Certificate CN19/42081

The management system of

CLINDIAG SYSTEMS CO., LTD.

29, Zhiyuan Road, Jurong Economic Development Zone,
Zhenjiang City, Jiangsu Province, 212400, P.R. China.

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, Development, Production, Marketing and Service of Fully Automatic Biochemistry Analyzer, Semi-Automatic Biochemistry Analyzer, Haematology Analyzer, Microplate Reader, Coagulometer, Microplate Washer, Platelet Function Analyzer, Electrolyte Analyzer, Auto POCT Chemistry Analyzer

This certificate is valid from 4 June 2019 until 3 June 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 29 March 2022
Issue 1. Certified since 4 June 2019

Multiple certificates have been issued for this scope
The main certificate is numbered CN19/42078.00

Digitally signed by Poiata Vitalie
Date: 2021.07.08 11:09:24 EEST
Reason: MoldSign Signature
Location: Moldova

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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REGISTRATION NO. 04719Q10805R0S

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Clindiag Systems Co., Ltd.

Registered Address: No.29 Zhiyuan Road, Jurong Economic Development Zone, Jiangsu Province, P.R.China Postcode: 212400
Manufacturing Address: No.29 Zhiyuan Road, Jurong Economic Development Zone, Jiangsu Province, P.R.China

Has been assessed and conformed to the following standard(s)
GB/T19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

The Design, Development, Production and Service of Semi-Automatic Biochemistry Analyzer, Coagulometer Analyzer, Semi-Automatic Electrolyte Analyzer, Semi-Automatic Microplate Reader, Microplate Washer, Automatic Urine Analyzer And Urine Test Strips, Fully Automatic Biochemistry Analyzer, Fully Automatic Hematology Analyzer,

Date of issue: July 16, 2019
Date of expiry: July 15, 2024

Director: Zhuangchen

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

MANAGEMENT SYSTEM
CNAS C047 - Q

Note:The Certificate Information are available on the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn) or the Website of CMD (www.cmdc.com.cn).

SGS

Statement of Compliance

This is to state that Technical Documentation (BS001, Rev 1.0) for Product(s)

Semi-Automatic Biochemistry Analyzer
(Model: SA-30A,SA-30B,SA-30C,SA-20,SA-10)

(IVD products other than those covered by Annex II, IVD for self-testing and devices for Performance evaluation according to manufacturer's declaration)

Manufactured by

CLINDIAG SYSTEMS CO., LTD.

29 Zhiyuan Road, Jurong Economic Development Zone, Zhenjiang, Jiangsu Province, P.R.China

Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 98/79/EEC for in Vitro Diagnostic Medical Device

For SGS-CSTC Standards Technical Services Co., Ltd.
System & Services Certification Division

Reference No: CN/SZH8791-1
Valid from Jan.2018 to Jan.2023
Issuel.Certificate since Jan.2018

CE

SGS-CSTC Standards Technical Services Co., Ltd. Shanghai Branch

SGS Bldg, 11/F, Building B, No. 900, Yishan Road, Xuhui District, Shanghai, China

While all due care and skill was exercised in carrying out this assessment, SGS-CSTC accepts responsibility only for proven gross negligence. This certificate relates only to the medical device as described in the technical file reviewed on the date shown. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products. This is not a legal document and cannot be used as such. This certificate remains the property of SGS-CSTC Standards Technical Services Co., Ltd. to whom it must be returned on request.

CLINDIAG

CLINDIAG SYSTEMS B.V.B.A.

SA-10/20

Chemistry Analyzer

ISO9001:2008 & ISO13485:2003

CE

Headquarters
Add: Steenberg 66, Pollare/Ninove(9401), Belgium
Tel: 0032 54 250 936
Fax: 0062 54 243 058
Website: http://www.clindiag.be
E-mail: marketing@clindiag.be

U.S. Office
Add: 1351 S. Leavitt Ave, Suite 104 Orange City, Florida 32763 USA
Tel: 001 386 456 1235
Fax: 001 407 358 5024
E-mail: info@clindiagusa.com

India Office
Add: B-1177-78, G.D. Colony Mayur Vihar Phase-III, Delhi-110096
Ph: 0091 11 22618779
Fax: 0091 11 22618780
E-mail: contact@clindiagindia.com

Features

- Easy operation by one button.
- End point, kinetic, fixed time, multistandard, bichromatic, etc.
- Filter wavelengths: 340/405/492/510/546/578/620nm, 2 more open filter positions, others on request.
- With 20 incubating positions.
- Large memory to store 200 test programs and 1000 testing results.
- Excellent Q.C function, Q.C chart can be stored, displayed and printed.
- 3 levels temperature: 25℃, 30℃, 37℃ can be selected in flow cell and incubating.
- Real time graph can be displayed and printed.

Technical Specifications

Model	SA-10	SA-20
Reading cuvette	Direct reading cuvette	Both through cell and direct reading cuvette
Incubating Positions	20 incubating positions	
Photometric System	Light source: 6V, 10 W longlife halogen lamp	
	Filters: 340/405/492/510/546/578/620nm, 2 more open filter positions, ±2nm pass-hand	
	Wavelength accuracy: ±2nm	
Measuring System	Measuring range: 0-2.500 O.D.	
	Photometric linearity: ±2% from 0 to 2.000 O.D.	
	Photometric accuracy: ±2% from 0 to 2.000 O.D.	
	Drift<0.005 O.D.	
	Carry over≤1%	
Incubator Temperature Control	25℃, 30℃, 37℃ RT	
	Precision: ±0.1℃	
Display	Back-illuminated LCD	
Printer	Built-in thermal printer	
Interface	RS-232	
Power Supply	AC 110V 60Hz / 220V 50Hz	
Dimensions	34cmX38cmX18cm	
Weigh	8.5kg	

CLINDIAG...

The Reference for Quality and Service

Certificate

Standard **ISO 9001:2015**

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

Certificate Holder:

BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

Scope:

Design, development, manufacture, distribution, servicing of:
-Instruments and reagents for clinical diagnostic.
-Instruments and reagents for agro-alimentary analysis.
Distribution and service of reagents and instruments for veterinary diagnosis.

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

Validity:

The certificate is valid from 2019-12-19 until 2022-12-18.
First certification 1996

2019-12-20

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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Annex to certificate

Standard **ISO 9001:2015**

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

No.	Location	Scope
/02	BIOSYSTEMS S.A. Pol. Ind. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labeling and assembly of reagent. Storage, and shipping of: - Instruments and reagents for diagnosis and reagents for clinical diagnosis.- Instruments and reagents for agri-food analysis.- Instruments and reagents for veterinary diagnosis.

2019-12-20

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Am Grauen Stein · 51105 Köln

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TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacture, distribution and servicing of instruments and reagents for clinical diagnostic
(see attachment for sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-01-08
Certificate Registration No.:	SX 60145545 0001
An audit was performed. Report No.:	28300434 004
This Certificate is valid until:	2022-12-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2020-01-08

D. Swiatko

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60145545 0001
Report No.: 28300434 004

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

Scope:

Site included:

Polígono Industrial Can Tapioles
Naves 7, 12 y 13
08110 Montcada i Reixac
Spain

Activity: Labelling and assembling of reagents, warehousing and shipment of instruments and reagents for clinical diagnostic

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-01-08

D. Swiatko

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CE

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#042/05-2014

Wir / *We*

TECO Medical Instruments Production and Trading GmbH
Name des Herstellers / Manufacturer's *name*
Dieselstrasse 1, 84088 Neufahrn, Germany
Anschrift / *Address*

erklären in alleiniger Verantwortung, dass das Produkt – IVD-Blutgerinnungsmessgerät,
declare under our own responsibility, that the product – IVD Coagulation analyzer

COAX 1 channel, ref. 85001
COAX 2 channels, ref. 85002
COAX 4 channels, ref. 85004
Bezeichnung, Typ oder Modellname / *name, type or model*

allen anwendbaren Anforderungen der folgenden Richtlinien entspricht:	*meets all applicable requirements of:*
1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"	*1. Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products"*
2. Richtlinie 2014/30/EU über Elektromagnetische Verträglichkeit	*2. Directive 2014/30/EU on electromagnetic Compatibility*
3. Richtlinie 2011/65/EU RoHS II	*3. Directive 2011/65/EU RoHS II*
4. Richtlinie 2014/35/EU Niederspannungsrichtlinie	*4. Directive 2014/35/EU Low Voltage*
Das QM-System des Herstellers ist zertifiziert nach:	*The QM-system of the manufacturer is certified for:*
EN ISO 13485:2016	***EN ISO 13485:2016***

Diese Erklärung bescheinigt die Übereinstimmung mit den genannten Harmonisierungsrechtsvorschriften, beinhaltet jedoch keine Zusicherung von Eigenschaften.

This declaration attests the accordance with the mentioned harmonization rule but does not include a warranty of properties.

Konformitätsbewertungsverfahren:

Conformity assessment procedure:

Gemäß Anhang III der Richtlinie 98/79/EG

According to Annex III of Directive 98/79/EC

Ort und Datum der Unterzeichnung:
Place and date of issue:

Neufahrn, 25.03.2019
Neufahrn, March 25, 2019

Christian Hötzl
General Manager

Medical Instruments
TECO
Production+Trading GmbH

COAX

Semi-automated coagulometers

With 1, 2 or 4 optical channel.

- **Prepared for the daily routine and the upcoming requirements.**
- **High quality in the results.**
- **Nearly maintenance free.**

Specifications

Code	85001	85002	85004
Optical channels	1	2	4
Wavelenght (µm)	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	
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	Code
1 pack 500 cuvettes	85020

99820
BTS/11-17

Ginper Group

BioSystems

BioSystems S.A.
Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 08 11
biosystems@biosystems.es www.biosystems.es

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

BioSystems
REAGENTS & INSTRUMENTS

COAGULATION LINE

BioSystems

Coagulation *is a change of physical state of the blood due to the conversion of a soluble plasma protein, fibrinogen, into a solid gel, fibrin.*

The management and control of anticoagulant therapy and the assessment of pre and post surgical states, among others requires a proper evaluation of the coagulation cascade. Several tests help the physician in the diagnosis of alterate coagulation states and management of coagulopathy.

