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ORDIN DE PLATA NR.: 105                                TIP.DOC. 1 :
                                DATA EMITERII:luni, 17 februarie:
=====:
PLATITI: 2500-00          LEI: Doua Mii Cinci Sute lei 00 ban :
i                                                                    :
                                                                    :
=====:
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-1738932432297 din :          :
18.02.2025 :          :
:          :          :
:          :          L.S. :
=====:
                                CODUL TRANZACTIEI:001: _____ :
DATA PRIMIRII:17/02/2025 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTATOR:Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAAEi65avx+fXSldAAAAAQOLMA0GCSq:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTI0MDEyNTEzMzNmNlOxDTI3MDEyNTExNDM1NlowgZ8xCzAJBgNVBAYTAk1EMRA:
gYDVQQIEWdNb2xkb3ZhmREwDwYDVQQHEWhDaG1zaW5hdTEWMBQGA1UEChMNQml :
_____:
(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCCB1QCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAAEi65avx+fXSldAAAAAQOLMA0GCSqG:
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTI0MDEyNTEyMzNmNlOxDTI3MDEyNTExNDMzNVowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEWdNb2xkb3ZhmREwDwYDVQQHEWhDaG1zaW5hdTEWMBQGA1UEChMNQmlv :
_____:
L.S. (semnatura electronica) :
CONDUCTATOR: _____ :
(semnatura manuala) :
CONTABIL-SEF: _____ :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:-----:

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MOTIVUL REFUZULUI : L.S. :
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CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2501358**

din
от **06.02.2025**

1. Destinația / Назначение

Pentru participarea la proceduri de achiziții 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 21.02.2025

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

Șefă DDF Rîșcani

Funcția/Должность

Semnătura/Подпись

CĂUȘ Viorica

Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: **GOJAN Claudia**
Numele și prenumele/Фамилия и имя

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

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

semnătura

MD 0101250





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

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

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

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

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

Data înregistrării de stat: **12.08.2010**

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

Obiectul principal de activitate:

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

Capitalul social: **5400 lei.**

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

Asociații:

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

Beneficiar efectiv:

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

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

Beneficiar efectiv:

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

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

Beneficiar efectiv:

3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

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

**Registrator în domeniul
înregistrării de stat**

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



Rusu Diana



EB 0461494



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

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

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

Республика Молдова, MD-2068
мун. Кишинэу, бул. 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

Lista fondatorilor Biosistem-mld SRL

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

Cod Fiscal: 1010600028048; IBAN: MD95ML00000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poștală a băncii: mun. Chișinău, bd. Moscovei, 14/1;

Scrisoare de informare

Prin prezenta, SRL „Biosistem mld”, va informeaza ca conform “*legii Nr. 160 din 22-07-2011 privind reglementarea prin autorizare a activității de întreprinzător*”, cu modificarile ulterior adoptate de parlamentul RM, *Importul, comercializarea, asistența tehnică si reparația dispozitivelor medicale* nu mai este activitate licentiata. Respectiv nu mai sunt eliberate licente pentru acest gen de activitate, iar licentele cu termenul de valabilitate expirat nu mai sunt prelungite.



Vitalie Poiata

L.Ș.

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2023 - 31.12.2023

Entitatea: BIOSISTEM MLD S.R.L.

Cod CUIÎO: 40717392

Cod IDNO: 1010600028048

Sediul:

MD:

Raionul(municipiul): 106, DDF RASCANI

Cod CUATM: 0150, SEC.RISCANI

Strada: Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice

Forma de proprietate: 16, Proprietate colectivă

Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:

Telefon: +37322808719

WEB:

E-mail: zmii13@mail.ru

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

Numărul mediu al salariaților în perioada de gestiune: 10 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

la

Anexa 1

| 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 | | | |
| A. | ACTIVE IMOBILIZATE | | | |
| | I. Imobilizări necorporale | | | |
| | 1. Imobilizări necorporale în curs de execuție | 010 | | |
| | 2. Imobilizări necorporale în exploatare, total | 020 | | |
| | din care: | | | |
| | 2.1. concesiuni, licențe și mărci | 021 | | |
| | 2.2. drepturi de autor și titluri de protecție | 022 | | |
| | 2.3. programe informatice | 023 | | |

| | | | |
|---|-----|---------|---------|
| 2.4. alte immobilizări necorporale | 024 | | |
| 3. Fond comercial | 030 | | |
| 4. Avansuri acordate pentru immobilizări necorporale | 040 | | |
| Total immobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040) | 050 | | |
| II. Immobilizări corporale | | | |
| 1. Immobilizări corporale în curs de execuție | 060 | | |
| 2. Terenuri | 070 | | |
| 3. Mijloace fixe, total | 080 | 3384131 | 4438372 |
| din care: | | | |
| 3.1. clădiri | 081 | | |
| 3.2. construcții speciale | 082 | | |
| 3.3. mașini, utilaje și instalații tehnice | 083 | 3363063 | 4423127 |
| 3.4. mijloace de transport | 084 | | |
| 3.5. inventar și mobilier | 085 | 21068 | 15245 |
| 3.6. alte mijloace fixe | 086 | | |
| 4. Resurse minerale | 090 | | |
| 5. Active biologice immobilizate | 100 | | |
| 6. Investiții imobiliare | 110 | | |
| 7. Avansuri acordate pentru immobilizări corporale | 120 | 5250844 | 2337159 |
| Total immobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120) | 130 | 8634975 | 6775531 |
| 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 immobilizate | | | |
| 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 | 8634975 | 6775531 |
| B. | ACTIVE CIRCULANTE | | | |
| | I. Stocuri | | | |
| | 1. Materiale și obiecte de mică valoare și scurtă durată | 240 | 13899 | 24776 |
| | 2. Active biologice circulante | 250 | | |
| | 3. Producția în curs de execuție | 260 | | |
| | 4. Produse și mărfuri | 270 | 11123640 | 11490033 |
| | 5. Avansuri acordate pentru stocuri | 280 | | |
| | Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280) | 290 | 11137539 | 11514809 |
| | II. Creanțe curente și alte active circulante | | | |
| | 1. Creanțe comerciale curente | 300 | 4552459 | 2646694 |
| | 2. Creanțe ale părților afiliate curente | 310 | | |
| | inclusiv: creanțe aferente intereselor de participare | 311 | | |
| | 3. Creanțe ale bugetului | 320 | 27696 | 45618 |
| | 4. Creanțele ale personalului | 330 | | |
| | 5. Alte creanțe curente | 340 | | |
| | 6. Cheltuieli anticipate curente | 350 | | |
| | 7. Alte active circulante | 360 | 2268111 | 2251145 |
| | Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360) | 370 | 6848266 | 4943457 |
| | III. Investiții financiare curente | | | |
| | 1. Investiții financiare curente în părți nefiliate | 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 | 10281443 | 27361722 |
| | TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410) | 420 | 28267248 | 43819988 |

| | | | | |
|----|--|-----|----------|----------|
| | TOTAL ACTIVE (rd.230 + rd.420) | 430 | 36902223 | 50595519 |
| | P A S I V | | | |
| | CAPITAL PROPRIU | | | |
| | I. Capital social și neînregistrat | | | |
| | 1. Capital social | 440 | 5400 | 5400 |
| | 2. Capital nevărsat | 450 | () | () |
| | 3. Capital neînregistrat | 460 | | |
| | 4. Capital retras | 470 | () | () |
| | 5. Patrimoniul primit de la stat cu drept de proprietate | 480 | | |
| | Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480) | 490 | 5400 | 5400 |
| | II. Prime de capital | 500 | | |
| | III. Rezerve | | | |
| | 1. Capital de rezervă | 510 | | |
| | 2. Rezerve statutare | 520 | | |
| C. | 3. Alte rezerve | 530 | | |
| | Total rezerve (rd.510 + rd.520 + rd.530) | 540 | | |
| | IV. Profit (pierdere) | | | |
| | 1. Corecții ale rezultatelor anilor precedenți | 550 | X | |
| | 2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți | 560 | 35876971 | 29813141 |
| | 3. Profit net (pierdere netă) al perioadei de gestiune | 570 | X | 18618853 |
| | 4. Profit utilizat al perioadei de gestiune | 580 | X | () |
| | Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580) | 590 | 35876971 | 48431994 |
| | 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 | 35882371 | 48437394 |
| D. | DATORII PE TERMEN LUNG | | | |
| | 1. Credite bancare pe termen lung | 630 | | |
| | 2. Împrumuturi pe termen lung | 640 | | |
| | din care: | | | |
| | 2.1. împrumuturi din emisiunea de obligațiuni | 641 | | |
| | inclusiv: împrumuturi din emisiunea de obligațiuni convertibile | 642 | | |
| | 2.2. alte împrumuturi pe termen lung | 643 | | |
| | 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 | | |
| | din care: | | | |
| | 2.1. Împrumuturi din emisiunea de obligațiuni | 721 | | |
| | inclusiv: împrumuturi din emisiunea de obligațiuni convertibile | 722 | | |
| | 2.2. alte împrumuturi pe termen scurt | 723 | | |
| | 3. Datorii comerciale curente | 730 | 5266 | 59765 |
| | 4. Datorii față de părțile afiliate curente | 740 | | |
| E. | inclusiv: datorii aferente intereselor de participare | 741 | | |
| | 5. Avansuri primite curente | 750 | 143160 | 273711 |
| | 6. Datorii față de personal | 760 | 866 | |
| | 7. Datorii privind asigurările sociale și medicale | 770 | | |
| | 8. Datorii față de buget | 780 | 831429 | 1766706 |
| | 9. Datorii față de proprietari | 790 | | |
| | 10. Venituri anticipate curente | 800 | | |
| | 11. Alte datorii curente | 810 | 39131 | 57943 |
| | 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 | 1019852 | 2158125 |
| | 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 | | |
| F. | TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870) | 880 | 36902223 | 50595519 |

