Method	END POINT	1x 60ml	1x 15ml
2321638008	C3	Complement 3	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321639008	C4	Complement 4	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321640008	IgA	Immunoglobulin-A	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321641008	IgM	Immunoglobulin-M	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321642008	IgG	Immunoglobulin-G	Immune Transmission Turbidity Method	END POINT	1x50ml	1x10ml
2321643008	ASO	Anti Streptolysin O	Latex Enhanced Immunoturbidimetric Method	END POINT	1x40ml	1x10ml
2321644008	RF	Rheumatoid Factor	Latex Enhanced Immunoturbidimetric Method	END POINT	1x40ml	1x10ml
2321652001	CRP	C-Reactive Protein	Latex Enhanced Immunoturbidimetric Method	END POINT	2x70ml	2x8ml
2321647003	TRF	Transferrin	Immunoturbidimetric Method	END POINT	1x50ml	1x10ml

BF-6880

Automatic Hematology Analyzer



The BF-6880 is a five-part automatic hematology analyzer which inherit the excellent performance of BF series hematology analyzers. BF-6880 dedicate to screen abnormal samples precisely adopt more less sample combine with the latest technique, which provide both efficient and benefit.

Product Features:

- ◎5-part differential, 25 report parameters, 10 research parameters, 4 histograms and 1 scattergram
- ◎CBC+DIFF mode: 80 tests per hour
- ◎Whole blood, pre-diluted mode
- ◎Environmental friendly cyanide-free reagent
- ◎Automatic sampling and emergency access
- ◎Large storage capacity, up to 100,000 samples
- ◎Display type is external computer
- ◎Supporting LIS interface

Order Information:

Product Number	Description	Pack Size
1520401008	DIRUI BF-6880 Automatic Hematology Analyzer	1 instrument+computer

Product Number	Description	Volume	Pack Size
2321703006	BF-FDT Lyse	500ml/ bottle	1 bottle
2321703008	BF-6500 Lyse(SLS- I)	500ml/ bottle	1 bottle
2321703005	BF-FDO Lyse	5L/ barrel	1 barrel
2321702002	BF-Diluent	20L/ barrel	1 barrel
2321701003	BF Detergent	50ml/ bottle	1 bottle
2321701006	BF Detergent	500ml/ bottle	1 bottle
2321704004	Control for Automatic Hematology 5-part(Level1)	2.5ml/ bottle	1 bottle
2321704005	Control for Automatic Hematology 5-part(Level2)	2.5ml/ bottle	1 bottle
2321704006	Control for Automatic Hematology 5-part(Level3)	2.5ml/ bottle	1 bottle

BF-6800

Automatic Hematology Analyzer



The BF-6800 is a five-part automatic hematology analyzer with large storage capacity, barcode scanning, automatic loading, mixing and rinsing functions. Which inherit the performance of BF series hematology analyzers, offers accurate and reliable results by less sample consumption. Cap piercing will be more secure for customers.

Product Features:

- ◎5-part differential, 24 report parameters, 10 research parameters, 4 histograms and 1 scattergram
- ◎CBC+DIFF mode: 60 tests per hour
- ◎Whole blood, pre-diluted blood
- ◎Build-in re-examination rule
- ◎Environmental friendly cyanide-free reagent
- ◎Automatic sampling and emergency access
- ◎Large storage capacity, up to 100,000 samples
- ◎Display type is external computer
- ◎Supporting LIS interface

Order Information:

Product Number	Description	Pack Size
1520401002	DIRUI BF-6800 Automatic Hematology Analyzer	1 instrument+computer

Product Number	Description	Volume	Pack Size
2321703006	BF-FDT Lyse	500ml/ bottle	1 bottle
2321703008	BF-6500 Lyse(SLS- I)	500ml/ bottle	1 bottle
2321703005	BF-FDO Lyse	5L/ barrel	1 barrel
2321702002	BF-Diluent	20L/ barrel	1 barrel
2321701002	BF Detergent	10ml/ bottle	1 bottle
2321701003	BF Detergent	50ml/ bottle	1 bottle
2321704004	Control for Automatic Hematology 5-part(Level1)	2.5ml/ bottle	1 bottle
2321704005	Control for Automatic Hematology 5-part(Level2)	2.5ml/ bottle	1 bottle
2321704006	Control for Automatic Hematology 5-part(Level3)	2.5ml/ bottle	1 bottle

BF-6500

Automatic Hematology Analyzer



The BF-6500 is an economic and compact design of five-part differential hematology analyzer. It offers accurate and reliable results, high-efficient automatic analysis, intelligent alarm function and user friendly operation.

Product Features:

- ◎5-part differential, 24 report parameters, 10 research parameters, 4 histograms and 1 scattergram
- ◎CBC+DIFF mode: 60 tests per hour
- ◎Whole blood, pre-diluted blood
- ◎Build-in re-examination rule
- ◎Environmental friendly cyanide-free reagent
- ◎Manual sampling
- ◎Large storage capacity, up to 100,000 samples
- ◎Display type is external computer
- ◎Supporting LIS interface

Order Information:

Product Number	Description	Pack Size
1520401003	DIRUI BF-6500 Automatic Hematology Analyzer	1 instrument+ computer

Product Number	Description	Volume	Pack Size
2321703006	BF-FDT Lyse	500ml/ bottle	1 bottle
2321703008	BF-6500 Lyse(SLS- I)	500ml/ bottle	1 bottle
2321703005	BF-FDO Lyse	5L/ barrel	1 barrel
2321702002	BF-Diluent	20L/ barrel	1 barrel
2321701002	BF Detergent	10ml/ bottle	1 bottle
2321701003	BF Detergent	50ml/ bottle	1 bottle
2321704004	Control for Automatic Hematology 5-part(Level1)	2.5ml/ bottle	1 bottle
2321704005	Control for Automatic Hematology 5-part(Level2)	2.5ml/ bottle	1 bottle
2321704006	Control for Automatic Hematology 5-part(Level3)	2.5ml/ bottle	1 bottle

BF-5180

Automatic Hematology Analyzer



The BF-5180 is a five-part automatic hematology analyzer, with a large LCD touch screen, barcode scanning, automatic loading, mixing and rinsing functions. It also provides both efficiency and benefit for customers. Based on semiconductor laser flow cytometry, cytochemical staining technique, and the high-precision SRV (Sample Rotatory Valve) quantification technique, offers accurate and reliable results. Intelligent and flexible re-examine function and user-friendly design contribute to easy operation.

