REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

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

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531522** data **15.09.2023**

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**
Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
3. Acordarea asistenţei medicale de către instituţiile medico-sanitare private
4. Comerţul cu ridicata al calculatoarelor,echipamentelor periferice şi software-ului
5. Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul
6. Consultaţii în domeniul sistemelor de calcul

Capitalul social: **5400** lei.

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

Asociaţii:
1. POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%
Beneficiar efectiv:
1.1. POIATA VITALIE, IDNP 0983103892591,

2. NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
2.1. NASEDCHIN ALEXANDR, IDNP 2002001070747,

3. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
3.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

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

Registrator în domeniul înregistrării de stat

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

Rusu Diana

EB 0461494

Date cu caracter personal

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

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

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

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

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

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

Lista fondatorilor Biosistem-mld SRL

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

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 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

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DECLARATION OF CONFORMITY

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, located at Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nan-shan, 518057, Shenzhen, P. R. China, hereby confirm that:
We herewith declare that the products listed in Attachment I meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. The conformity assessment route is according to 98/79/EC Annex III (not includes Section 6).

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

Product Category(ies): Clinical Chemistry Analyzer, Hematology Analyzer, Microplate washer, Microplate reader, Urine Analyzer, Chemiluminescence Immunoassay Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Reagents for Chemiluminescence Immunoassay Analyzer,Urinalysis reagent strips.

Products: Attachment I

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

We hereby certify that the forgoing is a true and accurate statement.

Place, Date Of Issue : Shenzhen, **2016-09-01**

Chuanbin Tan

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

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

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ATTACHMENT I

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

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

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		Calibrator SC-CAL PLUS Hematology Calibrator BC-3D Hematology Control
Auto Hematology Analyzer	BC-3600、 BC-3300、 BC-3300CT、 BC-3600CT	M-30D DILUENT M-30CFL LYSE M-30R RINSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5800、 BC-5600	M-58LEO(I) LYSE M-58LEO(II) LYSE M-58LH LYSE M-58LBALYSE M-58DDILUENT PROBE CLEANSER S50 Calibrator B55 Hematology Control SC-CAL PLUS Hematology Calibrator BC-5D Hematology Calibrator
Auto Hematology Analyzer	BC-6600、 BC-6800	M-68DR DILUENT M-68DS DILUENT M-68LD LYSE M-68LN LYSE M-68LB LYSE M-68LH LYSE M-68FN DYE M-68FR DYE M-68FD DYE PROBE CLEANSER BC-6D Hematology control BC-NRBC Hematology Control BC-RET Hematology Control SC-CAL PLUS Hematology Calibrator BR60 Hemalology Control
Auto Hematology Analyzer	BC-5310	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control

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Auto Hematology Analyzer	BC-5390	M-53D DILUENT M-53LEO(I) LYSE M-53LEO(II) LYSE M-53LH LYSE M-53P PROBE CLEANSER S50 Calibrator B55 Hematology Control
Auto Hematology Analyzer	BC-5150、BC-5000、HM-500X	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER S50 Calibrator B55 Hematology Control BC-5D Hematology control SC-CAL PLUS Hematology Calibrator
Urine Analyzer	UA-66、UA-600、UA-600T	Urinalysis reagent strips
Auto Hematology Analyzer	BC-20s、BC-21s、BC-30s、BC-31s、HM-200X	M-30D DILUENT M-30CFL LYSE PROBE CLEANSER B30 Hematology Control S30 Hematology Calibrator
Auto Hematology Analyzer	BC-5390 CRP BC-5180 CRP	M-53D DILUENT M-5 LEO(I) LYSE M-5 LEO(II) LYSE M-53 LH LYSE LC LYSE Probe Cleanser S50 Calibrator B55 Hematology Control C-reactive Protein Control C-reactive Protein (CRP) Calibrator C-reactive Protein (CRP) Kit (Latex Immunoturbidimetric Method)
Auto Sample Processing System	CAL 8000	/
Auto Slide Maker & Stainer	SC-120	M-68DS DILUENT PROBE CLEANSE
Automated Glycohemoglobin Analyzer	H50 H50P	Analytical Column Eluent A Eluent B Hemolysis Solution M-30P PROBE CLEANSER Hemoglobin A1c Control