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2023 până la 31.12.2023

Anexa 2

| Indicatori | Cod rd. | Perioada de gestiune |
|------------|---------|----------------------|
|------------|---------|----------------------|

| | | precedenta | curenta |
|--|----------|-------------------|----------------|
| 1 | 2 | 3 | 4 |
| Venituri din vânzări, total | 010 | 40621876 | 58891757 |
| din care: | | | |
| venituri din vânzarea produselor și mărfurilor | 011 | 39203671 | 57105542 |
| venituri din prestarea serviciilor și executarea lucrărilor | 012 | 1390733 | 1771148 |
| venituri din contracte de construcție | 013 | | |
| venituri din contracte de leasing | 014 | | |
| venituri din contracte de microfinanțare | 015 | | |
| alte venituri din vânzări | 016 | 27472 | 15067 |
| Costul vânzărilor, total | 020 | 22086174 | 32917436 |
| din care: | | | |
| valoarea contabilă a produselor și mărfurilor vândute | 021 | 21991682 | 32793096 |
| costul serviciilor prestate și lucrărilor executate terților | 022 | 92356 | 124340 |
| costuri aferente contractelor de construcție | 023 | | |
| costuri aferente contractelor de leasing | 024 | | |
| costuri aferente contractelor de microfinanțare | 025 | | |
| alte costuri aferente vânzărilor | 026 | 2136 | |
| Profit brut (pierdere brută) (rd.010 - rd.020) | 030 | 18535702 | 25974321 |
| Alte venituri din activitatea operațională | 040 | 128694 | 829270 |
| Cheltuieli de distribuire | 050 | 15271 | 4167 |
| Cheltuieli administrative | 060 | 3076978 | 3996115 |
| Alte cheltuieli din activitatea operațională | 070 | 1325483 | 879808 |
| Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070) | 080 | 14246664 | 21923501 |
| Venituri financiare, total | 090 | 1530710 | 1070406 |
| din care: | | | |
| venituri din interese de participare | 091 | | |
| inclusiv: veniturile obținute de la părțile afiliate | 092 | | |
| venituri din dobânzi | 093 | 250190 | 337916 |
| 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 | 1280520 | 732490 |

| | | | |
|---|-----|----------|----------|
| Cheltuieli financiare, total | 100 | 512939 | 1786338 |
| 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 | 512939 | 1786338 |
| Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100) | 110 | 1017771 | -715932 |
| 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 | 1017771 | -715932 |
| Profit (pierdere) pînă la impozitare (rd.080 + rd.150) | 160 | 15264435 | 21207569 |
| Cheltuieli privind impozitul pe venit | 170 | 1872862 | 2588716 |
| Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170) | 180 | 13391573 | 18618853 |

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 |
| | Capital social și neînregistrat | | | | | |
| | 1. Capital social | 010 | | | | |
| | 2. Capital nevărsat | 020 | () | () | () | () |
| | 3. Capital neînregistrat | 030 | | | | |
| I. | 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) | | | | | |
| IV. | 1. Corecții ale rezultatelor anilor precedenți | 120 | X | | | |
| | 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 sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230) | 240 | | |

Documente atașate - Notă explicativă (fișierul pdf)

Recipisa

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 26.03.2024 17:05:42

Recipisa 2

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 09.04.2024 09:26:11

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs.
Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.



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

Pau Vila Cases Ph.D
CEO
BioSystems

Summary

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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.

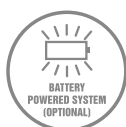
Instruments



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



A25

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

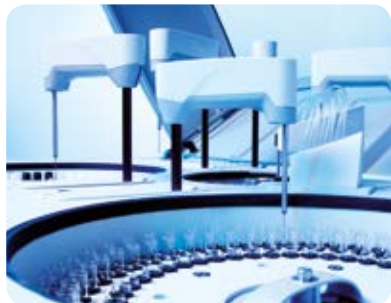
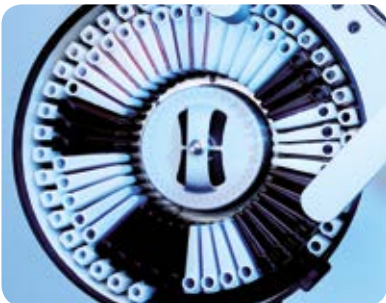
- ▶ STAT and Routine Laboratories Benchtop Random Clinical Chemistry Analyzer.
- ▶ Dynamic Baseline with SMART LED Technology.
- ▶ High reagent and sample capacity (88 positions), the highest grade in flexibility.
- ▶ Barcoded dedicated reagents.
- ▶ Highly accurate dispensing.
- ▶ 120 - cuvette rotor 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



HA LOADER

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 |



COAX

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 lucilliae</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 adsorbed) 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

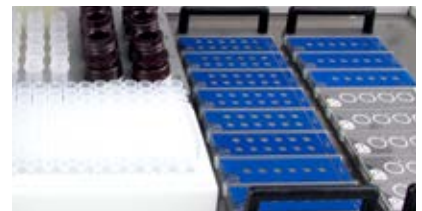
- ▶ Yearly program for the comparison of results between laboratories
- ▶ Monthly measurements of different control materials
- ▶ The final report summarises all monthly reports and shows additional data on performance
- ▶ On-line participation through www.prevecal.net

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



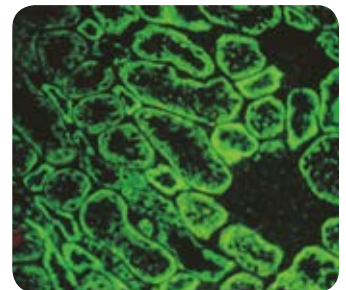
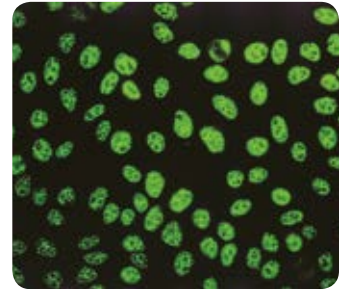
Code 84101

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 |

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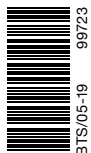




Ginger Group



BioSystems



Manufactured by: **BioSystems S.A.**
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biosystems@biosystems.es - www.biosystems.es



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

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

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



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

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

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®
D I A G N O S T I C S

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

(AR) Authorized Representative

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

Authorized Officer:


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



CERTIFICATO DI ACCREDITAMENTO

Accreditation Certificate

ACCREDITAMENTO N. **0017P REV. 00**
ACCREDITATION N.

EMESSO DA **DIPARTIMENTO LABORATORI DI PROVA**
ISSUED BY

SI DICHIARA CHE **BIO-GROUP MEDICAL SYSTEM S.r.l.**
WE DECLARE THAT

Sede/Headquarters:
- Loc. Campiano 9/b - 47867 Talamello RN

È CONFORME AI REQUISITI **UNI CEI EN ISO/IEC 17043:2010**
DELLA NORMA

MEETS THE REQUIREMENTS **ISO/IEC 17043:2010**
OF THE STANDARD

QUALE **Organizzatori di prove valutative interlaboratorio**
AS **Proficiency Testing Provider**

Data di 1^a emissione
1st issue date
14-11-2018

Data di modifica
Modification date
14-11-2018

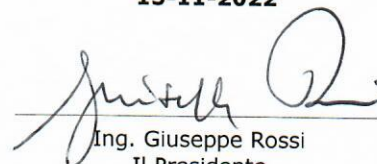
Data di scadenza
Expiring date
13-11-2022



Dott.ssa Silvia Tramontin
Il Direttore di Dipartimento
The Department Director



Dott. Filippo Trifiletti
Il Direttore Generale
The General Director



Ing. Giuseppe Rossi
Il Presidente
The President

L'accreditamento attesta la competenza tecnica dell'Organizzazione relativamente al campo di accreditamento riportato nell'Elenco Schemi allegato al presente certificato di accreditamento.

Il presente certificato non è da ritenersi valido se non accompagnato dagli Elenchi Schemi, che possono variare nel tempo.

La vigenza dell'accreditamento può essere verificata sul sito web (www.accredia.it) o richiesta al Dipartimento di competenza.

The accreditation certifies the technical competence of the organisation limited to the scope detailed in the attached Enclosure. The present certificate is valid only if associated to the annexed schedule, that may vary in the time.

Confirmation of the validity of accreditation can be verified on website www.accredia.it or by contacting the relevant Department.



BIO GROUP – MEDICAL SYSTEM Srl
Strumentazione e Diagnostici
 Loc. Campiano, 9/B – 47867 Talamello (RN)
 e.mail: info@biogroupmedicalsistem.com
 Tel. +39 0541 920686
 Fax +39 0541 922130

Declaration of conformity certificate

We: Bio Group Medical System Srl Loc. Campiano 9/B, Talamello (RN) 47867 Italy
 Ensure and declare with sole responsibility that the products:

| | |
|---|--|
| Internal code: MSEQUALITYCH-MSEQSCH12-MSEQSCH4 EDMA Code: 38220000 | Commercial name: QS Clinical Chemistry First lot introduced in market: 112-NB |
| Internal code: MSEQUALITYPS EDMA Code: 38220000 | Commercial name: QS Specific Protein First lot introduced in market: 220-NB |
| Internal code: MSEQUALITYEF EDMA Code: 38220000 | Commercial name: QS Electrophoresis First lot introduced in market: 220-NB |
| Internal code: MSEQUALITYE8-MSEQSE12 EDMA Code: 30021095 | Commercial name: QS Hematology First lot introduced in market: 2020-EN |
| Internal code: MSEQUALITYC-MSEQSC12-MSEQSC4 EDMA Code: 38220000 | Commercial name: QS Coagulation First lot introduced in market: 084 |
| Internal code: MSEQUALITYI-MSEQSI12-MSEQSI4 EDMA Code: 38220000 | Commercial name: QS Immunology First lot introduced in market: 360 |
| Internal code: MSEQUALITYB EDMA Code: 38220000 | Commercial name: QS Bacteriology First lot introduced in market: 326 |
| Internal code: MSEQUALITYS EDMA Code: 38220000 | Commercial name: QS Serology First lot introduced in market: 1020-SI |
| Internal code: MSEQUALITYU EDMA Code: 38220000 | Commercial name: QS Urine First lot introduced in market: 002-U |
| Internal Code: MSEQUALITYH-MSEQSHB12 EDMA Code: 38220000 | Commercial name: QS HBAIC First lot introduced in market: 001-H |
| Internal Code: MSEQUALITYD EDMA Code: 38220000 | Commercial name: QS Drug of Abuse First lot introduced in market: 330-D |
| Internal Code: MSEQUALITYSO EDMA Code: 38220000 | Commercial name: QS FOB First lot introduced in market: 110-F |
| Internal Code: MSEQUALITYESR EDMA Code: 30021095 | Commercial name: QS ESR First lot introduced in market: 001-V |
| Internal Code: MSEQUALITYCM EDMA Code: 38220000 | Commercial Name: QS Cardiac Marker First lot introduced in market: 201-C |

meet the provisions of Council Directive 98/79/CE, annex I, as expected according to Council Directive 98/79/CE, annex III, concerning In Vitro Medical-Diagnostic Devices, which apply to us.