Product Features:

- ◎5-part differential, 24 report parameters, 6 research parameters, 3 histograms and 2 scattergrams
- ◎80 tests per hour
- ◎Independent channel for Basophil measurement
- ◎Standard barcode reader and auto loader
- ◎Whole blood mode, and pre-dilute mode
- ◎Large storage capacity, up to 10,000 samples
- ◎LIS interface, supporting remote maintenance
- ◎Large LCD touch screen
- ◎Automatic barcode scanning

Order Information:

Product Number	Description	Pack Size
1520402001	BF-5180 Automatic Hematology analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2321703004	BF-SLS Lyse	500ml/ bottle	1 bottle
2321703002	BF-FDT Lyse	500ml/ bottle	1 bottle
2321703003	BF-FBA Lyse	5L/ barrel	1 barrel
2321703001	BF-FDO Lyse	5L/ barrel	1 barrel
2321702001	BF-Diluent	20L/ barrel	1 barrel
2321701001	BF-Detergent	50ml/ bottle	1 bottle
2321704001	Control for Automatic Hematology 5-part(Level1)	2.5ml/ bottle	1 bottle
2321704002	Control for Automatic Hematology 5-part(Level2)	2.5ml/ bottle	1 bottle
2321704003	Control for Automatic Hematology 5-part(Level3)	2.5ml/ bottle	1 bottle

BCC-3600

Hematology Analyzer



The BCC-3600 is a 3-part differential hematology analyzer offers accurate and reliable result with high efficient test through the classical test method.

Product Features:

- ◎3-part differential, 21 report parameters and 3 histograms
- ◎60 tests per hour
- ◎Whole blood mode, pre-diluted mode
- ◎Build-in re-examination rule
- ◎Up to 14 alarm information of paramorphia cell
- ◎Environmental friendly cyanide-free reagent
- ◎Friendly data management system
- ◎Large storage capacity up to 10,000 samples
- ◎Large color and high resolution LED displayer

Order Information:

Product Number	Description	Pack Size
1520401009	DIRUI BCC-3600 Hematology Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2320303008	BCC Series Lyse	500ml/ bottle	1 bottle
2320302013	Diluent	20L/barrel	1 barrel
2320305003	BCC Series Probe Cleanser	50ml/bottle	1 bottle
2320305004	BCC Series Probe Cleanser	500ml/bottle	1 bottle
2320307001	Control for Automatic Hematology 3-part(Level1)	2ml/bottle	1 bottle
2320307002	Control for Automatic Hematology 3-part(Level2)	2ml/bottle	1 bottle
2320307003	Control for Automatic Hematology 3-part(Level3)	2ml/bottle	1 bottle

BCC-3000B

Hematology Analyzer



BCC-3000B is a 3-part differential hematology analyzer, which is using digital filtering, blood cells overlap calibration, fitting curve, floating threshold technology to enhance accurate and reliable results.

Product Features:

- ◎3-part differential, 20 parameters, 3 histograms
- ◎60 test per hour
- ◎Whole blood mode, pre-dilute blood mode
- ◎Large storage capacity , up to 1000 samples
- ◎LIS interface, supporting remote maintenance
- ◎Built-in thermal printer, optional external printer

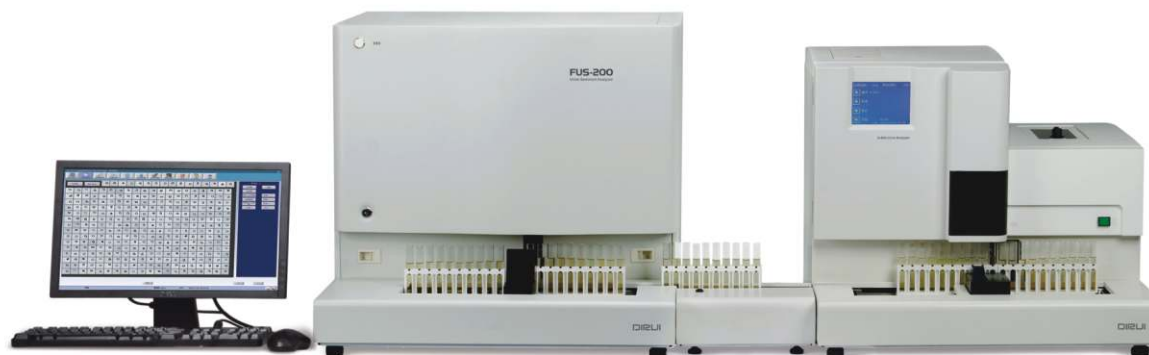
Order Information:

Product Number	Description	Pack Size
1520401001	DIRUI BCC-3000B Hematology Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2320301001	Cleanser	10L/ barrel	1 barrel
2320303001	Lyse	500ml/ bottle	1 bottle
2320302001	Diluent	20L/ barrel	1 barrel
2320304001	B-Z Cleanser	70ml/ bottle	1 bottle
2320305001	Probe Cleanser	50ml/ bottle	1 bottle
2320307001	Control for Automatic Hematology 3-part(Level1)	2ml/ bottle	1 bottle
2320307002	Control for Automatic Hematology 3-part(Level2)	2ml/ bottle	1 bottle
2320307003	Control for Automatic Hematology 3-part(Level3)	2ml/ bottle	1 bottle

Automatic Urinalysis System

(FUS-200 incorporates H-800)



Dirui urine sediment analyzer FUS-200 adopts flow cytometry and digital imaging to conduct quantitative analysis of urine formed elements with high precision, providing customers with reliable data. FUS-200 can be incorporated with H-800, fully automatic urine analyzer, to make up a fully automatic urinalysis workstation.