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		Hemoglobin A1c Calibrator
Flow Cytometer	BriCyte E6	Sheath Fluid Cleaning Solution
Lysing Solution	/	/
CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent HLA-B27 Reagent	/	/
Laboratory Data Management Software	/	/
Mindray labXpert Software	/	/
Specific Protein Analyzer	CRP-M100	M-68DS Diluent LC Lyse CRP Cleanser Probe Cleanser
Auto Hematology Analyzer	BC-5120 BC-5130 BC-5140	M-52D DILUENT M-52DIFF LYSE M-52LH LYSE PROBE CLEANSER
Chemistry Analyzer	BS-300、BS-320	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit
Chemistry Analyzer	BS-400、BS-420	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette

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		Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	Perfect plus	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit
Chemistry Analyzer	BS-380、BS-390	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit
Chemistry Analyzer	BS-350、BS-330	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode

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		Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Semi-auto Chemistry Analyzer	BA-88A	/
Chemistry Analyzer	BS-120、BS-130、BS-180	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200、BS-220	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Chemistry Analyzer	BS-200E/BS-220E BS-330E/BS-350E	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode

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		Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit Reaction cuvette Mindray reagent bottles Bar code module
Microplate reader	MR-96A	/
Microplate washer	MW-12A	/
Chemistry Analyzer	BS-800、BS-820、BS-800M、BS-820M、BS-1800、BS-1800 plus	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System（RMS）
Chemistry Analyzer	BS-2000、BS-2000M、BS-2200、BS-2200M	ISE module MR Na electrode MR K electrode MR Cl electrode MR reference electrode MR Serum Standard MR Urine Standard MR Urine Quality Control MR Buffer Solution MR Detergent Solution MR Na/K Check Solution Built-in sample/reagent bar code reader External Air Pump Water Supply Unit Remote Maintenance System（RMS）

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Chemistry Analyzer	BS-600、BS-620	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Drainage unit Water supply unit External vacuum pump unit
Chemistry Analyzer	BS-480、BS-490	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Built-in sample/reagent bar code reader Remote management system (RMS) Water supply module External air pump
Chemistry Analyzer	BS-430、BS-450、BS-460	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode

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		Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code module Water supply unit Probe clog detection module
Chemistry Analyzer	BS-230、BS-240	ISE Module, 4-channel (No consumables) Sodium Electrode Potassium Electrode Chloride Electrode Reference Electrode Lithium Electrode Spacer Electrode Reagent Pack Na/K/Cl Cleaning Solution Kit Troubleshooting Kit Urine Diluent, 125 ml Urine Diluent, 500 ml Bi-Level Quality Control Kit Tri-Level Quality Control Kit CD80 detergent Reaction cuvette Mindray reagent bottles Bar code reader(optional)
Chemiluminescence Immunoassay Analyzer	CL-2000i、CL-2200i	Hand-held bar code reader External vacuum pump Reaction cuvette Waste Bin
Chemiluminescence Immunoassay Analyzer	CL-1000i、CL-1200i	Built-in sample bar code reader Built-in reagent bar code reader Reaction cuvettes. waste container
α-Amylase（α-AMY）Kit（IFCC Method）	/	/