To this purpose, we guarantee and declare, on our own responsibility, what follows:

- ◆ Subsequent lots will be consistent with technical specification of the first lot. This conformity will be attested on the quality control certificate.
- ◆ The specified item satisfy the all dispositions applicable of Directive 98/79/CE
- ◆ We undertake in storing and placing to the competent Authority disposal the technical dossier of the product, as required by Council Directive 98/79/CE, annex III, as well as the production and control registrations for a period of at least 5 years after the last production date of the last lot.
- ◆ The specified device is designed, manufactured, and commercialized with date of first release not preceding the present one.

The present conformity declaration has validity of a maximum of 5 years.

Moreover, the manufacturer declare to have established and to maintain an appropriate procedure to guarantee the post-sale surveillance, as requested by Council Directive 98/79/CE.




Talamello, January the 29th, 2019

BIO GROUP
MEDICAL SYSTEM SRL
 Loc. Campiano 9/B - 47867 Talamello (RN)
 P.IVA C.Fisc. 0096170419

Cap. Soc. € 75.300,00 i.v. – Reg. Trib. Pesaro 7163 C.C.I.A.A. 98204 – P.IVA C.Fisc. 0096170419



| | | | |
|--|---|--|--|
|  | HEMATOLOGY 8 PARAMETERS APRIL 2019 | RdP: Re issued ZKN247_18_2019_4.pdf | |
| | Participant : ZKN247 Sample Lot : HE-19040 | Issued on 14/05/2019 Authorized by RQS Paolo Cocci | |

Bio-Group Medical System s.r.l.

QS Division

qs@biogroupmedicalsistem.com

+39 054920686 int 3

Cycle: HEMATOLOGY 8 PARAM.

Enroled participants : 278

Subcontract Activities: Homogeneity and stability test and sera production. The PTP declares the assumption of responsibility towards the participants for the subcontracted work

Authorized by: RQS Paolo Cocci

Coordinator: COP Matteo Montini

Contacts: email: help@biogms.com

Telephone: +390541920686 **Fax:** +390541920180


Proficiency test object: Blood

Lot: HE-19040


Lot expiration: 2019-06-30

Homogeneity and Stability: Sera Homogeneity: data available on request

Confidentiality: All communications relating to the QS programs take place in a confidential manner between the QS Division and each individual laboratory. Participants are assigned a specific confidential identification code. These reserved codes are known to the QS Division, to the single laboratory and to the appointed officers.

| | | | |
|--|---|--|--|
|  | HEMATOLOGY 8 PARAMETERS APRIL 2019 | RdP: Re issued ZKN247_18_2019_4.pdf | |
| | Participant : ZKN247 Sample Lot : HE-19040 | Issued on 14/05/2019 Authorized by RQS Paolo Cocci | |

| Analit | RDS |
|---------------|------------|
| RDW/IDR-SD | 0,1500 |
| MCHC | 0,1500 |
| MPV | 0,1500 |
| WBC/GB | 0,1500 |
| RBC/GR | 0,1500 |
| HGB | 0,1500 |
| MCV/VMG | 0,1500 |
| MCH/TCMH | 0,1500 |
| RDW/IDR | 0,1500 |
| PLT/PLQ | 0,1500 |
| HCT | 0,1500 |

| | | |
|--|---|--|
|  | HEMATOLOGY 8 PARAMETERS APRIL 2019 | RdP: Re issued ZKN247_18_2019_4.p df |
| | Participant : ZKN247 Sample Lot : HE-19040 | Issued on 14/05/2019 Authorized by RQS Paolo Cocci |

PT target value assignment procedure

For each measurement of this evaluation test, the assigned value is determined using the robust average calculated according to Algorithm A ISO 13528: 2015.

Assigned value uncertainty is determined according to formula:

$$U_{x_{pt}} = 1,25 \left(\frac{s^*}{\sqrt{p}} \right)$$

where s^* is the robust standard deviation and p is participants number

Assigned Relative Deviation Standard is determined according to formula

$$\sigma_{pt} = RDS * x_{pt}$$

Performance index is evaluated according to equation B.3 ISO 17043:2010

$$Z \text{ Score} = \frac{x_i - x_{pt}}{\sigma_{pt}}$$

If standard uncertainty is more than 30% of Assigned Relative Deviation Standard the performance index will determined according to the following equation

$$\frac{x_i - x_{pt}}{\sqrt{\sigma_{pt}^2 + U_{x_{pt}}^2}}$$

Where:

x_i = Participant measure

x_{pt} = Assigned value

σ_{pt} = Assigned standard deviation

$U_{x_{pt}}$ = Assigned value uncertainty

The exposed procedure is used for all the parameters of this PT

In this report are showed also these two error indexes

$D = x_i - x_{pt}$: Participant absolute error

$D_{\%} = \frac{(100 * D)}{x_{pt}}$: Absolute error in percentage



**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **WBC/GB**

Unit **10³μL/10⁹**

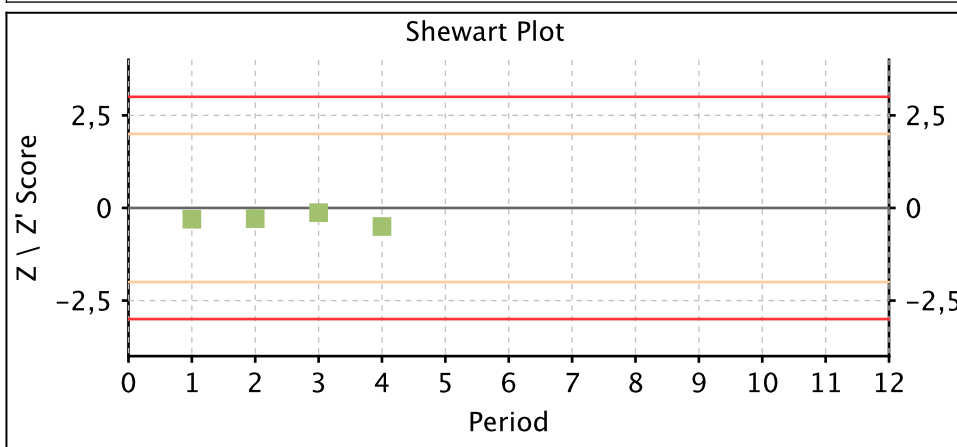
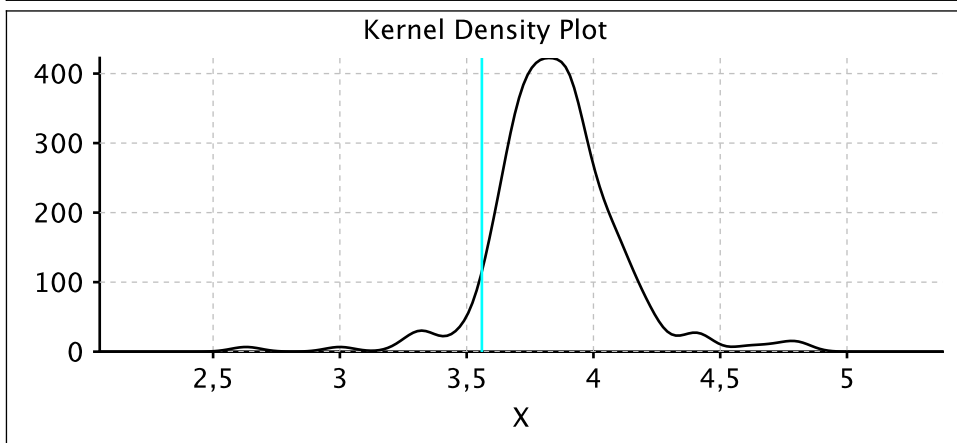
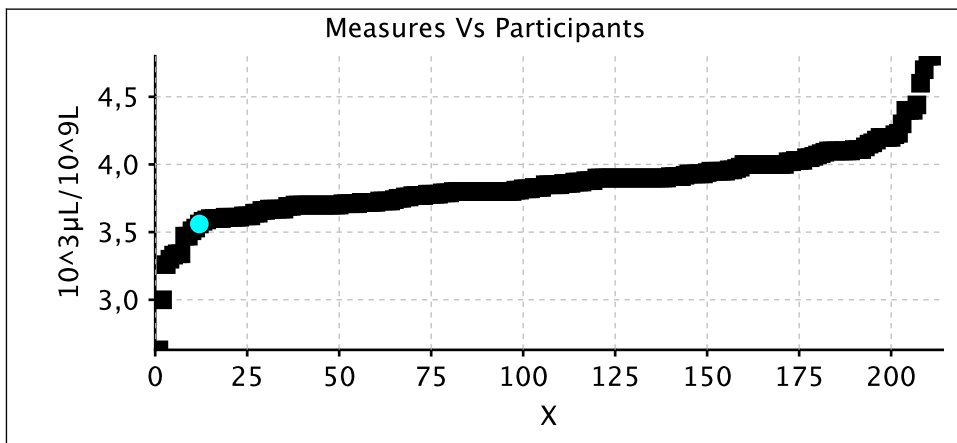
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **211**

| | |
|-----------------------------------|--------------|
| Measure | 3,56 |
| Z Score | -0,50 |
| Standard Deviation | 0,19 |
| Assigned Value (robustus mean) | 3,85 |
| Assigned DS | 0,58 |
| Standard Uncertainty | 0,02 |
| CV% | 5,00 |
| Difference | -0,29 |
| D% | -7,52 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **HGB**