Product Features:

- ◎ Offering the ability to fully integrate with the Dirui H-800 to provide an 120 samples/h total urinalysis solution
- ◎ Utilizing digital imaging analysis technology to facilitate precise identification of the visual components in urine
- ◎ No centrifugation or stain is required
- ◎ Environmentally friendly consumables do not require special disposal, saving time and cost
- ◎ Friendly design, maintenance and operation can be completed in minutes
- ◎ Complete QC system for accurate and reliable results
- ◎ World class after-sales service and support

Order Information:

Description	Pack Size
FUS-200+connection bridge+H-800+computer	1 set

Product Number	Description	Volume	Pack Size
2322003002	Sheath	20L/ barrel	1 barrel
2322001001	Diluent	500ml/ bottle	1 bottle
2322002001	Detergent	500ml/ bottle	1 bottle
2322006002	Standard Solution	60ml/ bottle	1 bottle
2322004001	Focus	125ml/ bottle	
2322005001	Positive Control	125ml/ bottle	1 box
2322005002	Negative Control	125ml/ bottle	
2322006001	Standard Solution	125ml/ bottle	
2310201025	DIRUI H10-800	100 strips/ bottle	1 bottle
2310201024	DIRUI H11-800	100 strips/ bottle	1 bottle
2310201022	DIRUI H12-800MA	100 strips/ bottle	1 bottle
2310201106	DIRUI H13-Cr(H-800)	100 strips/ bottle	1 bottle
2310201093	DIRUI H14-Ca(H-800)	100 strips/ bottle	1 bottle

Automatic Urinalysis System

(FUS-100 incorporates H-800)



Dirui urine sediment analyzer FUS-100 adopts flow cytometry and digital imaging to conduct quantitative analysis of urine formed elements with high precision, providing customers with reliable data. FUS-200 can be incorporated with H-800, fully automatic urine analyzer, to make up a fully automatic urinalysis workstation.

Product Features:

- © Offering the ability to fully integrate with the Dirui H-800 to provide an 60 samples/h total urinalysis solution
- © Utilizing digital imaging analysis technology to facilitate precise identification of the visual components in urine
- © No centrifugation or stain is required
- © Environmentally friendly consumables do not require special disposal, saving time and cost
- © Friendly design, maintenance and operation can be completed in minutes
- © Complete QC system for accurate and reliable results
- © World class after-sales service and support

Order Information:

Description	Pack Size
FUS-100+connection bridge+H-800+computer	1 set

Product Number	Description	Volume	Pack Size
2322003002	Sheath	20L/ barrel	1 barrel
2322001001	Diluent	500ml/ bottle	1 bottle
2322002001	Detergent	500ml/ bottle	1 bottle
2322006002	Standard Solution	60ml/ bottle	1 bottle
2322004001	Focus	125ml/ bottle	
2322005001	Positive Control	125ml/ bottle	1box
2322005002	Negative Control	125ml/ bottle	
2322006001	Standard Solution	125ml/ bottle	
2310201025	DIRUI H10-800	100 strips/ bottle	1 bottle
2310201024	DIRUI H11-800	100 strips/ bottle	1 bottle
2310201022	DIRUI H12-800MA	100 strips/ bottle	1 bottle
2310201106	DIRUI H13-Cr(H-800)	100 strips/ bottle	1 bottle
2310201093	DIRUI H14-Ca(H-800)	100 strips/ bottle	1 bottle

FUS-2000

Urinalysis Hybrid



The Fus-2000 is a fully automatic integrated urinalysis system, inheriting all the features of DIRUI FUS and H series. Focusing on the genuine physical images of each formed element keeps DIRUI leading the urinalysis domain.

Product Features:

- ◎High throughput : 120 tests/hour
- ◎Simplified and compact 2 in 1 design
- ◎Standardized urinalysis testing solution
- ◎Long walk-away operation with consecutive loading (50/270 samples optional)
- ◎Contributing comprehensive clinical information to doctors

Order Information:

Product Number	Description	Pack Size
1520601005	DIRUI FUS-2000 Urinalysis Hybrid	1 instrument+ computer

Product Number	Description	Volume	Pack Size
2322003002	Sheath	20L/ barrel	1 barrel
2322103004	Sheath	15L/ barrel	1 barrel
2322103001	Sheath	10L/ barrel	1 barrel
2322001001	Diluent	500ml/ bottle	1 bottle
2322006001	Standard Solution	125ml/ bottle	
2322004001	Focus	125ml/ bottle	1box
2322005001	Positive Control	125ml/ bottle	
2322005002	Negative Control	125ml/ bottle	
2322002001	Detergent	500ml/ bottle	1bottle
2320506002	Cleaning Liquid(turbidimeter)	50ml/ bottle	1 bottles
2320501001	H Series Urine Analyzer Specific Gravity Control-SG=1.005	8 ml/ bottle	1 bottle
2320501002	H Series Urine Analyzer Specific Gravity Control-SG=1.030	8 ml/ bottle	1 bottle
2320501003	H Series Urine Analyzer Specific Gravity Control-SG=1.050	8 ml/ bottle	1 bottle
2320502001	H Series Urine Analyzer Turbidity Control- 200NTU	8 ml/ bottle	1 bottle
2320502002	H Series Urine Analyzer Turbidity Control-700NTU	8 ml/ bottle	1 bottle
2320503001	H Series Urine Analyzer Color Control-red	8 ml/ bottle	1 bottle
2320503002	H Series Urine Analyzer Color Control-green	8 ml/ bottle	1 bottle
2320503003	H Series Urine Analyzer Color Control-blue	8 ml/ bottle	1 bottle
2320504001	H Series Urine Analyzer Specific Gravity Calibrator	8 ml/ bottle	1 bottle
2320505001	H Series Urine Analyzer Turbidity Calibrator	8 ml/ bottle	1 bottle
2320701001	Urinalysis Control (Positive)	8 ml/ bottle	1 bottle
2320702001	Urinalysis Control (Negative)	8 ml/ bottle	1 bottle

FUS-200

Urine Sediment Analyzer



The FUS-200 is an automatic urine microscopy analyzer and walk-away system that uses digital imaging and a highly trained network(All software) to classify and quantitate cells and formed particles in native uncentrifuged urine, based on multiple parameters.