The coagulation reagents have been specifically validated to Biosystems coagulometers.

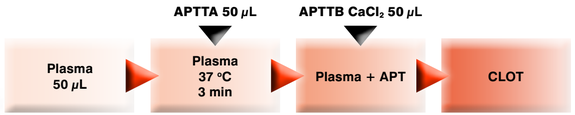
	Presentation	Code
APTT	4x4 mL	61004
APTT B ($CaCl_2$)	4x16 mL	61005
APTT	(4x4 mL+1x16 mL)	61009

Activated Partial Thromboplastin Time (APTT)

▸ **Principle of the method:**
The addition of the phospholipid cephalin to plasma samples in the presence of calcium and an activator induces the formation of the fibrin clot.
The method measures the clot formation time.

▸ **Intended use:**
- Screening assay used in the monitoring of heparin therapy
- As part of investigation of a possible bleeding disorder

PROCEDURE



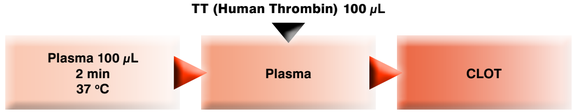
	Presentation	Code
TT	4x3 mL	61000

Thrombin Time (TT)

▸ **Principle of the method:**
Additon of human thrombin to plasma samples induces de formation of fibrin clot. The method measures the clot formation time.

▸ **Intended use:**
- To evaluate the level and function of fibrinogen
- To detect heparin contamination
- As part of investigation of a bleeding or thrombotic episode

PROCEDURE



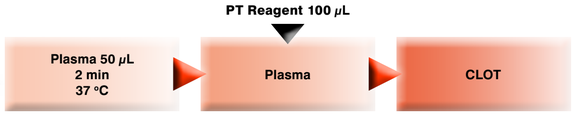
	Presentation	Code
PT	4x5 mL	61001

Prothrombin Time (PT)

▸ **Principle of the method:**
The addition of calcium thromboplastin to plasma induces the formation of the fibrin clot.
The method measures the clot formation time.

▸ **Intended use:**
- Screening assay used to monitor oral anticoagulant therapy
- It helps detect and diagnose a bleeding disorder

PROCEDURE



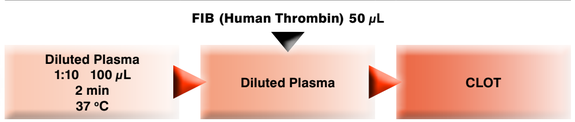
	Presentation	Code
Fib	4x2 mL	61002
Fib B (Imidazol)	4x15 mL	61003

Fibrinogen Clauss

▸ **Principle of the method:**
The Clauss method measures the rate of conversion of fibrinogen into fibrin in a diluted plasma in the presence of excess of thrombin. The measured clotting time is inversely proportional to fibrinogen concentration.

▸ **Intended use:**
- As part of an investigation of a possible bleeding disorder or thrombotic episode
- To help evaluate the risk of developing cardiovascular disease

PROCEDURE



	Presentation	Code
Calibrator	4x1 mL	61006
Control I	4x1 mL	61007
Control II	4x1 mL	61008

Calibrator and Controls

The Coagulation Calibrator is a lyophilized pooled human plasma containing component concentrations suitable for the calibration of measurement procedures.

The Coagulation Control is a lyophilized human plasma with stabilizer suitable for the quality control of the clinical laboratories. The product is intended for intralaboratory quality control purposes only and is supplied with intervals of suggested acceptable values.

CE Declaration of Conformity CE

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

Manufacturer:	Dirui Industrial Co., Ltd.
	95 Yunhe Street New& High Tech. Development Zone
	Changchun Jilin 130012 P.R. China
Authorized Representative :	Emergo Europe
	Molenstraat 15 2513 BH The Hague
	The Netherlands
Medical Device :	Product Name: Reagent strips for Urinalysis
	IVDD-Classification: Professional use

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

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

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

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive98/79/EC, Annex III.

Valid Since

May 9th, 2012

Changchun, China

Representative:

Yu Ge

Dirui Industrial Co., Ltd.

于歌

(place and date of issue)

(name and signature or equivalent marking of authorized person)

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

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 2018-05-03 至 2021-05-02。
此证书须经过符合要求的监督审核保持有效。

2018-05-03

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

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 City, Jilin Province 130012, P. R. China
Operation Address: same as above

Scope: Design and Development, Manufacture and Distribution 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 2018-05-03 until 2021-05-02.
It remains valid subject to satisfactory surveillance audits.

2018-05-03

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Dirui Industrial Co., Ltd.
95 Yunhe Street
New & High Tech.
Development Zone
Changchun
Jilin Province 130012
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of In vitro Diagnostic Medical Test Systems (see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-06-26
Certificate Registration No.:	SX 60127937 0001
An audit was performed. Report No.:	15047317 007
This Certificate is valid until:	2020-03-01

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-06-26

X. Ren

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax. +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60127937 0001
Report No.: 15047317 007

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

Scope:

Products:

- Urine Test Systems (Reagents, Analyzers, Controls)
- Hematology Test Systems (Reagents, Analyzers, Controls)
- Clinical Chemistry Test Systems (Reagents, Analyzers, Controls)
- Immunochemistry Test Systems (Reagents, Analyzers, Controls)
- Vaginal Infections Test Systems (Reagents, Analyzers, Controls)

Site included:

3333 Yiju Street, New & High Tech. Development Zone, Changchun, 130103 Jilin, China

Design and Development, Manufacture and Distribution of Urine Test Analyzers, Hematology Test Analyzers, Clinical Chemistry Test Analyzers, Immunochemistry Test Analyzers, Vaginal Infections Test Analyzers

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-06-26

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

X. Ren

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C E R T I F I C A T E
of Conformity

TÜVRheinland®

Registration No.: AK 50205311 0001

Report No.: 16800459 001

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

Product:
Analysis Equipment
(Urine Analyzer)

Identification:
Type Designation: H-50 H-100 H-300 H-500

Serial No.: Engineering Sample

Remark: Refer to test report 16800459 001 for details.

Tested acc. to:
EN 61326-1:2006
EN 61326-2-6:2006

The certificate of conformity refers to the above mentioned product. This is to certify that the specimen is in conformity with the assessment requirement mentioned above. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity.

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Certification Body

Sun Lixun

Date 24.06.2011

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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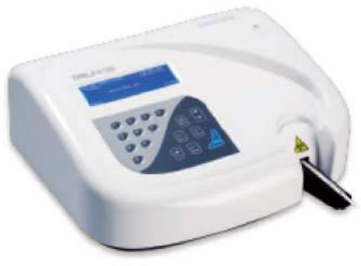
H-100

Urine Analyzer



DIRUI

H-100

Urine Analyzer

Product Characteristics:

- Adopting the advanced high luminosity cold light source with 4 -wavelength, which improves the sensitivity, accuracy, specificity, and reduces the interference from ambient light
- Adopting automatic waste handling system, which avoids cross-contamination between samples
- Built-in thermal printer with high speed and low noise; External stylus printer
- Connectable with DIRUI urine sediment analyzer
- Users can set an abnormal value flag by themselves
- International, regular and symbol system units display for option

Technical Specification:

- Test items: urobilinogen, bilirubin, ketone, Creatinine,Micro-albumin,blood, protein, nitrite,leukocytes, glucose, specific gravity, pH and VC, Ca.
- Test wavelength: 525nm, 572nm, 610nm, 660nm
- Test principle: Photoelectric colorimetry
- Suitable strips: DIRUI H8, H10, H11, H11-MA, Urinalysis strips
- Test throughput:120 strips/h or 60 strips/h optional
- Data storage: 5000 patient results
- Computer interface: RS-232 port; parallel printer interface
- Display: 240×64 dot-matrix LCD
- Language: Chinese, English, Russian, Polish, Italian, Spanish, Portuguese, Turkish, German, French
- Power supply: ~100-240V, 50Hz/60Hz
- Power: 40VA
- Dimensions: 385mm×337mm×166mm(L×W×H)
- Weight: 3.9kg
- Printer: Built-in thermal printer

Certified to
ISO 9001:2008 and ISO 13485:2003

DIRUI INDUSTRIAL CO.,LTD.
3333 Yiju Street,New&High Tech. Development Zone
Changchun,Jilin 130103,P.R.China
Tel:+86(431)81935329 85100409
Fax:+86(431)85172581 85083741
E-mail:dirui@dirui.com.cn Http://www.dirui.com.cn
·Specifications subject to change without notice.
20170508

DIRUI

H-500

Urine Analyzer

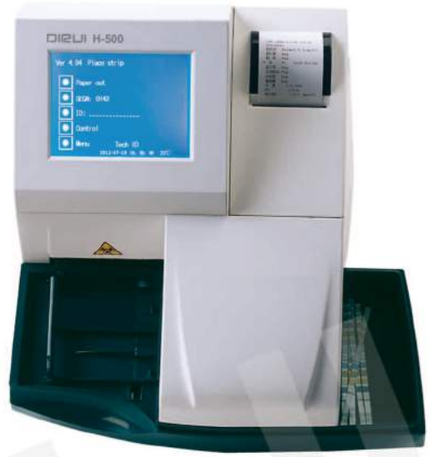
H-500

Urine Analyzer

DIRUI

Product Characteristics:

- Adopting the advanced high luminosity cold light source with 4 -wavelength, which improves the sensitivity, accuracy, specificity, and reduces the interference from ambient light
- Adopting automatic waste handling equipment, which avoids cross-contamination between samples
- Automatically rectify the test results influenced by non-specificity, pH, specific gravity, and color
- Built-in thermal printer with high speed and low noise; External stylus printer
- Connectable with urine sediment analyzer
- Users can set an abnormal value flag by themselves
- International, regular and symbol system units available for option



Technical Specification:

- Test items: urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocytes, glucose, specific gravity, pH and VC microalbumin creatinine, calcium
- Test wavelength: 525nm, 572nm, 610nm, 660nm
- Test principle: Photoelectric colorimetry
- Suitable strips: DIRUI H8, H10,H11 and H11MA(N) H12,H13-Cr,H14-Ca urinalysis strips
- Test throughput: 514strips/h
- Data memory: 5000 patient results
- Computer interface: RS-232 port; parallel printer interface
- Display: 5.7″ LCD
- Language: Chinese,English,Russian,Polish,Italian,Spanish,Portuguese, Turkish,Hungarian,German,French
- Power supply: 100~240VAC, 50Hz/60Hz
- Power: 40VA
- Dimensions: 395mm×382mm×304mm
- Weight: 7.4kg
- Printer: Built-in thermal printer

Certified to ISO 9001:2008 and ISO 13485:2003

DIRUI INDUSTRIAL CO.,LTD.