Unit **g/dL**

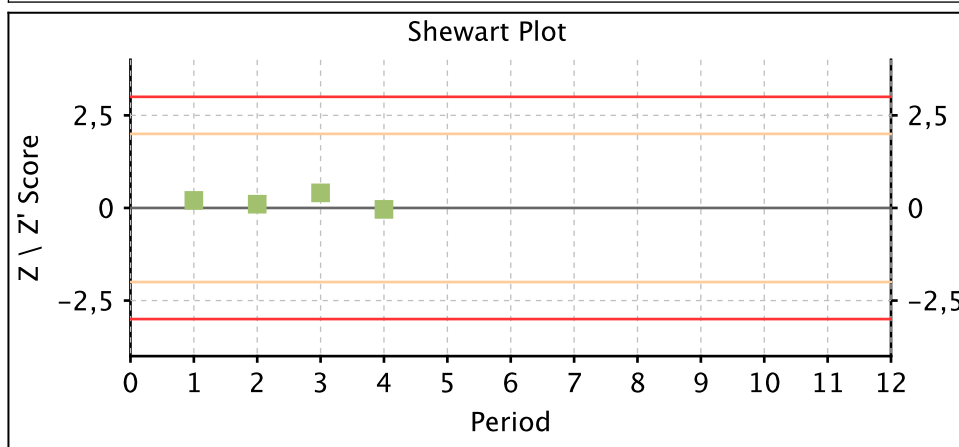
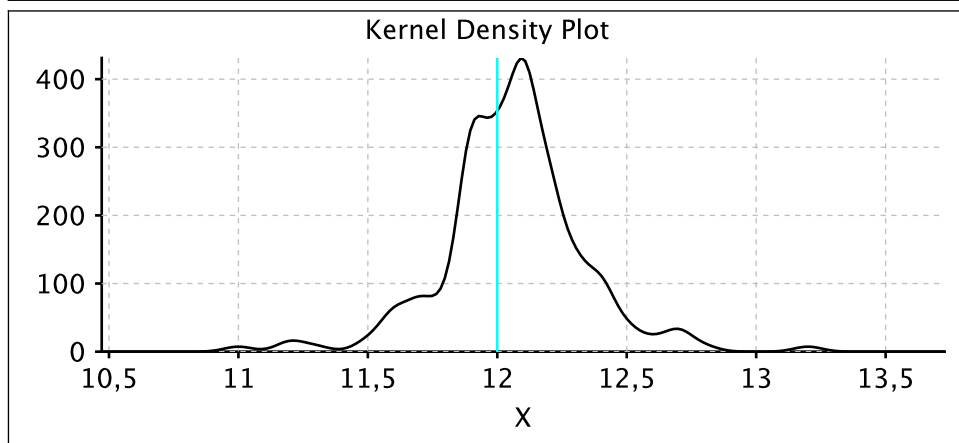
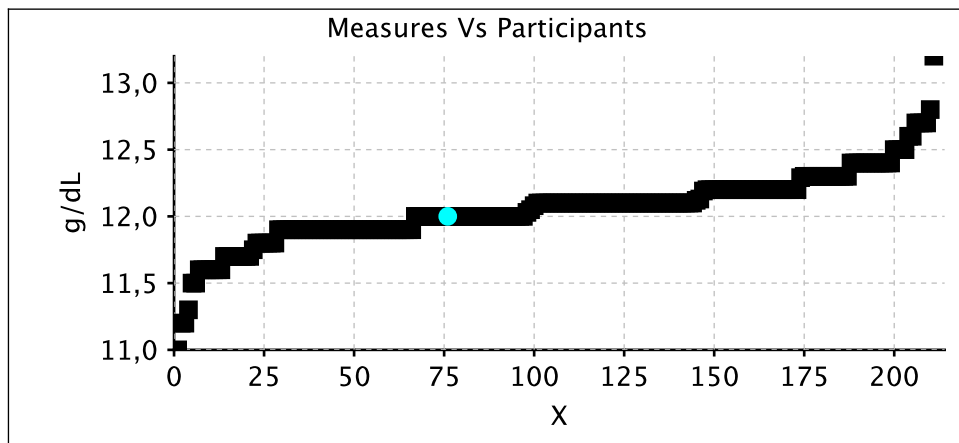
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **211**

| | |
|-----------------------------------|--------------|
| Measure | 12,00 |
| Z Score | -0,04 |
| Standard Deviation | 0,18 |
| Assigned Value (robustus mean) | 12,07 |
| Assigned DS | 1,81 |
| Standard Uncertainty | 0,02 |
| CV% | 1,46 |
| Difference | -0,07 |
| D% | -0,58 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **MCH/TCMH**

Unit **pg**

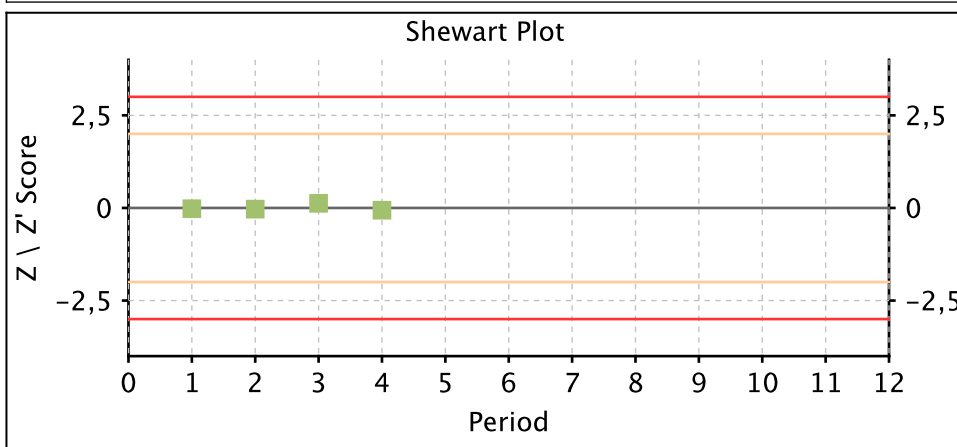
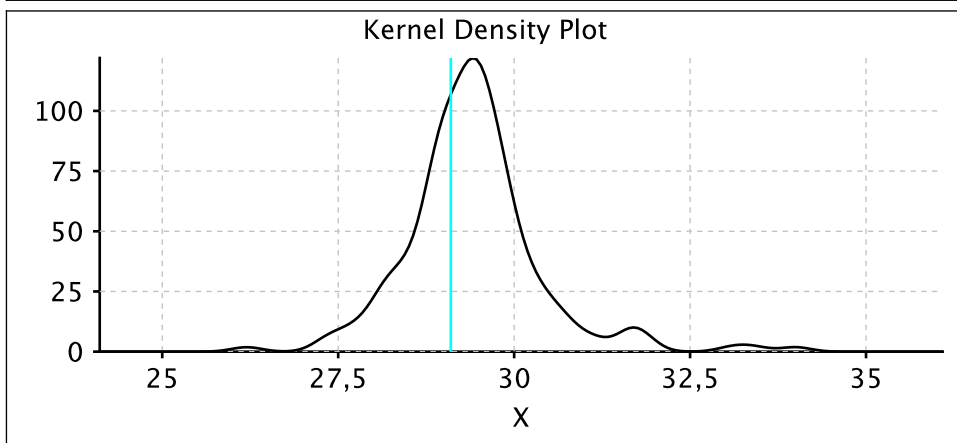
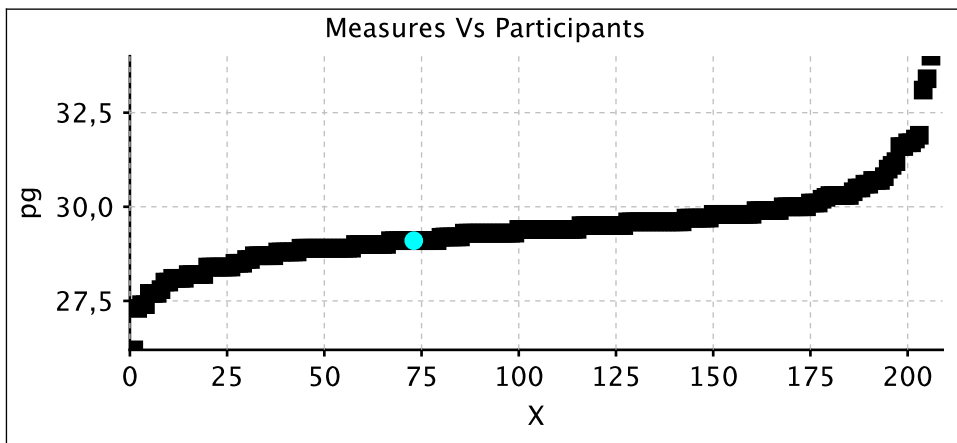
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **206**

| | |
|-----------------------------------|--------------|
| Measure | 29,10 |
| Z Score | -0,06 |
| Standard Deviation | 0,70 |
| Assigned Value (robustus mean) | 29,37 |
| Assigned DS | 4,41 |
| Standard Uncertainty | 0,06 |
| CV% | 2,37 |
| Difference | -0,27 |
| D% | -0,91 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **MCV/VMG**