Product Features:

- ◎ 120 tests/hour
- ◎ Provide objective quantitative analysis results
- ◎ Promptly achieve standardization screening procedures
- ◎ New parameters information facilitates prompting RBC information and UTI information
- ◎ Without centrifugation and stains is helpful for the cost saving

Order Information:

Product Number	Description	Pack Size
1530102007	DIRUI FUS-200 Urine Sediment Analyzer	1 instrument+computer

Product Number	Description	Volume	Pack Size
2322003002	Sheath	20L/ barrel	1 barrel
2322103004	Sheath	15L/ barrel	1 barrel
2322103001	Sheath	10L/ barrel	1 barrel
2322001001	Diluent	500ml/ bottle	1 bottle
2322006001	Standard Solution	125ml/ bottle	
2322004001	Focus	125ml/ bottle	1box
2322005001	Positive Control	125ml/ bottle	
2322005002	Negative Control	125ml/ bottle	
2322002001	Detergent	500ml/ bottle	1bottle
2322006002	Standard Solution	60ml/ bottle	1bottle

FUS-100

Urine Sediment Analyzer



The FUS-100 is an automatic urine microscopy analyzer and walk-away system that uses digital imaging and a highly trained network(All software) to classify and quantitate cells and formed particles in native uncentrifuged urine, based on multiple parameters.

Product Features:

- ◎ 60 tests/hour
- ◎ Provide objective quantitative analysis results
- ◎ Promptly achieve standardization screening procedures
- ◎ New parameters information facilitates prompting RBC information and UTI information
- ◎ Without centrifugation and stains is helpful for the cost saving

Order Information:

Product Number	Description	Pack Size
1520601001	DIRUI FUS-100 Urine Sediment Analyzer	1 instrument+ computer

Product Number	Description	Volume	Pack Size
2322003002	Sheath	20L/ barrel	1 barrel
2322103004	Sheath	15L/ barrel	1 barrel
2322103001	Sheath	10L/ barrel	1 barrel
2322001001	Diluent	500ml/ bottle	1 bottle
2322006001	Standard Solution	125ml/ bottle	
2322004001	Focus	125ml/ bottle	1 box
2322005001	Positive Control	125ml/ bottle	
2322005002	Negative Control	125ml/ bottle	
2322002001	Detergent	500ml/ bottle	1 bottle
2322006002	Standard Solution	60ml/ bottle	1 bottle

H-1000

Automatic Urine Analyzer



DIRUI H-1000 Automatic urine analyzer provides accurate results, and simple and friendly operation, and will be widely recognized as the most advanced automatic analyzer in the global market.

Product Features:

- ©Throughput is 450 samples/hour
- ©Strips capacity is 200 strips
- ©Accurate quantitative dripping technology avoids cross-contamination effectively
- ©Large LCD touch screen is convenient for customer to input sample information
- ©Integrated barcode reader helps you get sample ID easily
- ©The design of the STAT position gives priority to emergency samples
- ©Waste box can collect waste strips automatically
- ©Original reagent and strips help to ensure the result accuracy
- ©H-1000 can be connected with LIS, HIS
- ©Integrated with FUS series analyzers to be urinalysis system

Order Information:

Product Number	Description	Pack Size
1520301007	DIRUI H-1000 Automatic Urine Analyzer	1 instrument
1520301008	DIRUI H-1000 Automatic Urine Analyzer plus	1 instrument

Product Number	Description	Volume	Pack Size
2320506004	Cleaning Liquid(concentrated type)	200ml/ bottle	2 bottles
2320506002	Cleaning Liquid(turbidimeter)	50ml/ bottle	1 bottles
2310201025	DIRUI H10-800	100 strips/ bottle	1 bottle
2310201024	DIRUI H11-800	100 strips/ bottle	1 bottle
2310201022	DIRUI H12-800MA	100 strips/ bottle	1 bottle
2310201106	DIRUI H13-Cr(H-800)	100 strips/ bottle	1 bottle
2310201093	DIRUI H14-Ca(H-800)	100 strips/ bottle	1 bottle
2320501001	H Series Urine Analyzer Specific Gravity Control-SG=1.005	8 ml/ bottle	1 bottle
2320501002	H Series Urine Analyzer Specific Gravity Control-SG=1.030	8 ml/ bottle	1 bottle
2320501003	H Series Urine Analyzer Specific Gravity Control-SG=1.050	8 ml/ bottle	1 bottle
2320502001	H Series Urine Analyzer Turbidity Control- 200NTU	8 ml/ bottle	1 bottle
2320502002	H Series Urine Analyzer Turbidity Control-700NTU	8 ml/ bottle	1 bottle
2320503001	H Series Urine Analyzer Color Control-red	8 ml/ bottle	1 bottle
2320503002	H Series Urine Analyzer Color Control-green	8 ml/ bottle	1 bottle
2320503003	H Series Urine Analyzer Color Control-blue	8 ml/ bottle	1 bottle
2320504001	H Series Urine Analyzer Specific Gravity Calibrator	8 ml/ bottle	1 bottle
2320505001	H Series Urine Analyzer Turbidity Calibrator	8 ml/ bottle	1 bottle
2320701001	Urinalysis Control (Positive)	8 ml/ bottle	1 bottle
2320702001	Urinalysis Control (Negative)	8 ml/ bottle	1 bottle

H-800

Automatic Urine Analyzer



DIRUI H-800 Automatic urine analyzer deserves to be trusted as an expert in the urine analysis field. It is especially developed for laboratories turn around time and cost savings.