3333 Yiju Street,New&High Tech. Development Zone
Changchun,Jilin 130103,P.R.China
Tel:+86(431)81935329 85100409
Fax:+86(431)85172581 85083741
E-mail:dirui@dirui.com.cn Http://www.dirui.com.cn

·Specifications subject to change without notice.

20160902

DIRUI

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Certificate Holder:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **65-467-1304**

Effective Date: **2019-08-26**

Expiry Date: **2021-10-23**

Date of Issue: 2019-11-25

(Dawn M. Tibodeau)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Overall Scope Statement:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2019-11-25

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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TÜV SÜD

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag
DUNS No: 65-467-1304

Date of Issue: 2019-11-25

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106, Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Production of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag
DUNS No: 54-459-5743

Date of Issue: 2019-11-25

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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US-Letter / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Certificate Holder:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD ISO 9001

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **SH2005501**

Effective Date: **2020-08-12**

Expiry Date: **2023-06-30**

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Overall Scope Statement

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-MS
OCSM Accrédité CCN

America

C E R T I F I C A T E

No. QS5 044751 0140 Rev. 02

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-MS
OCSM Accrédité CCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor , Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-5000** Including reagents as following: **M-52D DILUENT** **M-52DIFF LYSE** **M-52LH LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-5150** Including reagents as following: **M-52D DILUENT** **M-52DIFF LYSE** **M-52LH LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling.) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1：2003+A1：2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Declaration of Conformity V 1.0

IEC 61010-2-010：2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-20s** Including reagents as following: **M-30D DILUENT** **M-30CFL LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2015-3-31

Place, Date of Issue: Shenzhen, 2015-3-31

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-30s** Including reagents as following: **M-30D DILUENT** **M-30CFL LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2015-3-31

Place, Date of Issue: Shenzhen, 2015-3-31

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-20s、BC-30s

Including reagents as following:

M-30D DILUENT

M-30CFL LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2011	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1：2003+A1：2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010：2005	Safety requirements for electrical equipment for measurement, control and

Declaration of Conformity V 1.0

	laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices
EN ISO13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-5150** Including reagents as following: **M-52D DILUENT** **M-52DIFF LYSE** **M-52LH LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1: 2003+A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Declaration of Conformity V 1.0

IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Chemistry Analyzer**
Model:	**BS-240**
Consumables:	Reaction cuvette Mindray reagent bottles CD80 detergent
Optional Module:	ISE unit bar code reader(optional)
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation
Conformity Assessment Route:	IVDD Annex III (not includes Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2016-03-29

Place, Date of Issue:	Shenzhen, 2016-03-29
Signature:	
Name of Authorized Signatory:	Mr. Wang XinBing
Position Held in Company:	Manager of Technical Regulation

证书编号：04717Q10183R5M

质量管理体系认证证书

兹证明

北京普利生仪器有限公司

（统一社会信用代码：91110108723969376Y）

注册地址：北京市海淀区上地群英科技园 5 号楼二层东　　邮编：100085

生产地址：北京市海淀区上地信息产业基地创业路 8 号群英科技园 5 号楼 2 层东侧；北京市海淀区上地创业路 8 号 5 号楼 4 层 5-6 号西侧

质量管理体系符合：

GB/T 19001-2008 idt **ISO 9001:2008**

体系覆盖：

全自动凝血分析仪、全自动红细胞沉降率测定仪、半自动凝血分析仪、全自动血液流变仪、半自动血液流变仪、活化部分凝血活酶时间(APTT)测定试剂盒(凝固法)、纤维蛋白原(FIB)测定试剂盒(凝固法)、凝血酶原时间(PT)测定试剂盒(凝固法)、凝血酶时间(TT)测定试剂盒(凝固法)、血液流变仪质控物的设计开发、生产和服务。

颁证日期：2017 年 05 月 26 日

有效期至：2018 年 09 月 15 日

总经理：

北京国医械华光认证有限公司

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

注：认证组织需通过年度监督审核后，此证书方为有效。 本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）或北京国医械华光

REGISTRATION NO. 04717Q10183R5M

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

Beijing Precil Instrument Co., Ltd.

Registered Address: 2F East 5 Building, Qunying kejiyuan, Shangdi Information Base, Haidian District, Beijing 100085, P. R. China

Manufacturing Address: East of 2F,Building No.5,Qunying Science and Technology Park,No.8 Chuangye Road, Shangdi Information Industry Base, Haidian District, Beijing, China; No. 5-6 West of 4F, Building No.5, No.8 Shangdi Chuangye Road, Haidian District, Beijing,China

Has been assessed and conformed to the following standard(s)
GB/T 19001-2008 idt ISO 9001:2008

The certificate is valid for the following scope:

The Design, Development, Production and Service of Auto Coagulation Analyzer, Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor , Semi-Auto Coagulation Analyzer , Auto Blood Rheometer, Semi-Auto Blood Rheometer, Activated Partial Thromboplastin Time Kit(Clotting assay) , Fibrinogen Kit(Clotting assay) , Prothrombin Time Kit(Clotting assay) , Thrombin Time Kit(Clotting assay) ,Quality Control Substance for Auto Blood Rheometer.

Date of issue: May 26, 2017
Date of expiry: September 15, 2018

General Manager:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS
中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

证书编号：04717Q10000190

医疗器械

质量管理体系认证证书

兹证明

北京普利生仪器有限公司

（统一社会信用代码：91110108723969376Y）

注册地址：北京市海淀区上地群英科技园5号楼二层东　　邮编：100085

生产地址：北京市海淀区上地信息产业基地创业路8号群英科技园5号楼2层东侧；北京市海淀区上地创业路8号5号楼4层5-6号西侧

质量管理体系符合：

YY/T 0287-2003 idt **ISO 13485:2003**

体系覆盖：

全自动凝血分析仪、全自动红细胞沉降率测定仪、半自动凝血分析仪、全自动血液流变仪、半自动血液流变仪、活化部分凝血活酶时间(APTT)测定试剂盒(凝固法)、纤维蛋白原(FIB)测定试剂盒(凝固法)、凝血酶原时间(PT)测定试剂盒(凝固法)、凝血酶时间(TT)测定试剂盒(凝固法)、血液流变仪质控物的设计开发、生产和服务。

颁证日期：2017年05月26日

有效期至：2019年03月01日

总经理：

北京国医械华光认证有限公司

注：认证组织需通过年度监督审核后，此证书方为有效。 本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）或北京国医械华光认证有限公司网站（www.cmdc.com.cn）上查询。 地址：北京市东城区安定门外大街甲88号中联大厦第5层 邮编：100011 电话：010-62351993

REGISTRATION NO. 04717Q10000190

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Beijing Precil Instrument Co., Ltd.

Registered Address: 2F East 5 Building, Qunying kejiyuan, Shangdi Information Base, Haidian District, Beijing 100085, P. R. China

Manufacturing Address: East of 2F,Building No.5,Qunying Science and Technology Park,No.8 Chuangye Road, Shangdi Information Industry Base, Haidian District, Beijing, China; No. 5-6 West of 4F, Building No.5, No.8 Shangdi Chuangye Road, Haidian District, Beijing,China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2003 idt ISO 13485:2003

The certificate is valid for the following scope:

The Design, Development, Production and Service of Auto Coagulation Analyzer, Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor , Semi-Auto Coagulation Analyzer , Auto Blood Rheometer, Semi-Auto Blood Rheometer, Activated Partial Thromboplastin Time Kit(Clotting assay) , Fibrinogen Kit(Clotting assay) , Prothrombin Time Kit(Clotting assay) , Thrombin Time Kit(Clotting assay) ,Quality Control Substance for Auto Blood Rheometer.

Date of issue: May 26, 2017

Date of expiry: March 01, 2019

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

Declaration of Conformity CE

Manufacturer: Beijing Precil Instrument Co., Ltd.
Room 203-204, 2F,Building 2,No.2, Tongji Middle Road,
Beijing Economic & Technological Development Area,
Beijing,100176,China

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

Product: Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor

Model: LBY-XC20B、LBY-XC40、LBY-XC40B

Classification: Others(Not listed in the Annex II, Directive 98/79/EC)

Conformity assessment route: Annex III(Except 6), Directive 98/79/EC

We herewith declare that the above-mentioned products meet the previsions of the following EC Council Directives 98/79/EC for in-vitro-diagnostics. All supporting documentation is retained under the premises of the manufacturer.