Unit **fL**

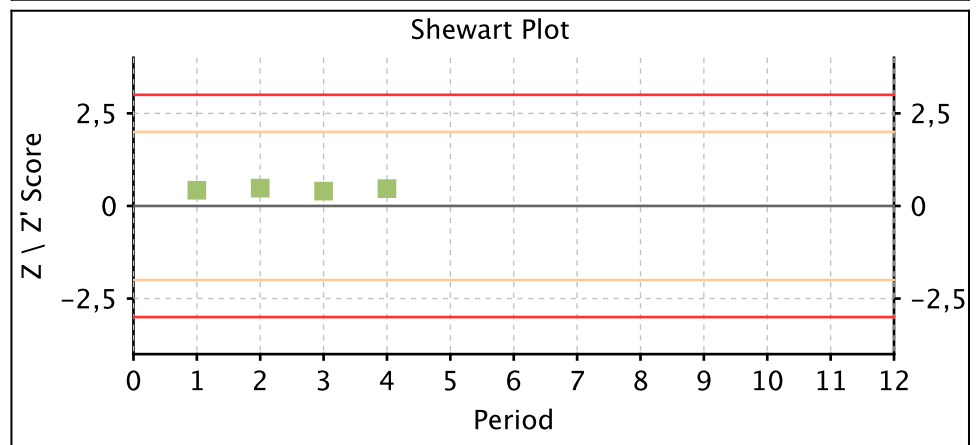
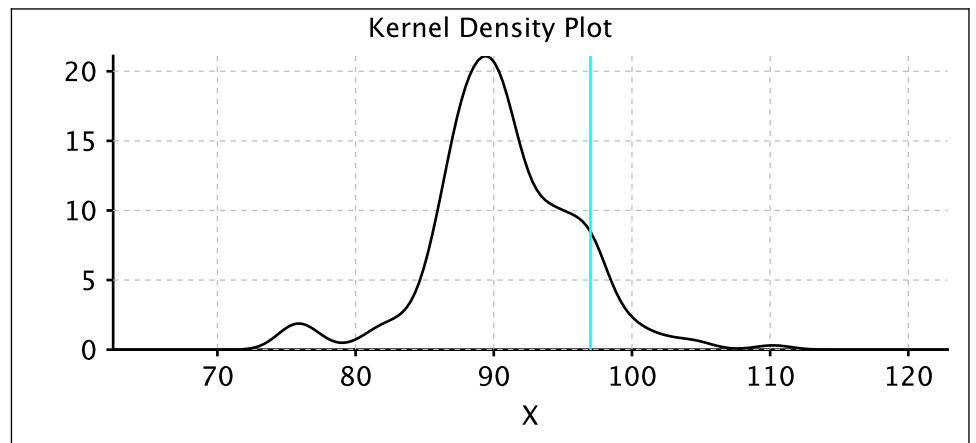
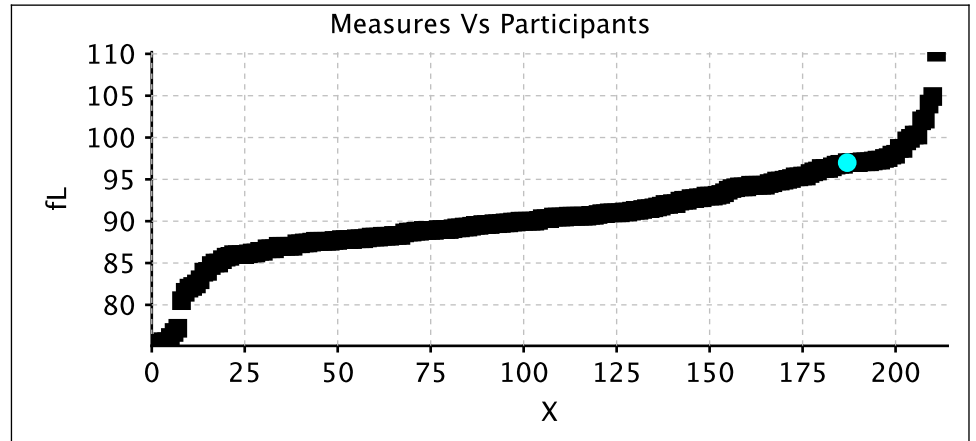
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **211**

| | |
|-----------------------------------|--------------|
| Measure | 97,00 |
| Z Score | 0,47 |
| Standard Deviation | 4,22 |
| Assigned Value (robustus mean) | 90,65 |
| Assigned DS | 13,60 |
| Standard Uncertainty | 0,36 |
| CV% | 4,65 |
| Difference | 6,35 |
| D% | 7,01 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **MCHC**

Unit **g/dL**

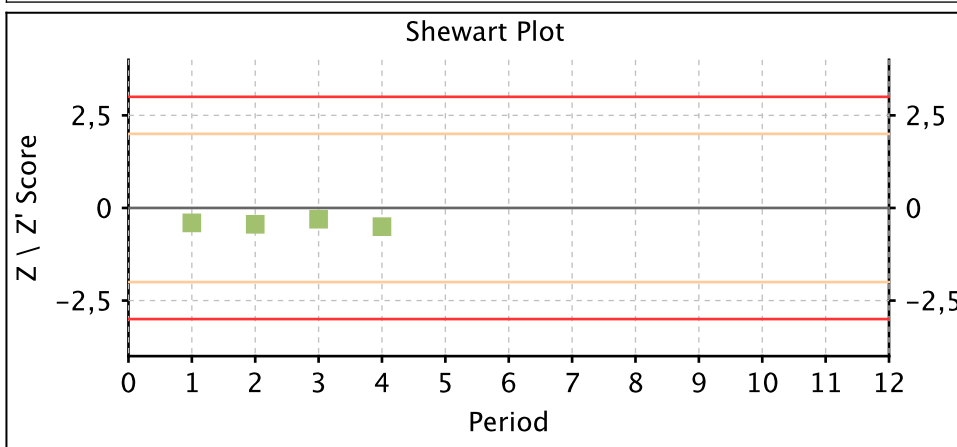
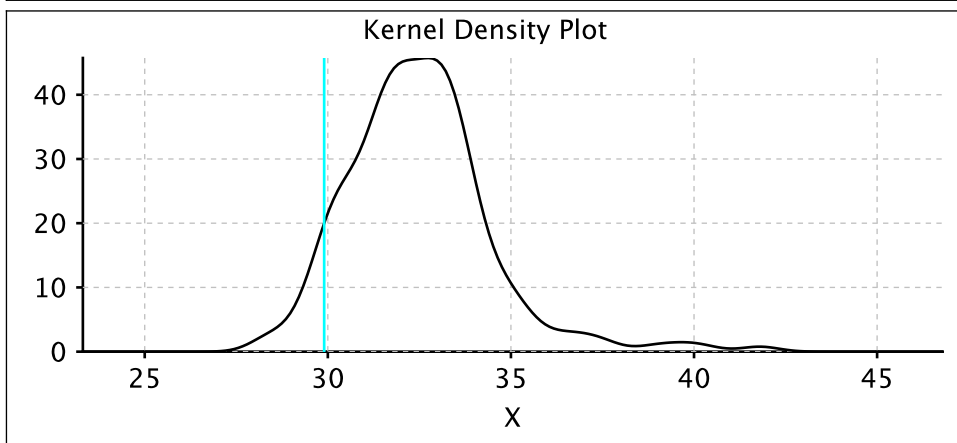
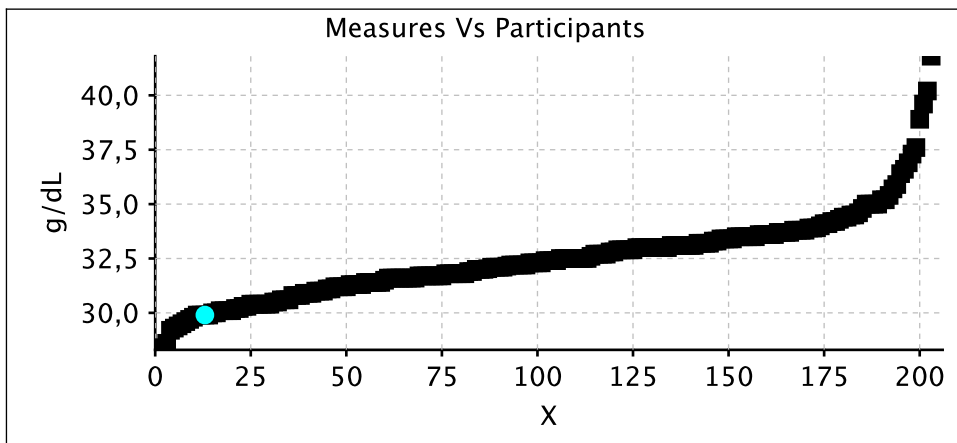
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **204**

| | |
|-----------------------------------|--------------|
| Measure | 29,90 |
| Z Score | -0,51 |
| Standard Deviation | 1,66 |
| Assigned Value (robustus mean) | 32,35 |
| Assigned DS | 4,85 |
| Standard Uncertainty | 0,15 |
| CV% | 5,14 |
| Difference | -2,45 |
| D% | -7,58 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **RDW/IDR**