Product features:

- ◎ Throughput is 240 samples/hour
- ◎ Strips capacity is 200 strips
- ◎ 14 test items are optional
- ◎ Accurate quantitative dripping technology avoids cross-contamination effectively
- ◎ Large LCD touch screen is convenient for customer to input sample information
- ◎ Reflectometer unit can provide more accurate results by SG, turbidity, and color.(optional)
- ◎ Integrated barcode reader helps you get sample ID easily
- ◎ The design of the STAT position gives priority to emergency samples
- ◎ Waste box can collect waste strips automatically
- ◎ Original reagent and strips help to ensure the result accuracy
- ◎ H-800 can be connected with LIS, HIS
- ◎ Integrated with FUS series analyzers to be urinalysis system

Order Information:

Product Number	Description	Pack Size
1520301001	DIRUI H-800 Automatic Urine Analyzer	1 instrument
1520301002	DIRUI H-800 Automatic Urine Analyzer plus	1 instrument

Product Number	Description	Volume	Pack Size
2320506004	Cleaning Liquid(concentrated type)	200ml/ bottle	2 bottles
2320506002	Cleaning Liquid(turbidimeter)	50ml/ bottle	1 bottles
2310201025	DIRUI H10-800	100 strips/ bottle	1 bottle
2310201024	DIRUI H11-800	100 strips/ bottle	1 bottle
2310201022	DIRUI H12-800MA	100 strips/ bottle	1 bottle
2310201106	DIRUI H13-Cr(H-800)	100 strips/ bottle	1 bottle
2310201093	DIRUI H14-Ca(H-800)	100 strips/ bottle	1 bottle
2320501001	H Series Urine Analyzer Specific Gravity Control-SG=1.005	8 ml/ bottle	1 bottle
2320501002	H Series Urine Analyzer Specific Gravity Control-SG=1.030	8 ml/ bottle	1 bottle
2320501003	H Series Urine Analyzer Specific Gravity Control-SG=1.050	8 ml/ bottle	1 bottle
2320502001	H Series Urine Analyzer Turbidity Control- 200NTU	8 ml/ bottle	1 bottle
2320502002	H Series Urine Analyzer Turbidity Control-700NTU	8 ml/ bottle	1 bottle
2320503001	H Series Urine Analyzer Color Control-red	8 ml/ bottle	1 bottle
2320503002	H Series Urine Analyzer Color Control-green	8 ml/ bottle	1 bottle
2320503003	H Series Urine Analyzer Color Control-blue	8 ml/ bottle	1 bottle
2320504001	H Series Urine Analyzer Specific Gravity Calibrator	8 ml/ bottle	1 bottle
2320505001	H Series Urine Analyzer Turbidity Calibrator	8 ml/ bottle	1 bottle
2320701001	Urianlysis Control (Positive)	8 ml/ bottle	1 bottle
2320702001	Urianlysis Control (Negative)	8 ml/ bottle	1 bottle

H-500

Urine Analyzer



DIRUI H-500 Semi-automatic urine analyzer's outstanding performance proves itself to be a reliable friend for medium laboratories.

Product features:

- ◎ Large touch screen is convenient for users' operation
- ◎ Built-in thermal printer can print results automatically
- ◎ Waste box can collect waste strips automatically
- ◎ 4 wavelength cold light source ensure the result accuracy
- ◎ High throughput is 420 samples/hour
- ◎ 14 test items are optional
- ◎ Large capacity of data memory is convenient for review

Order Information:

Product Number	Description	Pack Size
1520104001	DIRUI H-500 Urine Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2310201003	DIRUI H8	100 strips/ bottle	1 bottle
2310201002	DIRUI H10	100 strips/ bottle	1 bottle
2310201001	DIRUI H11	100 strips/ bottle	1 bottle
2310201021	DIRUI H11-MA	100 strips/ bottle	1 bottle
2310201037	DIRUI H13-Cr	100 strips/ bottle	1 bottle
2310201089	DIRUI H14-Ca	100 strips/ bottle	1 bottle

H-100

Urine Analyzer



DIRUI H-100 Semi-automatic urine analyzer offers ideal urine analysis solutions for small laboratories and hospitals.

Product features:

- © Friendly interface is convenient for users' operation
- © Built-in thermal printer can print results automatically
- © 4 wavelength cold light source ensure the result accuracy
- © Throughput is 60 samples/hour or 120 samples/hour
- © 14 test items are optional
- © Large capacity of data memory is convenient for reviewing
- © H-100 can connect computer with RS-232

Order Information:

Product Number	Description	Pack Size
1520102001	DIRUI H-100 Urine Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2310201003	DIRUI H8	100 strips/ bottle	1 bottle
2310201002	DIRUI H10	100 strips/ bottle	1 bottle
2310201001	DIRUI H11	100 strips/ bottle	1 bottle
2310201021	DIRUI H11-MA	100 strips/ bottle	1 bottle
2310201037	DIRUI H13-Cr	100 strips/ bottle	1 bottle
2310201089	DIRUI H14-Ca	100 strips/ bottle	1 bottle

Urinalysis Control



Urinalysis Control is original reagent from DIRUI, which can monitor both urine strips and urine analyzer`s status. Urinalysis Control offers UBG.BIL.KET.BLD.PRO.NIT.LEU.GLU.SG.PH.MALB.Cr .Ca totally 13 items.