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

Start of CE-Marking: 2017-12-01

Place, Date: Beijing, 2017-12-01

Signature:
Name of Authorized Signatory: Zhang Yaohui
Position Held in Company: Management Representative

Applied Standards List

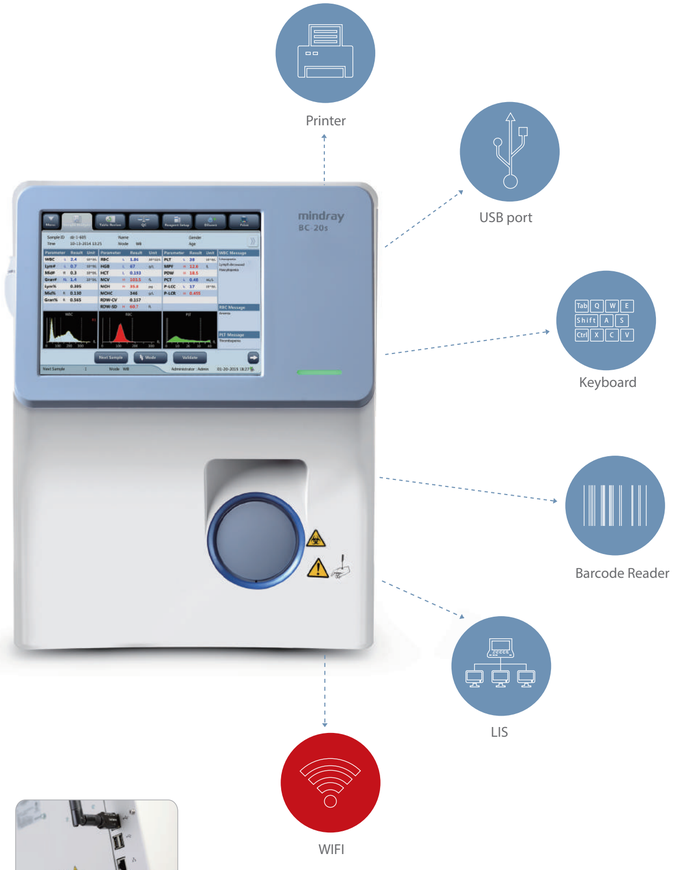
Product: Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor

Applied Standards:

EN 980:2008	Graphical symbols for use in the labeling of medical devices
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements IEC 61326-1:2005
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements IEC 61010-1:2001
EN 61010-2-081:2002 +A1:2003	Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes IEC 61010-2-081:2001
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:2002 (Modified)
EN62304:2006	Medical device software-Software life-cycle processes

Drafted by: 李志宏

Checked by:



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

BC-20s

Auto Hematology Analyzer

Technical Specifications

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

Performance

Parameter	Linearity Range	Precision (CV %)	Carryover
WBC(10^9/L)	0-100	≤3.5% (4.0-6.9) ≤2.0% (7.0-15.0)	≤0.5%
RBC(10^{12}/L)	0-8.00	≤1.5% (3.5-6.5)	≤0.5%
HGB(g/L)	0-280	≤1.5% (100-180)	≤0.5%
MCV(fL)		≤1.0% (70-110)	
PLT(10^9/L)	0-1000	≤5.0% (100-149) ≤4.0% (150-500)	≤1.0%

Parameters
19 parameters: WBC, Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT
3 histograms for WBC, RBC and PLT

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

Sample Volume
Prediluted mode 20μL
Whole blood mode 9 μL

Throughput
40 samples per hour

Display
8.4 inch TFT Touch Screen

Data Storage Capacity
Up to 200,000 results including numeric and graphical information

Communication
LAN Port supports HL7 protocol
Support bi-directional LIS

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

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

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

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

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

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680
E-mail: intl-market@mindray.com www.mindray.com
Mindray is listed on the NYSE under the symbol"MR"

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P/N: ENG-BC-20s-210285x6-20150331

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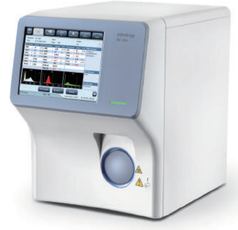
BC-20s

Auto Hematology Analyzer

Minimum Size,
Maximum Capability



mindray
healthcare within reach

What a 3-part should be

At Mindray we pride ourselves in our dedication and experience in developing better solutions for small labs. Our new line of 3-part hematology analyzers is the culmination of that effort. Compact yet powerful, full featured yet affordable, the BC-20s is what a 3-part analyzer should be.

Exclusive Feature

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

BC-20s

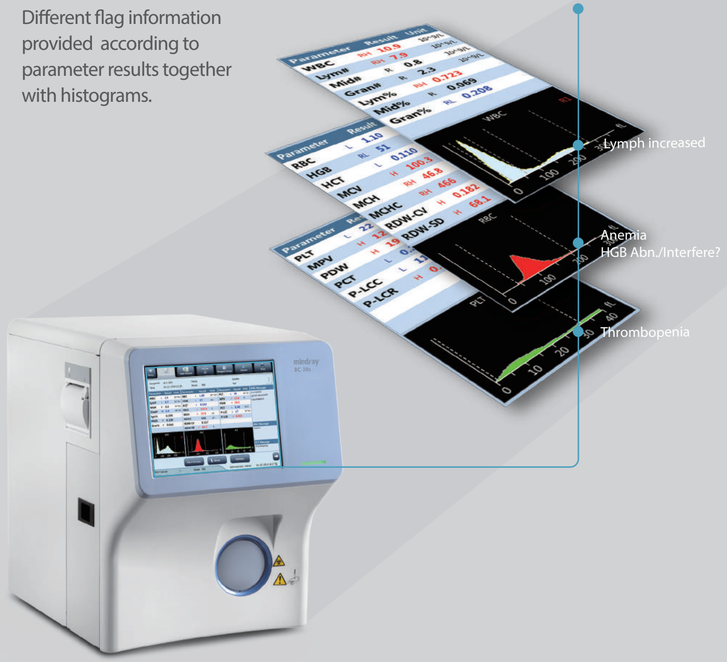
Auto Hematology Analyzer

Sample 1 : BC-20s shows flag "Lymph increased" which means a high number of Lymphocytes and/or immature cells. Meanwhile R1 flag is also displayed. Two kinds of flag messages are both supported to ensure clinicians have better understanding of sample results.

Sample 2 : Flag "Anemia" and "HGB Abn./Interfere?" are displayed. They mean the sample has shows either signs of Anemia, Abnormal Hemoglobin or sample is interfered such as by high value of Leukocytes or Agglutinated Erythrocytes.

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

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



Better Usability

Minimum size with the footprint similar to that of a 17 inch laptop, with space saving design that allows internal storage of lyse giving small labs more space. 8.4 inch TFT touch screen together with our powerful software enhances user operations and experience.

Higher Efficiency

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

Enhanced Performance

Higher throughput at 40 tests per hour.

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

Better Usability

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

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

Enhanced Performance

Higher throughput at 70 tests per hour.

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

BC-30s
Auto Hematology Analyzer

Technical Specifications

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

Performance

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

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

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

Sample Volume
Prediluted mode 20μL
Whole blood mode 9 μL

Throughput
70 samples per hour

Display
10.4 inch TFT Touch Screen

Multi-language
Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

Data Storage Capacity
Up to 500,000 results including numeric and graphical information

Communication
LAN Port supports HL7 protocol
Support bi-directional LIS

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

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

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

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

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

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680
E-mail: intl-market@mindray.com www.mindray.com
Mindray is listed on the NYSE under the symbol "MR"

mindray are registered trademarks or trademarks owned by Shenzhen Mindray Bio-medical Electronics Co., LTD.
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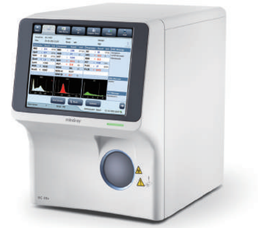
P/N: ENG-BC-30s-210285x6-20150623

mindray

BC-30s
Auto Hematology Analyzer

Minimum Size, Maximum Capability



mindray
healthcare within reach

BC-30s

Auto Hematology Analyzer

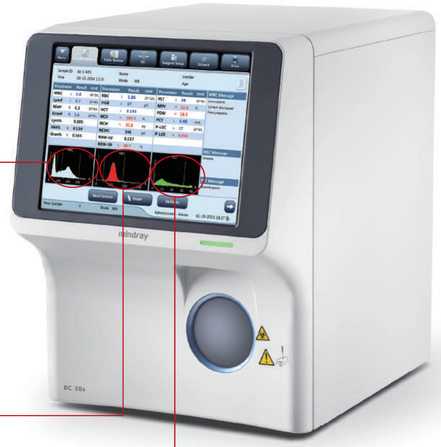
What a 3-part should be

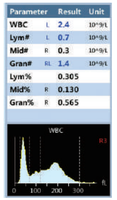
At Mindray we pride ourselves in our dedication and experience in developing better solutions for small labs. Our new line of 3-part hematology analyzers is the culmination of that effort. Compact yet powerful, full featured yet affordable, the BC-30s is what a 3-part analyzer should be.

Exclusive Feature

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

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

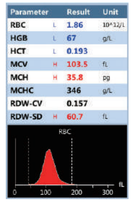




Leucopenia
Lymph decreased
Pancytopenia

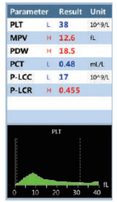
Sample 1 : BC-30s shows flags "Leucopenia", "Lymph decreased", "Pancytopenia" which mean white blood cell decreased, the low number of Lymphocyte and decreased of leukocyte, erythrocyte and plate count. Meanwhile "R3" flag is also displayed. Two kinds of flag messages are both supported to ensure clinicians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