Unit %

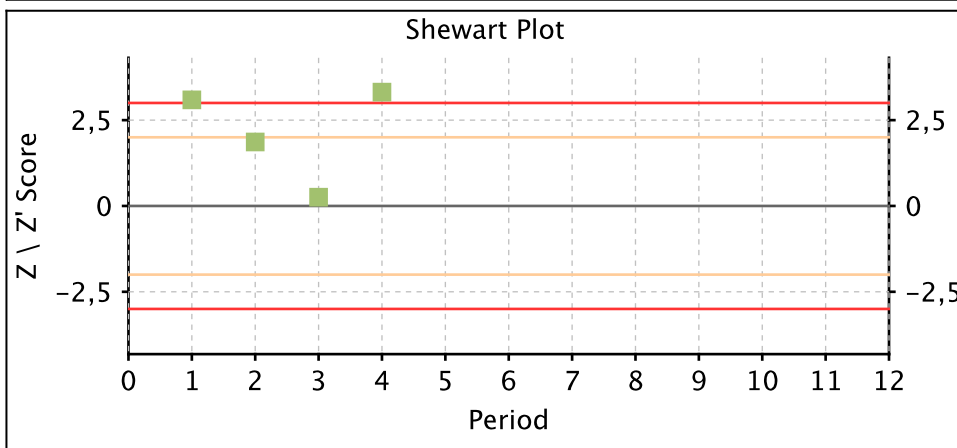
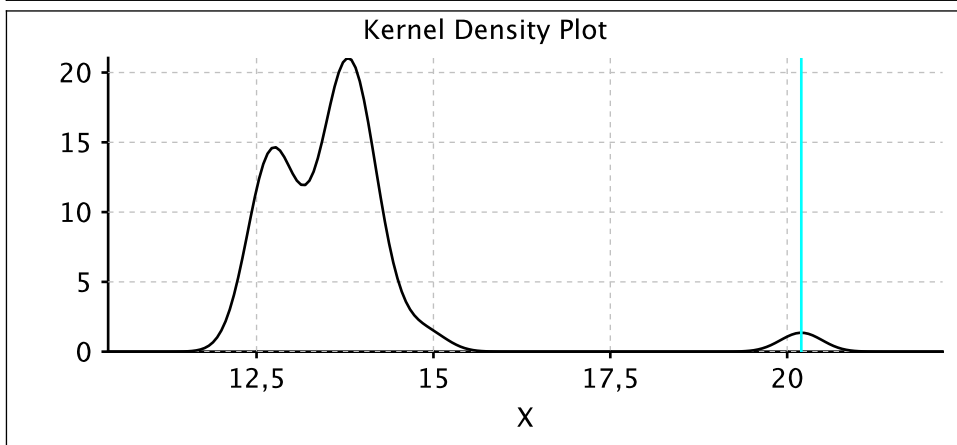
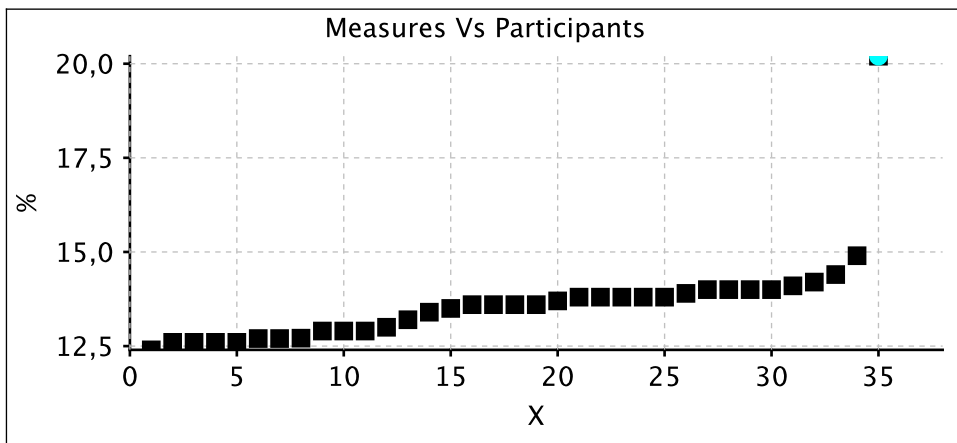
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **35**

| | |
|-----------------------------------|--------------|
| Measure | 20,20 |
| Z Score | 3,32 |
| Standard Deviation | 0,67 |
| Assigned Value (robustus mean) | 13,49 |
| Assigned DS | 2,02 |
| Standard Uncertainty | 0,14 |
| CV% | 4,94 |
| Difference | 6,71 |
| D% | 49,74 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **RBC/GR**

Unit **10⁶μL/10¹
2L**

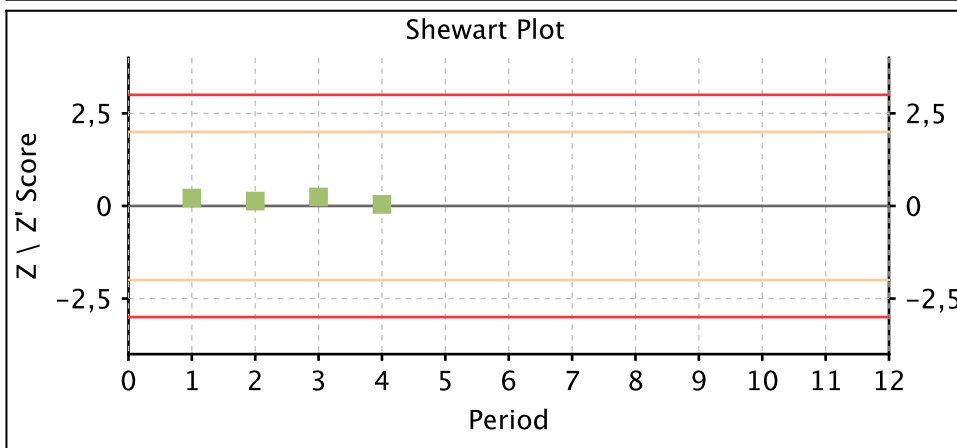
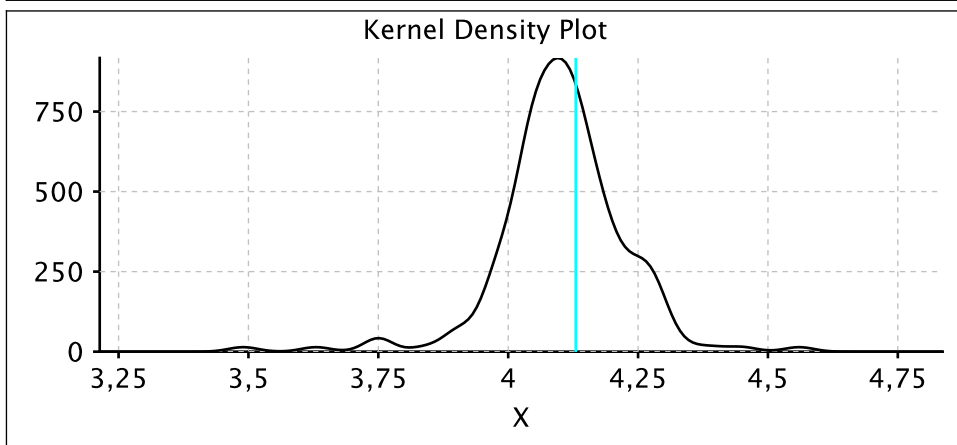
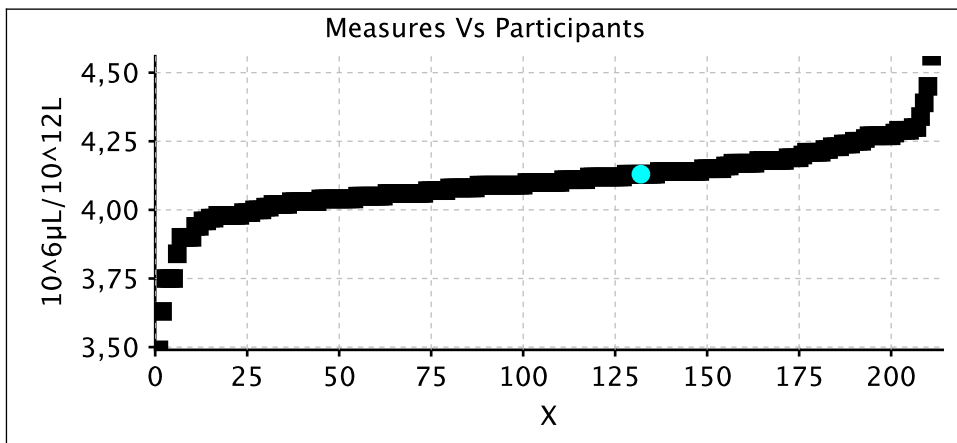
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **211**

| | |
|-----------------------------------|-------------|
| Measure | 4,13 |
| Z Score | 0,04 |
| Standard Deviation | 0,09 |
| Assigned Value (robustus mean) | 4,10 |
| Assigned DS | 0,62 |
| Standard Uncertainty | 0,01 |
| CV% | 2,24 |
| Difference | 0,03 |
| D% | 0,63 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **PLT/PLQ**

Unit **10³μL/10⁹**

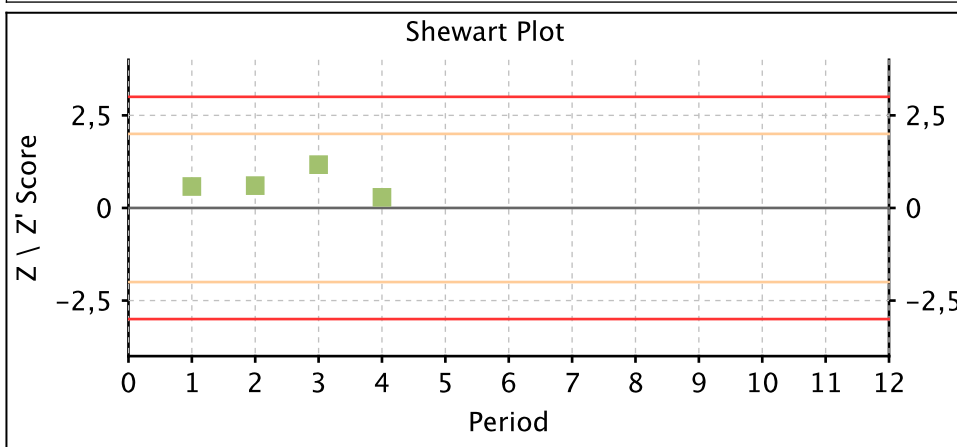
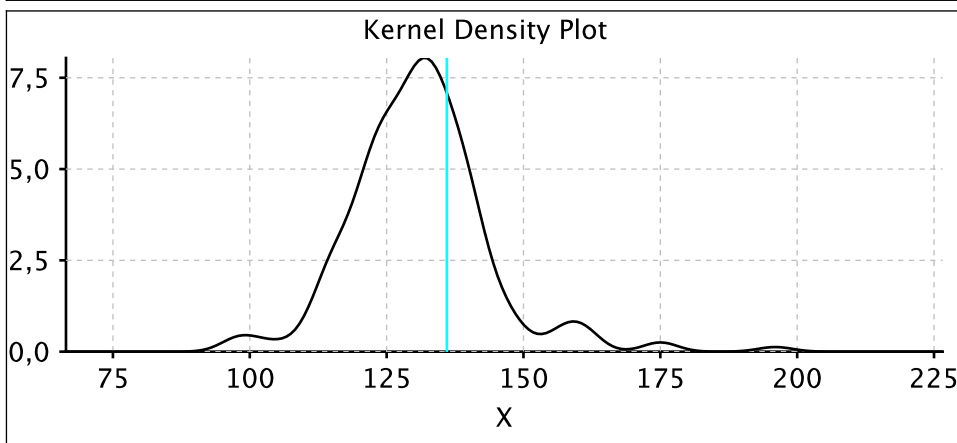
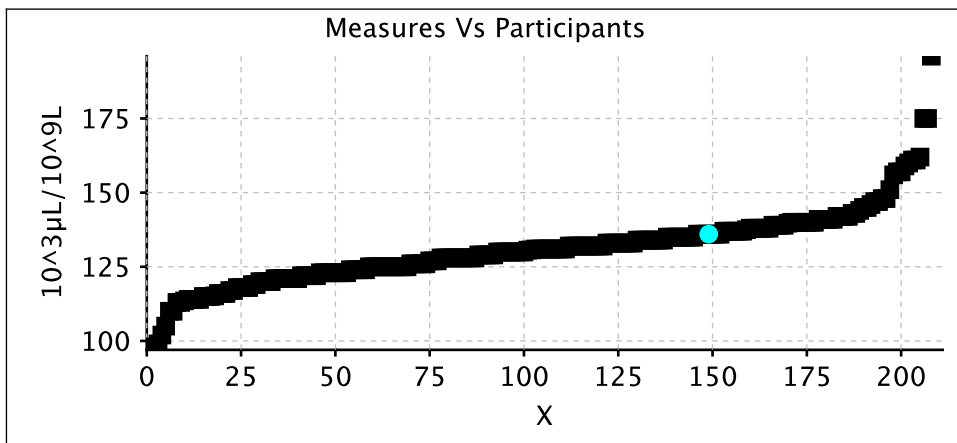
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **211**