Product features:

- © Liquid reagent without dissolution can be used directly to avoid manual sampling error
- © Free from material extracted from human urine to avoid the potential infection
- © The reagents are all non-toxic and environment friendly

Product Number	Description	Volume	Pack Size
2320701001	Urinalysis Control (Positive)	8ml/bottle	4 bottles
2320702001	Urinalysis Control (Negative)	8ml/bottle	4 bottles

FB-100

Fecal Occult Blood Analyzer



The FB-100 fecal occult blood analyzer conducts an automated quantitative analysis based on latex enhanced turbidimetric immunoassay, intended to detect small amounts of human hemoglobin in feces, which may be the only symptom at the early stage of colorectal cancer .

Product Features:

- ◎Compact design, easy operation
- ◎Fully automated
- ◎240 tests per hour, providing quantitative results
- ◎Special sampling tube allows for the standardization of sampling and accurate results
- ◎Large storage capacity: 12000 test results
- ◎LIS/HIS connection available

Order Information:

Product Number	Description	Pack Size
1520401007	DIRUI FB-100 Fecal Occult Blood Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2322406001	Fecal Occult Blood Analyzer Standard	Lyophilized Standard:2ml/bottlex2 Solvent:45ml/ bottlex1	1box
2322405001	Fecal Occult Blood Analyzer Control (High Value)	1ml/ bottlex6	1box
2322405002	Fecal Occult Blood Analyzer Control (Low Value)	1ml/ bottlex6	1box
2322407001	Fecal Occult Blood Analyzer Reagent Kit	Latex Reagent:12ml/ bottlex1 Diluent:160ml/ bottlex1	1box
2322407002	Fecal Occult Blood Analyzer Reagent Kit	Latex Reagent:6ml/ bottlex1 Diluent:80ml/ bottlex1	1box
2322407003	Fecal Occult Blood Analyzer Reagent Kit	Latex Reagent:9ml/ bottlex1 Diluent:120ml/ bottlex1	1box
2322407004	Fecal Occult Blood Analyzer Reagent Kit	Latex Reagent:18ml/ bottlex1 Diluent:200ml/ bottlex1	1box
2322402001	Fecal Occult Blood Analyzer Detergent	200ml/ bottle	1 bottle
2322408001	Special Sampling Tube	100/pack	1 pack

DIRUI

DIRUI INDUSTRIAL CO., LTD.

Address: 95 Yunhe Street, New & High Tech. Development Zone Changchun, Jilin 130012, P. R. China
Tel: +86 431 85100409 Fax: +86 431 85172581 E-mail: dirui@dirui.com.cn [Http://www.dirui.com.cn](http://www.dirui.com.cn)



Declaration of Conformity



According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: Dirui Industrial Co., Ltd.
95 Yunhe Street New& High Tech. Development Zone
Changchun Jilin 130012 P.R. China

Authorized Representative: Emergo Europe

Molenstraat 15 2513 BH The Hague
The Netherlands

Medical Device : Product Name: Reagent strips for Urinalysis

IVDD-Classification: Professional use

Lot/batches/Serial mber, Type, Periods of manufacture
(where applicable)

- DIRUI 1 ITEMS (GLU) DIRUI 1 ITEMS (KET) DIRUI 1 ITEMS (PRO)
- DIRUI 2 ITEMS (PRO, GLU) DIRUI 2 ITEMS (KET, GLU)
- DIRUI 3 ITEMS (PRO, PH, GLU) DIRUI 3 ITEMS (PRO, KET, GLU)
- DIRUI 4 ITEMS (PRO, PH, BLD, GLU) DIRUI 4 ITEMS (PRO, PH, SG, GLU)
- DIRUI 5 ITEMS (PRO, PH, BLD, KET, GLU)
- DIRUI 8 ITEMS DIRUI H8
- DIRUI 9 ITEMS
- DIRUI A10 DIRUI H10 DIRUI E10 DIRUI M10 DIRUI H10-800
- DIRUI H11 DIRUI H11-MA DIRUI H11-800
- DIRUI H11-800MA DIRUI H12-800MA
- DIRUI H13-Cr DIRUI H14-Ca
- DIRUI H13-Cr (H-800) DIRUI H14-Ca (H-800)

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.

Valid Since
May 9th, 2012
Changchun, China

Representative:
Yu Ge
Dirui Industrial Co., Ltd. 睿迪瑞医疗科技股份有限公司
于歌
(name and signature or equivalent marking of authorized person)

(place and date of issue)

DIAMOND[®]
DIAGNOSTICS



SmartLyte[®]

The World's Most Reliable Electrolyte Analyzer



SmartLyte®

The World's Most Reliable Electrolyte Analyzer

Sample

Whole Blood, Serum, Plasma, Urine or Dialysate

Sample Size

95 µl

Number of Parameters

3 (Simultaneously)

Detection Range

Blood Na⁺: 40-200 mmol/L

Dialysate K⁺: 1.7-15 mmol/L

Cl⁻: 50-200 mmol/L

Ca⁺⁺: 0.3-5.0 mmol/L

Li⁺: 0.2-5.5 mmol/L

Urine Na⁺: 3-300 mmol/L

K⁺: 5-120* mmol/L

Cl⁻: 15-300 mmol/L

*60-120 requires additional dilution

Reproducibility

Typical Within Run (n=30)

Blood, Serum, Plasma, Dialysate

Na⁺: CV ≤ 1% (120-160mmol/L)

K⁺: CV ≤ 2% (2.5-6 mmol/L)

Cl⁻: CV ≤ 2% (85-130 mmol/L)

Ca⁺⁺: SD ≤ 0.02 mmol/L (0.8-1.5 mmol/L)

Li⁺: SD ≤ 0.02 mmol/L (0.4-1.3 mmol/L)

(Lithium not typically measured in dialysate samples)

Urine

Na⁺: CV ≤ 5% (100-250 mmol/L)

K⁺: CV ≤ 5% (10-60 mmol/L)

Cl⁻: CV ≤ 5% (100-250 mmol/L)

(Calcium and Lithium are not typically measured in urine samples)

Display Resolution

Na⁺: 1 mmol/L or 0.1 mmol/L

K⁺: 0.1 mmol/L or 0.01 mmol/L

Cl⁻: 1 mmol/L or 0.1 mmol/L

Ca⁺⁺: 0.01 mmol/L or 0.001 mmol/L

Li⁺: 0.01 mmol/L or 0.001 mmol/L

Veterinary Options

Feline, Canine, Bovine, Equine, Swine, Ovine or Open

This analyzer is produced and distributed by Diamond Diagnostics Inc. There is no affiliation, connection, sponsorship or association between Diamond Diagnostics Inc. and Roche Diagnostics.