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

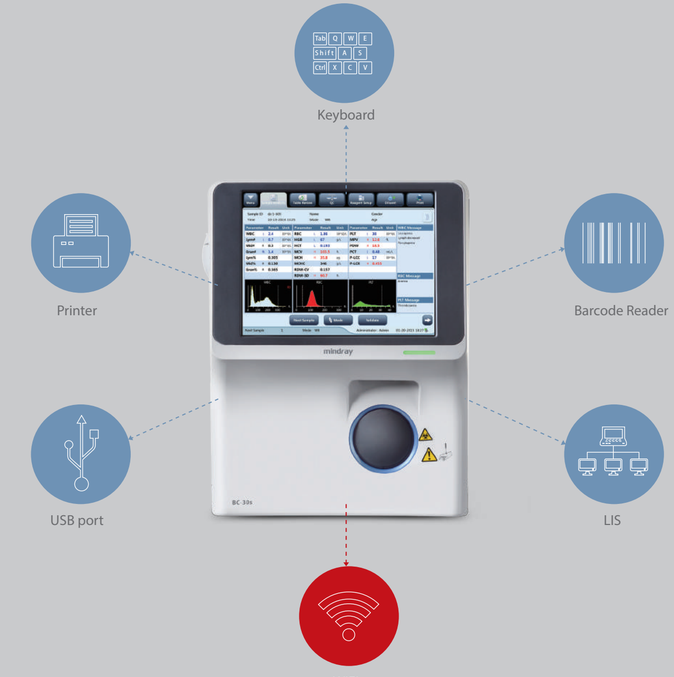


Anemia

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



Thrombopenia



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

mindray

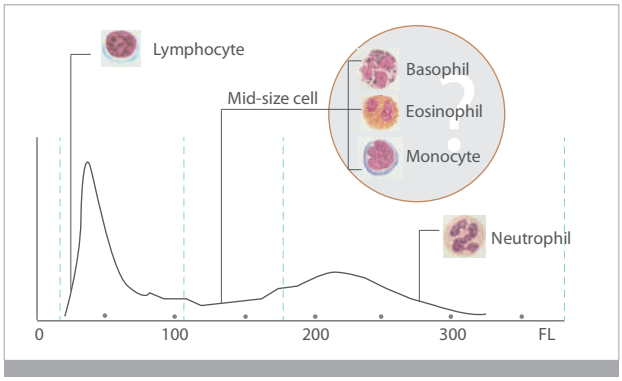
BC-5150

Auto Hematology Analyzer

A “CUTE” 5-part

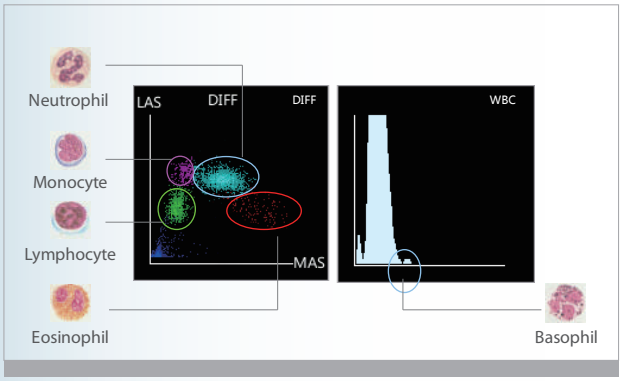
Why do we need 5-part hematology analyzers?

WBC differential: 3-part



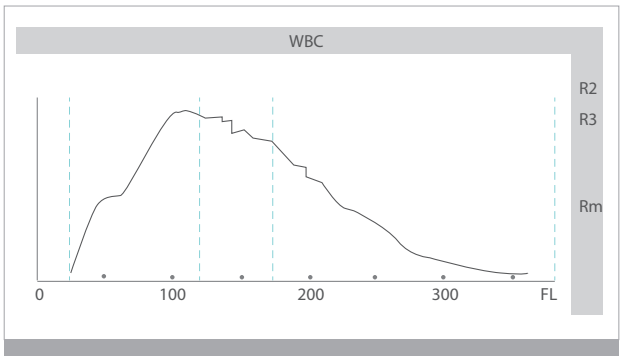
3-part hematology analyzers can not differentiate Basophil, Eosinophil and Monocyte. Additionally, Lymphocyte and Neutrophil results are easily affected by abnormal cells.

WBC differential: 5-part



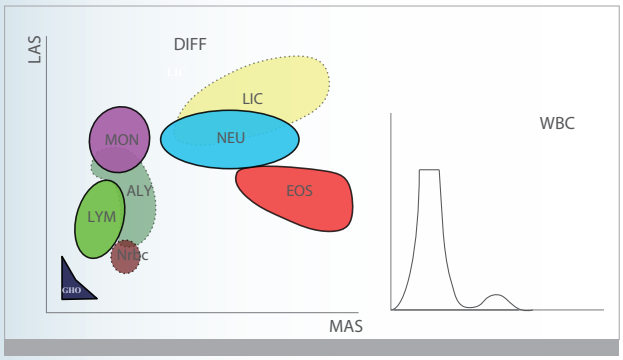
5-part hematology analyzers can provide Lymphocyte, Monocyte, Neutrophil, Eosinophil and Basophil results for every sample. Additionally, the 5-part results are less affected by abnormal cells.

Flag information: 3-part



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

Flag information: 5-part



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

Dr Marisela Ramos, lab manager

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

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

BC-5150

Auto Hematology Analyzer

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

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

WBC 5-part differentiation, 25 reportable parameters and 24 research parameters, 3 histograms and 4 scattergrams

Whole blood mode, Capillary whole blood mode and Prediluted mode

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

Dedicated optical counting channel for Basophil measurement

Powerful capability of flagging abnormal cells

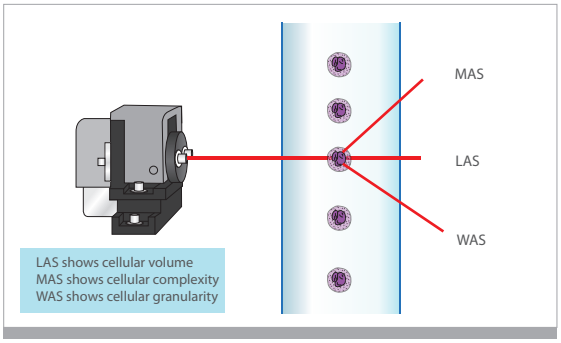
10.4 inch large TFT touch screen with user-friendly software

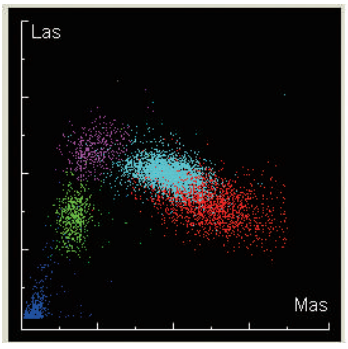
Large storage capacity: up to 250,000 samples

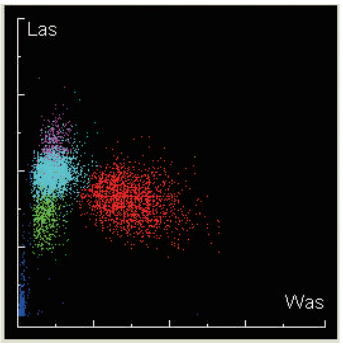
Throughput: 60 samples per hour

Sample volume is only 15μL which is ideal for pediatrics

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







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

Compact

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

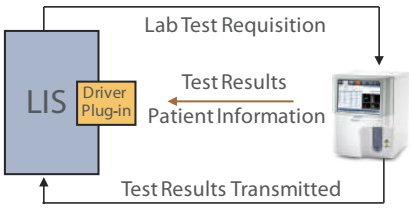
Utility

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

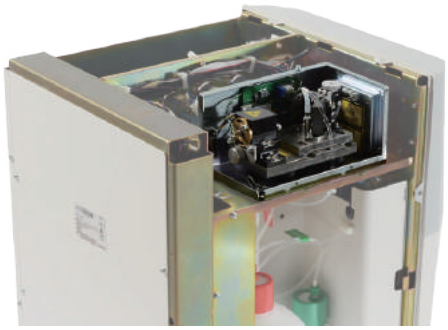
BC-5150 inherits it's convenient and proven powerful software design from BC-6800 and BC-3600 platforms, the friendly interface is ideal for small sized labs.

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

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

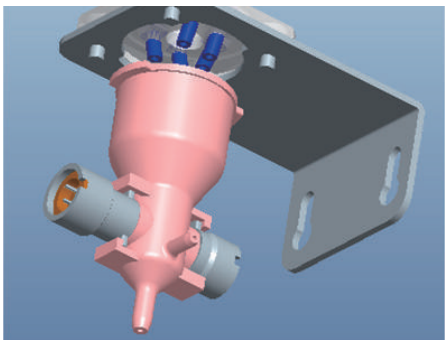


BC-5150 supports bi-directional LIS with test results and patient information. HL7 protocol is supported as well.



Technology

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



Improved DC impedance technology is used to count and size the RBC and PLT. The smaller counting aperture (50 μm in diameter) provides better performance on samples with low PLT.

Efficient

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

Technical Specifications

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

Parameters
25 parameters: WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#, Mon#, Neu#, Eos#, Bas#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC.
24 research parameters including LIC%, LIC#, ALY%, ALY#,PLT Clump#, PLT Clump%, Lip#, Lip%, NRBC#, NRBC%, Blast#, Blast%, PDW-SD,NLR,PLR, Neu-X, Neu-Y, Neu-Z, Lym-X, Lym-Y, Lym-Z, Mon-X, Mon-Y, Mon-Z
3 histograms for WBC, RBC and PLT
4 scattergrams for WBC differential

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

Performance

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

Sample Volume

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

Throughput
60 samples per hour

Display
10.4 inch TFT Touch Screen

Multi-language
Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

Data Storage Capacity
Up to 250,000 results including numeric and graphical information

Communication
LAN port supports HL7 protocol

Interface
USB, LAN
Support bi-directional LIS

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

Operating Environment
Temperature: 10°C~30°C
Humidity: 20%~85%
Air pressure : 70 kPa~106 kPa

Power requirement
100V-240V
50Hz/60Hz

Dimension and Weight
Depth(400 mm) x width(320 mm) x height(410 mm)
Weight :24kg

www.mindray.com

P/N: ENG-BC-5150-210285x6P-20190806
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mindray
healthcare within reach

BS-240

Clinical Chemistry Analyzer

mindray

healthcare within reach

Flexible loading:

Up to **80** sample positions,

Up to **80** reagent positions.

(40 fixed + 40 interchangeable)

Smart-Sampling Technology

Automatic hemolysate preparation for

HbA1c test

100µl
minimum reaction volume

Upgraded auto-washing system ensures low carryover and low water consumption.