| | |
|-----------------------------------|--------------|
| Measure | 136,0 |
| Z Score | 0,29 |
| Standard Deviation | 10,19 |
| Assigned Value (robustus mean) | 130,40 |
| Assigned DS | 19,56 |
| Standard Uncertainty | 0,88 |
| CV% | 7,82 |
| Difference | 5,60 |
| D% | 4,30 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **HCT**

Unit **%**

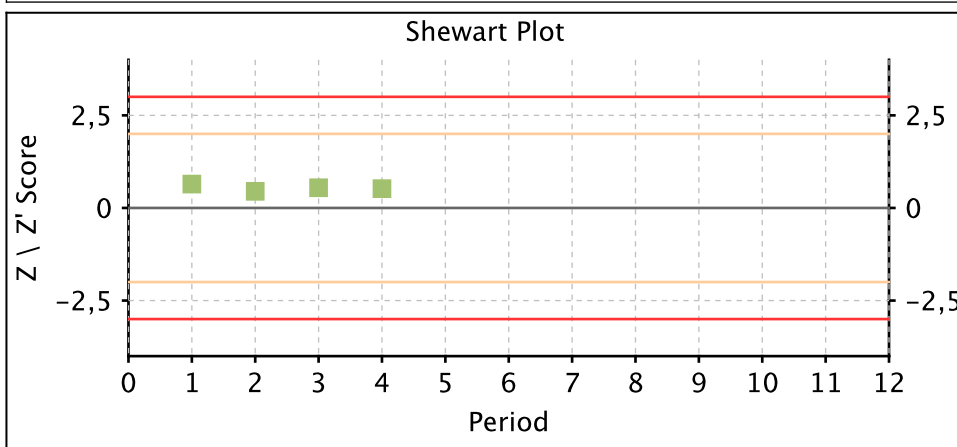
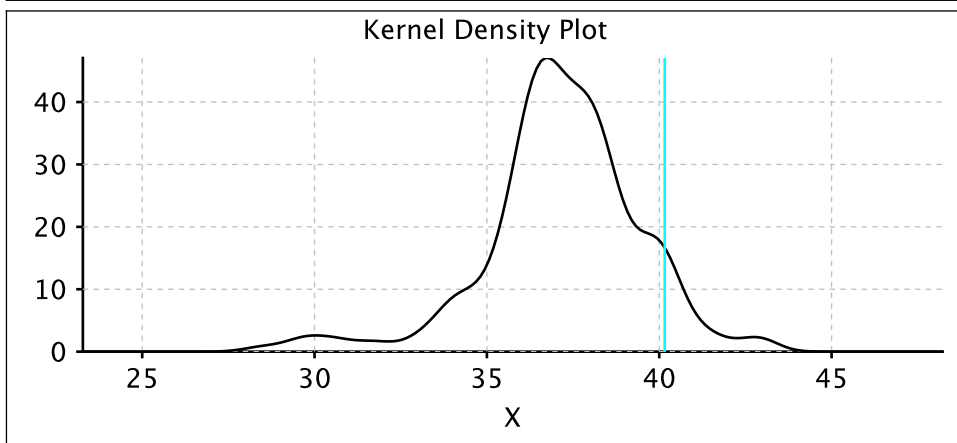
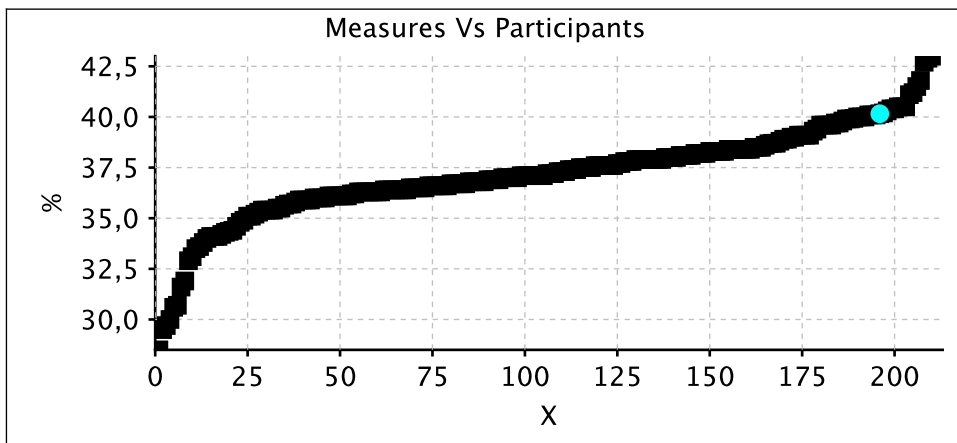
RDS **0,1500**

Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **211**

| | |
|-----------------------------------|--------------|
| Measure | 40,16 |
| Z Score | 0,52 |
| Standard Deviation | 1,74 |
| Assigned Value (robustus mean) | 37,25 |
| Assigned DS | 5,59 |
| Standard Uncertainty | 0,15 |
| CV% | 4,67 |
| Difference | 2,91 |
| D% | 7,82 |





**HEMATOLOGY 8 PARAMETERS
APRIL 2019**

RdP: Re issued
**ZKN247_18_2019_4.p
df**

**Participant : ZKN247
Sample Lot : HE-19040**

Issued on 14/05/2019
Authorized by RQS
Paolo Cocci

Analyte **MPV**

Unit **fl**

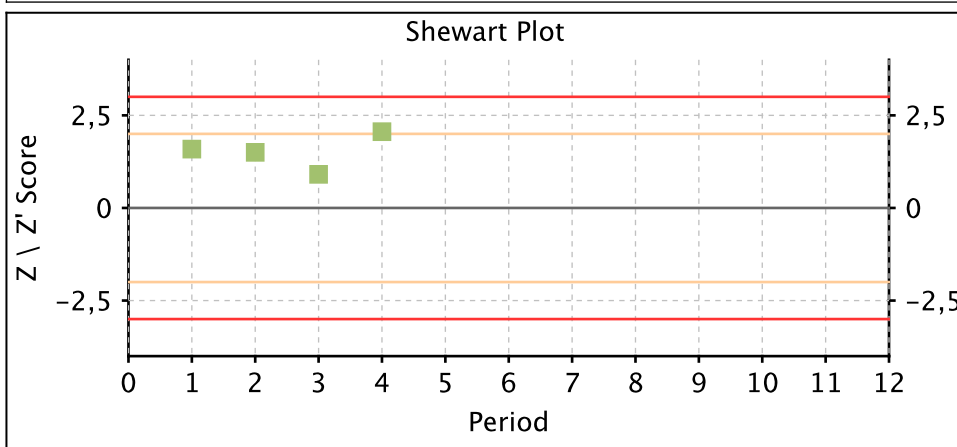
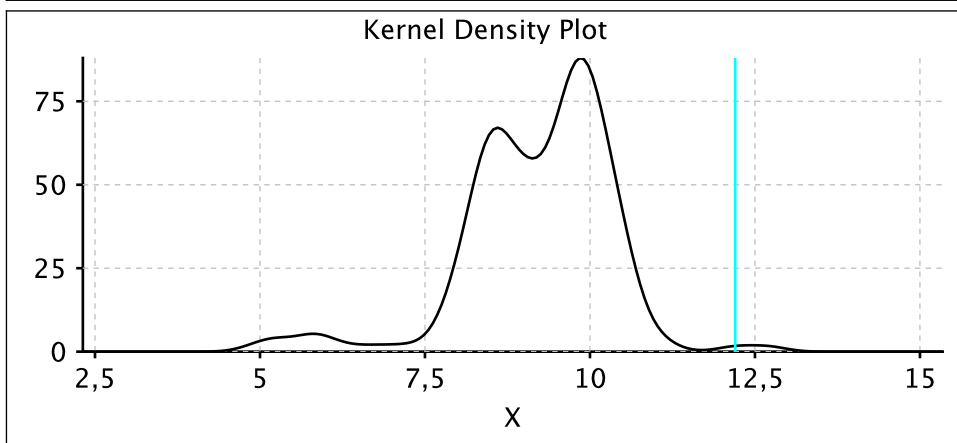
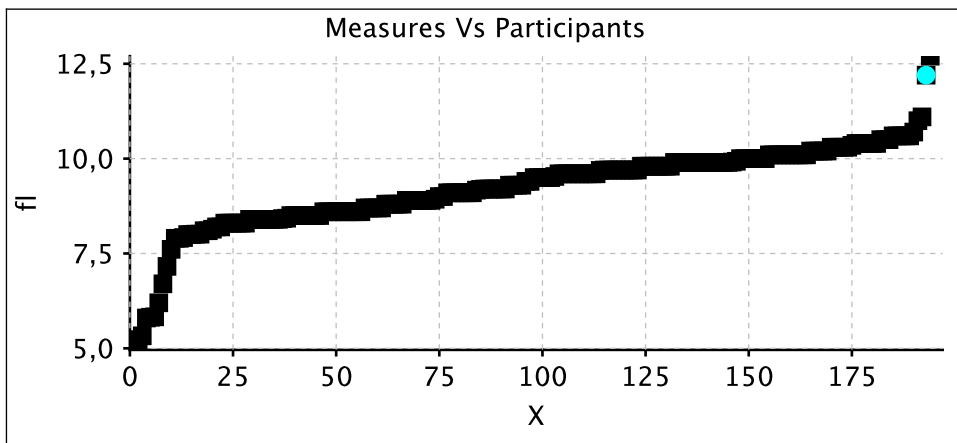
RDS **0,1500**