Analysis Time

60 sec without printout (60 per hour)

72 sec with printout (50 per hour)

Data Storage

1000 Patient Results

500 Level 1 QC Results

500 Level 2 QC Results

500 Level 3 QC Results

Calibration

2 Point every 4 hours

On Demand

1 Point after every Measurement

User Input

Keypad, External Keyboard

External Barcode Scanner (optional)

Output

Graphic backlit display

Graphic 16 column printer

RS232 LIS Communication

Ambient Conditions

15-32°C, Room temperature (60-90°F)

<85% humidity

Languages

English, Chinese, French, German, Italian, Korean
Japanese, Portuguese, Russian, Spanish, Polish

Power

100-240V ~ 50/60 Hz (self adjusting)

1.6 A max, 50 Watts max

Size & Weight

13.2 x 12.4 x 12" or 335 x 315 x 295 mm

14 lbs or 6 kgs

DIAMOND®
DIAGNOSTICS

333 Fiske Street, Holliston, MA 01746
Tel: 508-429-0450 | Fax: 508-429-0452
www.diamonddiagnostics.com

SOP23-0020F REV09 08/11/17

DECLARATION OF CONFORMITY

Diamond Diagnostics Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechnikai eszközökről szóló Európai Unió 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics Inc. assure et declare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics Inc. 确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Européia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/EC Европейского союза о медицинском оборудовании для диагностики In-vitro.

Vitro Diagnostica Medical Device 98/79EC المنجاة المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعلية
ان شركة دايموند داياغنونستكس تصرح و تؤكد أن

Diamond Diagnostics Inc. dichiara ed assicura che I prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispositivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 產品(s) / Produto(s) / Продукт(ы) / المنتج(ق) / Prodott(i) ;

Model: Diamond Diagnostics SmartLyte/CareLyte/Gemlyte

Reagent & Controls:

AV-BP5186D Fluid Pack	AV-BP0521D Deproteinizer	AV-BP1025D ISE Cleaning Solution
AV-BP0380D Electrode Conditioning Solution	AV-BP0344D Urine Diluent	

Electrodes & Accessories:

AV-BP0413D Na+ Electrode		
AV-BP0359D K+ Electrode	AV-BP5027D Peristaltic Pump Tubing	AV-BP5193D Pinch Valve Tubing Kit
AV-BP0570D Cl- Electrode	AV-BP5006D Sample Probe	AV-BP5014D Shutdown Kit
AV-BP0360D Ca++ Electrode	AV-BP5036D Sample Sensor	AV-BP5194D Startup Kit
AV-BP0962D Li+ Electrode	AV-BP5019D Reference Electrode Housing	AV-BP9043D Fillport Assembly
AV-BP5026D Reference Electrode	AV-BP5025D Printer Paper	

(AR) Authorized Representative

Diamond Diagnostics Kft.
6 Óradna Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Authorized Officer:

Kathy Fisher
Kathy Fisher
Global Quality Manager

Date: 30 April, 2018

Manufacturer's name: Diamond Diagnostics Inc. (USA)

Manufacturer's address: 333 Fiske Street
Holliston, MA 01746 USA
Tel: +1 (508) 429-0450
Fax: +1 (508) 429-0452

Quality Systems Registration

ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure

Annex III, Self-Declared



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2101045-1

Organization: Dirui Industrial Co., Ltd.
95 Yunhe Street, New & High Tech. Development Zone, Changchun,
130012 Jilin, P.R. China

Scope: Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers and In-Vitro Diagnostic Test Kits used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers, Nucleic Acid Extraction Reagent and Specimen Receptacle for Clinical Laboratory Use.

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

Report No.: 190131562 110
Effective date: 2021-04-30
Expiry date: 2023-03-01
Issue date: 2021-05-08



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2101045-1

Organization: Dirui Industrial Co., Ltd.
95 Yunhe Street, New & High Tech. Development Zone, Changchun,
130012 Jilin, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Dirui Industrial Co., Ltd. 95 Yunhe Street, New & High Tech. Development Zone, Changchun, 130012 Jilin, P.R. China	Design and Development, Manufacture of In-Vitro Diagnostic Test Kits used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers, Nucleic Acid Extraction Reagent and Specimen Receptacle for Clinical Laboratory Use.

Report No.: 190131562 110
Effective date: 2021-04-30
Expiry date: 2023-03-01
Issue date: 2021-05-08



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2101045-1

Organization: Dirui Industrial Co., Ltd.
95 Yunhe Street, New & High Tech. Development Zone, Changchun,
130012 Jilin, P.R. China

The scope of certification also covers the following:

/02 c/o Dirui Industrial Co., Ltd.
3333 Yiju Street, New & High Tech.
Development Zone, Changchun,
130103 Jilin, P.R. China

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Analyzers used in the Detection of Blood Analyte, Cancer, Cardiac Markers, Coagulation Blood, Endocrine Disorders, Immune Status, Protein Metabolism, Sexually Transmitted Diseases, Infectious Disease, Therapeutic Drug Monitoring, Disease Status, Renal Function Assessment, Liver Function Assessment, Pancreas Function Assessment, Blood Fat Test, Physiological Markers for Clinical Laboratory Use.

Report No.: 190131562 110
Effective date: 2021-04-30
Expiry date: 2023-03-01
Issue date: 2021-05-08



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



MAGYAR SZABVÁNYÜGYI TESTÜLET
HUNGARIAN STANDARDS INSTITUTION

H-1082 Budapest, Horváth Mihály tér 1.