BS-240

Clinical Chemistry Analyzer

Compact Size with Robust Functions

Independent mixing bar

Built-in barcode reader

Intelligent software with user-friendly interface

Step-by-step maintenance guide

Waterfall probe cleaning

BS-240

Complete traceability process

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

Traceability chain of Mindray measurement system (Glu)

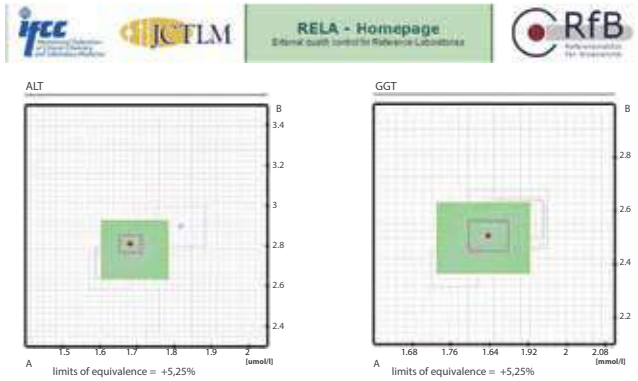
Traceability	Material	Calibration / Value Assignment	Procedure	Implementation	Uncertainty *Uc(y)*
		SI unit,mmol/L			
	Reference material SRM 917C		Primary Reference measurement procedure		
	Mindray Master Calibrator		CDC Hexokinase reference method		
	Mindray Product Calibrator		Mindray standard Measurement system		
	Routine Sample		End user' Routine Mindray		
		Result			

External quality assurance for reference measurement

Mindray participates in RELA (External quality control for reference laboratory) and CAP (College of American Pathologists external quality control).

EQA for Mindray Reference laboratory——RELA

Mindray reference laboratory has passed RELA for 6 consecutive years.



More RELA results please refer to: www.dgkl-rfb.de/81

RELA

All the items Mindray participate RELA

ALT AMY ALP CK GGT GLU LDH TB TP UA UREA

EQA for Mindray Testing System—— CAP

Mindray testing system has passed CAP for 6 consecutive years.

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org
Advancing Excellence

CAP Number: 7198395-01 **Kit#** 1
Institution: Shenzhen Mindray Biomed Elec Co Ltd
Attention: Lixing Liu MD
City / State: Hongkong HK CH 518055

Kit ID: 25733824
Kit Mailed: 6/3/2013
Original Evaluation: 7/8/2013

EVALUATION
ORIGINAL

C-B 2013 Chemistry

CAP

CAP #: 7198395 **Subspecialty :** Routine Chemistry

Regulated Analyte	Proficiency Event 2012 3 Test Event	Score	%	Proficiency Event 2013 1 Test Event	Score	%	Proficiency Event 2013 2 Test Event	Score	%	Current Event Performance Interpretation	Cumulative CLIA '88 Performance Interpretation
ALT	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Albumin	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Alkaline Phosphatase	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Amylase	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
AST	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Bilirubin, Total	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Calcium, Total	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Chloride	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Cholesterol, Total	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Cholesterol, HDL	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Creatine Kinase	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Creatinine	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Glucose	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Iron, Total	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
LD	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Magnesium	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Potassium	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Sodium	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Protein, Total	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Triglycerides	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Urea Nitrogen	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful
Uric Acid	C-C	5/5	100	C-A	5/5	100	C-B	5/5	100	Satisfactory	Successful

Reagent menu

Hepatic Panel

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

Renal Panel

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

Immune Panel

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

Diabetes Panel

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

Cardiac panel

- Creatine Kinase (CK)
- Creatine Kinase-MB (CK-MB)
- Lactate Dehydrogenase (LDH)
- α-Hydroxybutyrate Dehydrogenase(α-HBDH)
- High sensitive C-reaction protein(HS-CRP)

Inorganic & Anemia

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

Lipid Panel

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

Rheumatism Panel

- C-reactive protein (CRP)
- Rheumatoid Factor (RF)
- Antibodies Against Streptolysin O (ASO)

Lung Panel

- Adenosine Deaminase (ADA)
- Angiotensin Converting Enzyme(ACE)

Pancreatitis Panel

- α-Amylase (α-AMY)
- Lipase (LIP)

BS-240

Clinical Chemistry Analyzer

Technical Specifications

System function
Automatic, Discrete, Random Access, Bench-top
STAT sample priority
Throughput: Up to 200 tests/hour, up to 400 tests/hour with ISE
Measuring principles: Absorbance photometry, Turbidimetry, Ion Selective Electrode technology
Methodology: End-point, Fixed-time, Kinetic, optional ISE, Single/Dual/ reagent chemistries, monochromatic / bi-chromatic
Original system pack reagent ready to use
Close system and open system is optional

Reagent/Sample Handling
Reagent/Sample tray: 80 positions for reagents and 40 positions for samples in 24-hour refrigerated compartment (2~12℃)
Reagent volume: 10~250μl, step by 0.5μl
Sample volume: 2~45μl, step by 0.1μl
Reagent/Sample probe: Liquid level detection, vertical collision protection and inventory checking, reagent pre-warming
Probe cleaning: Automatic washing for interior and exterior
Carry over < 0.05%
Automatic sample dilution: Pre-dilution and post-dilution

Internal bar code reader (optional)
Used for sample and reagent programming
Be applicable to various bar code systems of Codabar、ITF (Interleaved Two of Five)、code128、code39、UPC/EAN、Code93
Capable to communicate with LIS in bi-directional mode

Reaction System:
Reaction rotor: Rotating tray, containing 40 cuvettes
Cuvette: Reusable, optical length 5mm
Reaction volume: 100~360μl
Operating temperature: 37℃
Temperature fluctuation: ± 0.1℃

ISE Module (optional)
Measuring K+, Na+, Cl-

Mixing Unit
Independent mixing bar
Cuvette Washing: Washing station with pre-warmed detergent and water

Optical System
Light Source: Halogen-tungsten lamp
Wavelength: 8 wavelengths, 340nm、405nm、450nm、510nm、546nm、578nm、630nm、670nm
Absorption range: 0~4.0 Abs (10mm conversion), resolution 0.0001Abs
Stray Light 5.6Abs

Control and Calibration
Calibration modes: Linear (one point, two points and multi-points), Logit-Log 4P, Logit-Log 5P, spline, exponential, polynomial, parabola
Control Rules: X-R, L-J, Westgard multi-rule, Cumulative sum check, twin plot

Operation Unit
Operation system: Windows 8
Interface: RS-232

Working Conditions
Power Supply: 200~240V, 50/60Hz, ≤1000VA or 100~130V, 60Hz, ≤1000VA
Dimension: 690 mm (length) ×580 mm (depth) ×595 mm (height)
Weight: 79 kg
Water Consumption: ≤ 4 L/H

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680
E-mail: intl-market@mindray.com www.mindray.com

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P/N: ENG-BS-240-21285x8-20160105

mindray

PRECIL
A Mindray Company

www.precil.com.cn

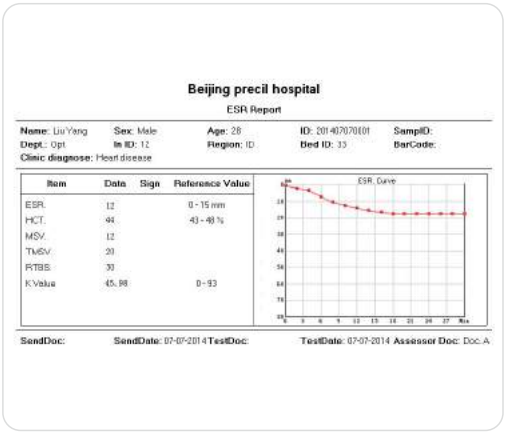
LBY-XC40B/ LBY-XC20B

Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor

Dynamic Scan， Easy Operation

LBY-XC40B/ LBY-XC20B

Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor



Beijing precil hospital

ESR Report

Name: Liu Yang Sex: Male Age: 28 ID: 20140707001 SampID:
Dept.: Opt In ID: 12 Region: ID Bed ID: 33 BarCode:
Clinic diagnose: Heart disease

Item	Data	Sign	Reference Value
ESR	12		0 - 15 mm
HCT	44		40 - 48 %
MSV	12		
TMSV	20		
RTBS	30		
K Value	45.98		0 - 93

ESR Curve

SendDoc: SendDate: 07-07-2014 TestDoc: TestDate: 07-07-2014 Assessor Doc: Doc A

Technical specifications

Testing Channel	40/20
Testing Time	60min/30min
Scanning Interval	2.5min
Accuracy	±5%
Channel Consistency	5%
Repeatability Error	≤3%
Report Unit	mm/h

Features

- Dynamic scanning of erythrocyte sedimentation process
- Automatically calibration to the test result at 25℃
- Auto induction of sample loading and auto testing
- Extremely easy operation: load and testing

PRECIL
A Mindray Company

Beijing Precil Instrument Co., Ltd.

Building No5,Shangdi Qunying Technology and Science Park, Haidian District ,Beijing, P.R.China(100085)

TEL: 0086-10-62971818 62987758 FAX: 0086-10-62987761 http://www.precil.com.cn

CE CE

Declaration of Conformity

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

We declare under our sole responsibility that:

Product Name:	HbA1c Test Kit (Dry Fluorescence Immunoassay)
Type/Model:	25T
Classification:	Others
Conformity Assessment Peocedure:	Directive 98/79/EC Annex III

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

DIRECTIVES

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

Nanjing, China March, 12,2020
Place, Date

Signature

CE CE

Declaration of Conformity

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

We declare under our sole responsibility that:

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

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

DIRECTIVES

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

Nanjing, China March, 12,2020
Place, Date

Signature

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 002596 0002 Rev. 00

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

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

Certification Mark:

Scope of Certificate:
**Design and Development,
Production and Distribution of
Dry Fluorescence Immunoassay Analyzer,
Dry Fluorescence Immunoassay test kits,
Hemagglutination Assay Kit(electrochemical method), Handheld coagulation Analyzer**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19126603
Valid from: 2020-02-26
Valid until: 2021-04-02

Date, 2020-02-26

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Test Items:

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

New items are available soon!