Analyzer **Erba Lachema**

Method **AUTOMATIC
COUNT**

Participants
number **195**

| | |
|-----------------------------------|--------------|
| Measure | 12,20 |
| Z Score | 2,06 |
| Standard Deviation | 0,88 |
| Assigned Value (robustus mean) | 9,32 |
| Assigned DS | 1,40 |
| Standard Uncertainty | 0,08 |
| CV% | 9,45 |
| Difference | 2,88 |
| D% | 30,88 |



| | | |
|--|---|--|
|  | HEMATOLOGY 8 PARAMETERS APRIL 2019 | RdP: Re issued ZKN247_18_2019_4.p df |
| | Participant : ZKN247 Sample Lot : HE-19040 | Issued on 14/05/2019 Authorized by RQS Paolo Cocci |

| Analyte | Assigned Value (robustus mean) | Measure | Standard Deviation | CV% | Z \ Z' | Z Score | D% | REMARK |
|----------|-----------------------------------|---------|-----------------------|------|--------|---------|-------|---------|
| WBC/GB | 3,85 | 3,56 | 0,19 | 5,00 | Z | -0,50 | -7,52 | OK |
| HGB | 12,07 | 12,00 | 0,18 | 1,46 | Z | -0,04 | -0,58 | OK |
| MCH/TCMH | 29,37 | 29,10 | 0,70 | 2,37 | Z | -0,06 | -0,91 | OK |
| MCV/VMG | 90,65 | 97,00 | 4,22 | 4,65 | Z | 0,47 | 7,01 | OK |
| MCHC | 32,35 | 29,90 | 1,66 | 5,14 | Z | -0,51 | -7,58 | OK |
| RDW/IDR | 13,49 | 20,20 | 0,67 | 4,94 | Z | 3,32 | 49,74 | ACTION |
| RBC/GR | 4,10 | 4,13 | 0,09 | 2,24 | Z | 0,04 | 0,63 | OK |
| PLT/PLQ | 130,40 | 136,00 | 10,19 | 7,82 | Z | 0,29 | 4,30 | OK |
| HCT | 37,25 | 40,16 | 1,74 | 4,67 | Z | 0,52 | 7,82 | OK |
| MPV | 9,32 | 12,20 | 0,88 | 9,45 | Z | 2,06 | 30,88 | WARNING |

Z indicates participant's performance score. Typically, the absolute value of Z obtained by the participant gives indications summarized in the following scheme:

- "indicates ""satisfactory"" performance and does not generate any signal"
- "indicates ""questionable"" performances and generates a warning signal"
- "indicates ""unsatisfactory"" performance and generates an Action signal"

For each parameter, the graphic representation of Shewart is also provided, which allows the evaluation of performance over time in accordance with point B4.2 ISO 17043: 2010 for the purposes of self-improvement.

This test report consists of N ° 14 pages



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**

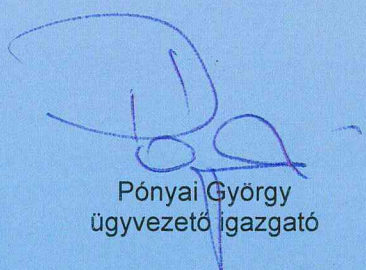
MSZ EN ISO 9001:2015 (ISO 9001:2015)

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.

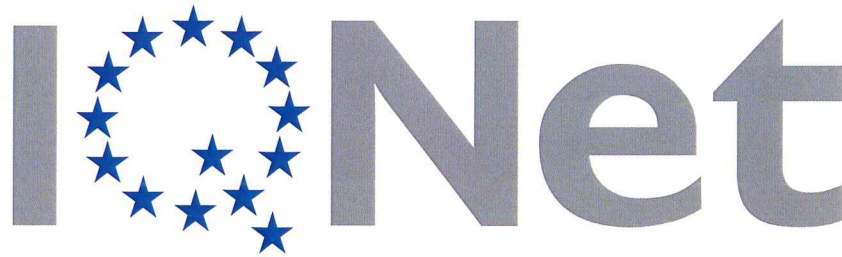
A tanúsítási okirat száma / Reg. number: **503/1341(2)**

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

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

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

页 1 / 1

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 |

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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



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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

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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.



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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, 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 |
|----------------|---|--------------|
| 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 steps 11 steps rinsing system
- ◎ LIS interface, supporting remote maintenance
- ◎ Wavelength: 340nm, 380nm, 405nm, 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, 405nm, 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 | R2: 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

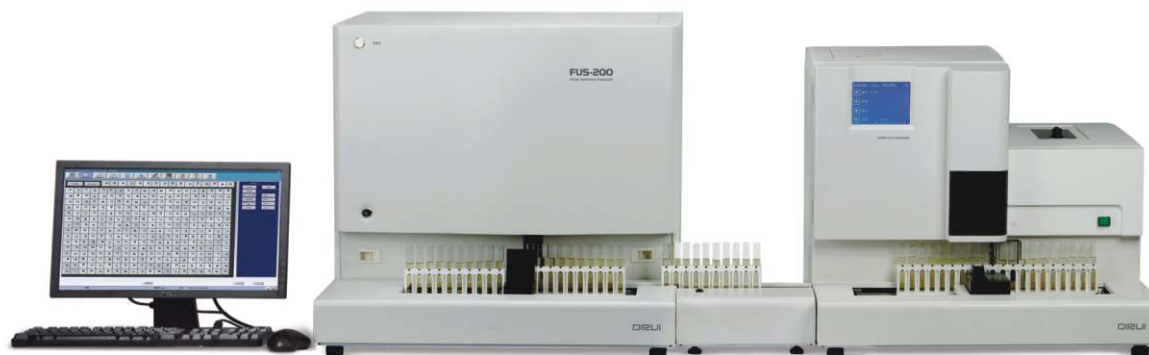
Order Information:

| 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

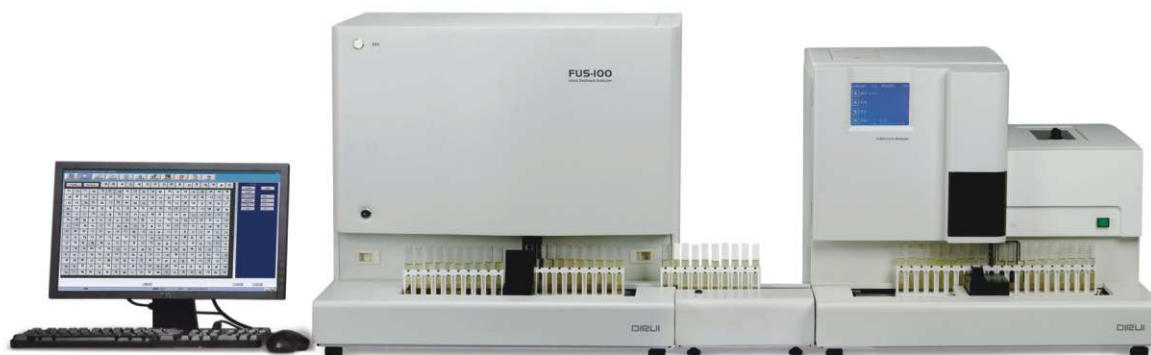
Order Information:

| 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 | Volume | Pack Size |
|----------------|--|---|--------------|
| 1520401007 | DIRUI FB-100 Fecal Occult Blood Analyzer | | 1 instrument |
| 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 H11 | DIRUI H11-MA | DIRUI M10 |
| DIRUI H11-800MA | | DIRUI H10-800 |
| DIRUI H13-Cr | | DIRUI H11-800 |
| DIRUI H13-Cr (H-800) | | DIRUI H12-800MA |
| | | DIRUI H14-Ca |
| | | 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. 睿睿达瑞医疗科技

于歌 股份有限公司



(place and date of issue)

(name and signature or equivalent marking of authorized person)



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)

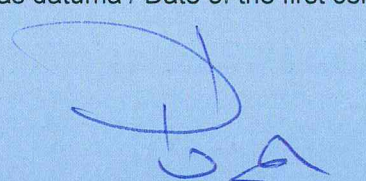


A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.
This certificate is valid together with the maintenance decision annually issued by MSZT.

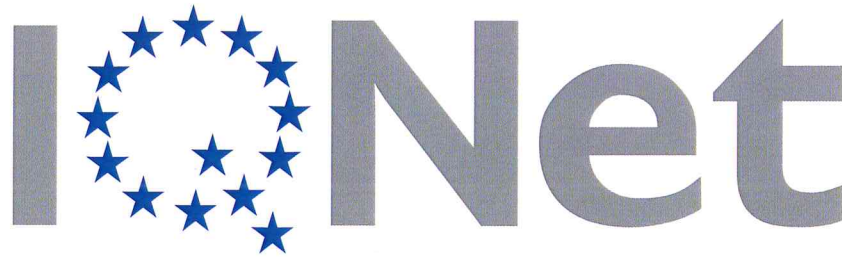
A tanúsítási okirat száma / Reg. number: **503/1342(2)**

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