TANÚSÍTÁSI OKIRAT CERTIFICATE

Tanúsítjuk, hogy a
We certify that the Management System of
Diamond Diagnostics Inc. Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.

Tanúsított székhely: H-1044 Budapest, Óradna utca 6.

irányítási rendszere megfelel a szabvány követelményeinek a következő alkalmazási területen:
ionszelektív laboratóriumi mérőműszerek és alkatrészek, fogyóanyagok gyártása és
klinikai diagnosztikai készülékek felújítása

meets the requirements of the standard for the following activities:
the manufacture of blood electrolyte systems, consumables and
re-manufacture of clinical diagnostic equipment

MSZ EN ISO 13485:2016 (ISO 13485:2016)

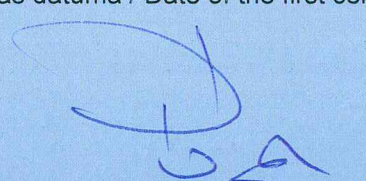


A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.
This certificate is valid together with the maintenance decision annually issued by MSZT.

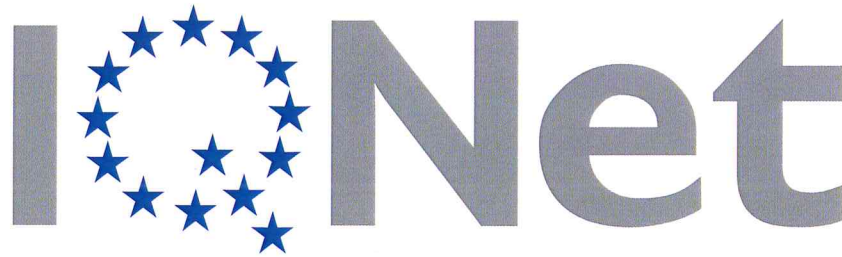
A tanúsítási okirat száma / Reg. number: **503/1342(2)**

Budapest, **2020. december 21.**

Az első tanúsítás dátuma / Date of the first certification: **2014. 06. 26.**


Pónyai György
ügyvezető igazgató





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

MSZT has issued an IQNet recognized certificate that the organization:

Diamond Diagnostics Inc.
Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.

Certified headquarters: H-1044 Budapest, Óradna utca 6.

has implemented and maintains a

Quality Management System

for the following scope

the manufacture of blood electrolyte systems, consumables and re-manufacture of clinical diagnostic equipment

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **21-12-2020**

First issued on: **26-06-2014**

Expires on: **21-06-2023**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: HU-MSZT-503/1342(2)-1262(2)

Alex Stoichitoiu
President of IQNet

György Pónyai
General Director of MSZT



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group
USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



MAGYAR SZABVÁNYÜGYI TESTÜLET
HUNGARIAN STANDARDS INSTITUTION
H-1082 Budapest, Horváth Mihály tér 1.

TANÚSÍTÁSI OKIRAT CERTIFICATE

Tanúsítjuk, hogy a
We certify that the Management System of
Diamond Diagnostics Inc. Magyarországi Fióktelepe
H-1044 Budapest, Óradna utca 6.
Tanúsított székhely: H-1044 Budapest, Óradna utca 6.

irányítási rendszere megfelel a szabvány követelményeinek a következő alkalmazási területen:
**ionszelektív laboratóriumi mérőműszerek és alkatrészek, fogyóanyagok gyártása és
klinikai diagnosztikai készülékek felújítása**

meets the requirements of the standard for the following activities:
**the manufacture of blood electrolyte systems, consumables and re-manufacture of
clinical diagnostic equipment**

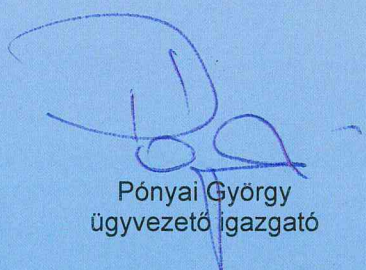
MSZ EN ISO 9001:2015 (ISO 9001:2015)

A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.
This certificate is valid together with the maintenance decision annually issued by MSZT.

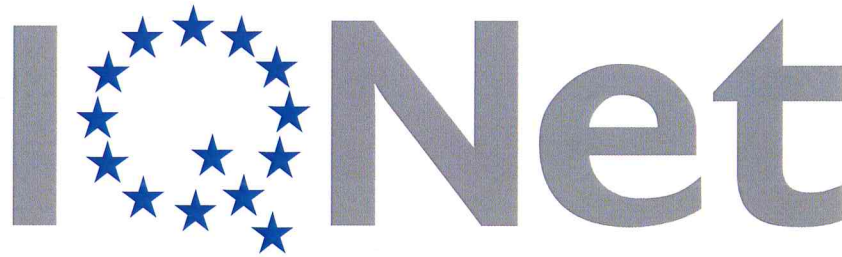
A tanúsítási okirat száma / Reg. number: **503/1341(2)**

Budapest, **2020. december 21.**

Az első tanúsítás dátuma / Date of the first certification: **2014. 06. 26.**


Pónyai György
ügyvezető igazgató





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

MSZT has issued an IQNet recognized certificate that the organization:

***Diamond Diagnostics Inc.
Magyarországi Fióktelepe***

H-1044 Budapest, Óradna utca 6.

Certified headquarters: H-1044 Budapest, Óradna utca 6.

has implemented and maintains a

Quality Management System

for the following scope

**the manufacture of blood electrolyte systems, consumables and
re-manufacture of clinical diagnostic equipment**

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **21-12-2020**

First issued on: **26-06-2014**

Expires on: **21-06-2023**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: HU-MSZT-503/1341(2)-1261(2)

Alex Stoichitoiu
President of IQNet

György Pónyai
General Director of MSZT



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group
USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com