Lansion Biotechnology Co., Ltd.

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

CE IVD

Lansionbio®

LS-1100

Dry Fluorescence Immunoassay Analyzer (Portable)

Quantitative

Rapid

Sensitive

Reliable

Accurate, Anytime and Anywhere

Lansion Biotechnology Co., Ltd.

LS-1100 Dry Fluorescence Immunoassay Analyzer (Portable)

Analyzer Introduction:

LS-1100 uses the advanced method of Time-resolved Fluorescence Immunoassay (TRFIA), for the in-vitro quantitative detection of bio-markers for Diabetes Mellitus, Inflammation, Cardiovascular Diseases, Hormone, Gastric Diseases, Renal Diseases, Tumor, etc.

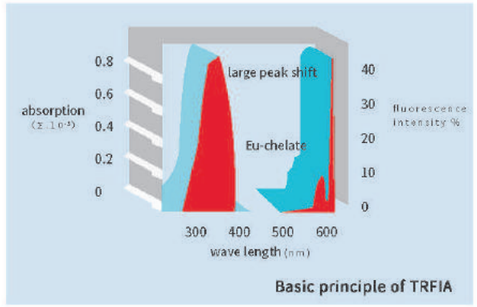
Application: Laboratory, ER, Cardiology, ICU, Respiratory, Pediatrics, etc.

Features:

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

Method	Time-resolved Fluorescence Immunoassay (TRFIA)
Specimen	Serum/Plasma/Whole Blood/Urine
Weight	1.3kg
Dimensions	225mm×152mm×105mm (L×W×H)
Screen	7 inch touch screen
Data Storage	⩾5000
Printer	Built-in thermal printer
Battery	Built-in lithium battery (super standby time)
Communication	RS232(LIS/HIS), RJ45, USB, WIFI, Bluetooth

Time-resolved Fluorescence Immunoassay (TRFIA) Method:



Basic principle of TRFIA

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

Easy Operation:

QR Code Calibration

Information Input

Sample Dispense

Automatic Detection

Result Output

HbA1c Test Kit（Dry Fluorescence Immune Method）Instruction

【PRODUCT NAME】HbA1c Test Kit

(Dry Fluorescence Immunochromatography)

【PACKAGING STANDARD】25 T/box

【INTENDED USE】

Suitable for in-vitro quantitative determination of HbA1c in whole blood.

【PRINCIPLES】

The HbA1c detection kit is made by the antigen — antibody reaction. The specimen is diffused forward due to capillarity, in which HbA1c binds to the antibody bound to the fluorescent granules. The composite is attached to a detection region with solidified antibody, and other fluorescent antibody particles attached to the quality control area. When the test kit inserted into the analyzer, the analyzer automatically scans the two ribbons and detects the fluorescence intensity emitted by the composite in the detection area and the quality control area, and calculates the content of the substance with the ratio of the two fluorescence values.

【MAIN INGREDIENTS】

1、HbA1c Test Strip

2、Other Ingredients: Instruction、SD Card、Diluent；

Note: Avoid affecting the test result, please do not use different batches of products.

【PRESERVATION AND STABILITY】

The kit is preserved at 4℃—30℃, validity period is 12 months.

【SPECIMEN DEMANDS】

The sample can use the whole blood, but the test should be made within 1 hour after the blood collection.

1.Whole Blood statically settled and precipitated.

2.Add 10ul of precipitated sample, slightly blown and hit for 20 times, fully mixed.

【TESTING STEPS】

1.Turn on the analyzer.

2.Read SD card.

3.Dispense 90ul of dilute whole blood sample at test strip.

4.Insert the strip into the analyzer after 5 minutes.

5.Analyze and detect, and then display test results.

6.Pull out the strip.

【REFERENCE INTERVAL】

4%-6%: blood glucose control

6%-8%: blood glucose control up to standard

＞8%: suggest to intensify blood glucose control

Note: It is suggested that each laboratory establish its own reference interval.

Reference Basis: With a sample book of 200 healthy people, the reference interval is determined by statistics.

【TEST RESULT EXPLANATION】

The incidence of diabetes in the world is very high, accounting for the ratio of immune diseases, which is as high as 2-5% in developed countries. The incidence of diabetes in China is also 2-3%, and also grows at 1 ‰ per year. Recent medical research shows that glycated hemoglobin in the blood (glycosylatedhemoglubin, GHb) (HbA1c) concentration is relatively stable, which can accurately reflect the blood glucose level during the last 1-3 months, for the early diagnosis of diabetes mellitus; it also can be applied to monitoring of blood glucose and judgment of chronic complications for patients with diabetes, , which brings widely clinical importance.

【LIMITATIONS】

This kit is only for the whole blood test.

The test result of this kit is only one of the diagnostic aids for the clinicians.

【PERFORMANCE CHARACTERISTICS】

1．Blank Limit: The blank limit of the kit is not more than 4%.

2．Accuracy: The relative deviation within the range of ±10%.

3．Repeatability: CV%≤15%.

4．Linear Range: within 4%-14%, R≥0.990.

5．HOOK Test: No Hook effect in high concentration samples.

6．Inter batch difference: Difference between the three batch of kits is not more than 15%.

7．Stability: Te kit conforms to the above 1-5 indicators after expiry time is full.

【PRECUSTIONS】

1．For in vitro diagnostic use only.

2．Do not insert the wet strip with blood or other fluids into the analyzer.

3．Do not use the damaged strip or strip in damaged pack.

4．Do not mix the ingredients of different kits.

【REFERENCES】

1. Bunn HF.蛋白质中非酶糖基化合物：与糖尿病相关.AM J Med 1981;70:331-8

2. Jovanovic L,Peterson CM,糖机化红血素的临床效用，AM J Med 1981;70:331-8

3. Molnar GD.临床中关于糖尿病的新陈代谢的管理。糖尿病 1978；27:216-25

【BASIC INFO】

REG. Company: Suzhou Lansion Biotechnology Co., Ltd

REG. Residence: F3, Building 1, No.8 Keling Road, High-tech District, Suzhou

Contact Details: 025-58577600

After-sales service unit: Suzhou Lansion Biotechnology Co., Ltd

Manufacturing Address: 025-58577600

Contact Details: 025-58577600

【PRODUCTION LICENCE NO.】

【REG. NO. / TECHINICAL REQUIREMENTS No.】

【INSTRUCTION APPROVAL DATE AND REVISION DATE】

【MANUFACTURING DATE】 Please check the label or packaging

DIAMOND
DIAGNOSTICS

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 Uniós 98/79/EC irányelvben foglaltaknak

Diamond Diagnostics, Inc. versichert und erklä 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) c- dessous sont conformes aux exigencies de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostici in vitro.

Diamond Diagnostics, Inc. asegura y declara que los productos listados a continuación cumplen con los requisites 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/ЕС Европейского союза о медицинском оборудовании для диагностики In-vitro.

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

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

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

Diamond Electrolyte Analyzers
Model: GEMLYTE, SMARTLYTE, SMARTLYTE PLUS, CARELYTE, CARELYTE PLUS, PROLYTE

(AR) Authorized Representative
Diamond Diagnostics Kft.
6 Óradna Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Authorized Officer: _____ **Date:** 30 April, 2018
Kathy Fisher
Global Quality Manager

Quality Systems Registration
ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure
Annex III, Self-Declared

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

CE

The names of various manufacturers and their instruments referred to herein may be protected by trademark or other law, and are used herein solely for purpose of reference. Diamond Diagnostics, Inc. expressly disclaims any affiliation with them or sponsorship by them.

NAH-4-0044/2018
IRÁNYÍTÁSI RENDSZEREKET
TANÚSÍTÓ SZERVEZET

THE INTERNATIONAL CERTIFICATION NETWORK

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

MSZT CERT

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 Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

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

MAGYAR SZABVÁNYÜGYI TESTÜLET
HUNGARIAN STANDARDS INSTITUTION

H-1082 Budapest, Horváth Mihály tér 1.

TANÚSÍTÁSI OKIRAT
CERTIFICATE

Tanúsítjuk, hogy a
We certify that the Management System of

Diamond Diagnostics Inc. Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.

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

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

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

MSZ EN ISO 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

SmartLyte® Plus

The Most Advanced Electrolyte Analyzer

Distributed By:

BIOSISTEM-MLD S.R.L.

SmartLyte® Plus

User Input
5" Touch Screen
Remote Access

Data Storage
10,000 Patient Results
10,000 QC Results per Level

Connectivity
LAN, Wifi, 4 USB ports
RS232, LIS

Analysis Time
28 sec (512/hour)

Calibration
2 Point every 4 hours
1 Point every sample
On Demand

Number of Parameters
5 Total
4 (Simultaneously)

Sample Size
Whole Blood, Serum (95 µl)
Plasma, QCs (95 µl)
Urine (180 µl)

Support
Online Service Interface

Languages
English, 中文, Français, Deutsch, Italian
이탈리아어, ポルトガル語, Português
Русский, Español, Türkçe, Indonesia

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

Parameter	Range	Reproducibility [1]	Resolution
Na^+	40-200 mmol/L	CV ≤ 1% (120-160mmol/L)	0.1 mmol/L
K^+	1.7-15 mmol/L	CV ≤ 2% (2.5-6 mmol/L)	0.01 mmol/L
Cl^-	50-200 mmol/L	CV ≤ 2% (85-130 mmol/L)	0.1 mmol/L
Ca^{++}	0.3-5.0 mmol/L	SD ≤ 0.02 mmol/L (0.8-1.5 mmol/L)	0.001 mmol/L
Li^+	0.2-5.5 mmol/L	SD ≤ 0.02 mmol/L (0.4-1.3 mmol/L)	0.001 mmol/L
Urine [2] Na^+	3-300 mmol/L	CV ≤ 2% (100-250 mmol/L)	0.1 mmol/L
K^+	5-120 mmol/L [3]	CV ≤ 1% (10-60 mmol/L)	0.01 mmol/L
Cl^-	15-300 mmol/L	CV ≤ 3% (100-250 mmol/L)	0.1 mmol/L

1-Typical Within Run (n=30) Blood, Serum, Plasma 2-Calcium and Lithium are not typically measured in urine samples
3-(60-120) requires additional dilution

Power
100-240V ~ 50/60 Hz (self adjusting)
1.6 A max, 50 Watts max

Size & Weight
13.2 x 12.4 x 12 in or 335 x 315 x 295 mm
14 lbs or 6 kgs

Ambient Conditions
Room temperature: 15-32°C/60-90°F
Humidity <85%

Not Commercially Available in the United States

BioSistem - MLD S.R.L.
16/1 Albisoara street, ap. 7, Chisinau, Republic of Moldova, MD-2001
+373 22 808 517 • biosistem.mld@gmail.com • www.biosistem-mld.com

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 090700 0029 Rev. 00

Holder of Certificate: **i-SENS, Inc.**
43, Banpo-daero 28-gil, Seocho-gu
Seoul 06646
REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Blood Glucose Monitoring System, Electrolyte Analyzer, Blood Ketone Monitoring System, HbA1c Analyzer, GAS Analyzer and Lancing Device**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74955792

Valid from: 2020-04-01
Valid until: 2023-03-31

Date, 2020-03-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 090700 0029 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

i-SENS, Inc.
4th floor, 39-36, Nonhyeon-ro 46beon-gil, Namdong-gu, Incheon 21655, REPUBLIC OF KOREA

i-SENS, Inc.
27-36, Gwangun-ro, Nowon-gu, Seoul 01891, REPUBLIC OF KOREA

i-SENS Wonju Factory
94-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do 26365, REPUBLIC OF KOREA

i-SENS, Inc.
27-34, Gwangun-ro, Nowon-gu, Seoul 01891, REPUBLIC OF KOREA

i-SENS Songdo Factory
12, Harmony-ro 275beon-gil, Yeonsu-gu, Incheon 22014, REPUBLIC OF KOREA

i-SENS, Inc.
43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, REPUBLIC OF KOREA

i-SENS Wonju Factory 2
200, Gieopdosi-ro, Jijeong-myeon, Wonju-si, Gangwon-do 26354, REPUBLIC OF KOREA

J.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

Specifications

Operating Parameters

Reportable Range
pH : 6.500~7.800
pCO_2 : 5.0~150.0 mmHg
pO_2 : 10~680 mmHg
Na^+ : 80~200 mmol/L
K^+ : 0.1~20.0 mmol/L
Ca^{2+} : 0.25~5.00 mmol/L
Cl^- : 50~150 mmol/L
Glu : 5~500 mg/dL
Lac : 0.2~15.0 mmol/L
Hct : 10~70%

Calculated Parameters
pH(T), pCO_2(T), pO_2(T), tCO_2, HCO_3^-, HCO_3^-(std), BE(ecf), BE(B), Anion gap(K), tHb, sO_2
Ca^{2+}(7.4), pO_2(A-a)

Sample Type
Heparinized whole blood

Sample Volume
100 µL

Sample Analysis Time
50 seconds

Cartridge

Test Panel Options
- CarePak 106
pH, Na^+, K^+, Ca^{2+}, Cl^-, Hct

- CarePak 108
pH, pCO_2, pO_2, Na^+, K^+, Ca^{2+}, Cl^-, Hct

- CarePak 110
pH, pCO_2, pO_2, Na^+, K^+, Ca^{2+}, Cl^-, Hct, Glu, Lac

Test Volume Options
50 tests / 2 or 3 weeks
100 tests / 2 or 3 weeks
200 tests / 2 or 3 weeks
300 tests / 2 or 3 weeks

Storage Condition
15~25 ℃

Components
- Micro-sensor card
- Cal1, Cal2, Cal3
- Reference solution
- Sampler & waste bag
- Valve and tubing
- EEPROM

Dimensions / Weight
182(W) x 148(H) x 100(D) mm
1.7 kg

Instrument & Connectivity

Computer
1.1 GHz dual core processor
SSD 32GB storage

Operating System
Microsoft® Windows® IoT10 Enterprise

Display
9 inch TFT LCD touch screen
wide view angle

Printer
2 inch thermal printer (built-in)

Dimensions / Weight
269(W) x 391(H) x 255(D) mm
8.4 kg (accessories excluded)

System Connectivity
Bidirectional LIS/HIS communication

Power Interface

Voltage
100~240 Va.c.

Frequency
50/60 Hz

Power Adaptor
Input: 100~240 Va.c., 1.5 A,
50/60 Hz, Max. 1.5A
Output: +24 Vd.c., Max. 2.7A

Battery Operation
Max. 2 hours

Interface
- 650nm Laser Diode scanner (built-in)
- 2 x USB 3.0
- Serial port (RS-232)
- Ethernet port (RJ45)
- HDMI interface (external display)

i·sens Sensing Ahead, Caring More
i-SENS, Inc.
43, Banpo-daero 28-gil, Seocho-gu, Seoul 06646, Korea **TEL** +82-2-910-0722 **FAX** +82-2-941-0868 **www.i-sens.com**
AD138 REV2 07/2019

i·SmartCare 10
Blood Gas Analyzer

One-Touch Care

pH | pCO_2 | pO_2 | Na^+ | K^+ | Ca^{2+} | Cl^- | Hct | Glu | Lac (NEW)

01 Maintenance Free

- All-in-One multi test cartridge contains all reagents & consumables
- Self-cleaning sample probe helps maintain sample integrity

02 Fast, Safe & Reliable Results

- EEPROM chip enables automatic cartridge information loading
- Fast patient test results: 50 seconds
- Fully automated calibration and system performance monitoring

03 Easy to Use & Simple Operation

- Syringe and capillary samples without adapters
- Built-in sample barcode scanner & printer
- Internal battery provides up to 2 hours of full operation without AC power
- One-touch design

04 Connectivity Management

- Analyzer monitoring including QC status
- Real-time data transfer to HIS/LIS
- Middleware keep strict quality control and strict data security & integrity

05 Efficiency

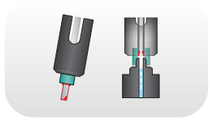
- Wide range of available cartridges (by analyte menu and volumes) allows for best-fit to testing needs
- Light weight and small foot-print

Intuitive Touch Screen Interface

- Microsoft® Windows® 10 operation
- 9 inch TFT LCD touch screen
- Wide view angle

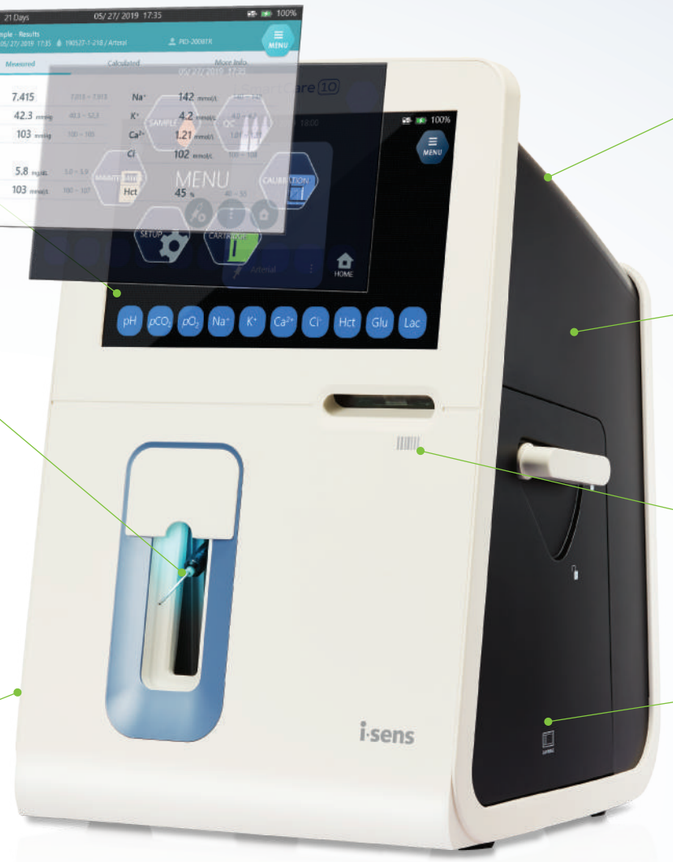
Intelligent Sample Probe

- Syringe or capillary position depending on sample type selection
- Rinses out septum and probe after each sample to avoid carry-over
- Illuminated sampling area for low-light testing environments
- Exposed probe only during sampling (automatically retracts for safety purposes)



Rechargeable Internal Battery

- Up to 2 hours of sample measurement



Built-In Printer

- Hard copy printout of patient and QC calibration results

External Input / Output Ports

- Serial port (RS-232)
- Ethernet port (RJ45)
- 2 x USB 3.0
- HDMI Interface (external display)

Built-In Barcode Scanner

- Internal barcode scanner enters samples and operator ID automatically

Built-In EEPROM Chip

- Automatic cartridge information recognition
- Prevention of copy reagents
- Ensures valid cartridges and quality of reagents are used

Care Connect®

DM

Management Function
- Analyzer, Material Registration Operator, Patient and Ward Management

POC Devices Integration
- CareSens Expert Plus, i-SmartCare 10, A1Care

Analyte Consolidation
- Glucose, Ketone, HbA1c, Blood Gas, Metabolites, Electrolytes

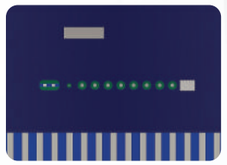
Quality Control
- Variety of QC Export Options and Statistics Reports

Data Connectivity
- HIS/LIS/EMR
- POCT1-A and HL7 Protocols

Convenient Device Management

Providing Differentiated Customer Value

Improved Work Efficiency



• Micro Sensor Technology

Micro sensors fabricated on i-SENS' unique screen-printed electrodes allow for accurate analysis of samples at small volumes

• All-in-One Multi Test Cartridge Technology

Each cartridge contains all reagents, sensors, calibration solutions and complete fluidic components from sampler to waste bag required for optimal testing