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Aspartate Aminotransferase（AST）Kit（IFCC Method）	/	/
Gamma-Glutamyltransferase（GGT）Kit（Szasz Method /IFCC stand.）	/	/
Lactate Dehydrogenase（LDH）Kit（IFCC Method）	/	/
Alanine Aminotransferase（ALT）Kit（IFCC Method）	/	/
C-Reactive Protein Kit(Turbidimetry Method)	/	/
Apolipoprotein B Kit (Turbidimetry Method)	/	/
Apolipoprotein A1 Kit (Turbidimetry Method)	/	/
Triglycerides Kit(GPO-POD Method)	/	/
Bilirubin Total Kit(DSA Method)	/	/
Creatinine Kit(Modified Jaffe Method)	/	/
Albumin Kit(Bromcresol Green Method)	/	/
Bilirubin Direct Kit(DSA Method)	/	/
Total Protein Kit(Biuret Method)	/	/
Magnesium Kit(Xylidyl Blue Method)	/	/
α-Hydroxybutyrate Dehydrogenase Kit(DGKC Method)	/	/
Total Cholesterol kit(CHOD-POD Method)	/	/
Alkaline Phosphatase Kit(IFCC Modified Method)	/	/
Urea Kit(Urease-GLDH,UV Method)	/	/
Uric Acid Kit(Uricase-peroxidase Method)	/	/

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Glucose Kit (GOD-POD Method)	/	/
Phosphorus Kit(Phosphomolybdate Method)	/	/
Calcium Kit(Arsenazo III Method)	/	/
Lipoprotein(a) Kit(Turbidimetry Method)	/	/
Complement C3 Kit(Turbidimetry Method)	/	/
Complement C4 Kit(Turbidimetry Method)	/	/
Immunoglobulin M Kit(Turbidimetry Method)	/	/
Immunoglobulin G Kit(Turbidimetry Method)	/	/
Prealbumin Kit(Turibidimetry Method)	/	/
Glucose Kit (HK Method)	/	/
Immunoglobulin A Kit(Turbidimetry Method)	/	/
Bilirubin Total Kit(VOX Method)	/	/
Creatine Kinase Kit(IFCC Method)	/	/
Total Bile Acids Kit(Enzymatic Cycling assay)	/	/
Creatinine Kit(Sarcosine Oxidase Method)	/	/
HDL-Cholesterol kit(Direct Method)	/	/
Bilirubin Direct Kit(VOX Method)	/	/
LDL-Cholesterol Kit(Direct Method)	/	/
Creatine Kinase-MB Kit(IFCC Method)	/	/

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HDL&LDL Cholesterol Control P	/	/
Prealbumin Control N&P	/	/
Lipids Calibrator	/	/
Specific Proteins Calibrator	/	/
Multi Sera Calibrator	/	/
CK-MB Calibrator	/	/
Lipoprotein(a) Calibrator	/	/
Multi Control Sera N Multi Control Sera P	/	/
Prealbumin Calibrator	/	/
Lipoprotein(a) Control N&P	/	/
Lipids Control N Lipids Control P	/	/
CK-MB Control N CK-MB Control p	/	/
Specific Proteins Control N Specific Proteins Control P	/	/
Cholinesterase(CHE) Kit (DGKC Method)	/	/
Carbon Dioxide (CO2) Kit (Enzymic Method)	/	/
Iron (Fe) Kit (Colorimetric Assay)	/	/
Fructosamine (FUN) Kit(Colorimetric Assay)	/	/
Antibodies Against Streptolysin O Kit(Particle-enhanced Immunoturbidimetric Assay Method	/	/
Homocysteine Kit(Enzymatic Assay Method)	/	/
Rheumatoid Factor Kit(Particle-enhanced Immunoturbidimetric Assay Method)	/	/

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Lipase Kit(Enzymatic Colorimetric Assay Method)	/	/
Hemoglobin A1c Kit (Enzymatic Assay Method)	/	/
Unsaturated Iron Binding Capacity (UIBC) Kit (Colorimetric Method)	/	/
Microalbuimn (MALB) Kit	/	/
Ferritin (FER) Kit	/	/
Transferrin (TRF) Kit	/	/
TRF Calibrator	/	/
TRF Control	/	/
FER Calibrator	/	/
Multimmun Control	/	/
MALB Calibrator	/	/
MALB Control	/	/
UIBC Control	/	/
UIBC Calibrator	/	/
α-L-Fucosidase Kit (CNPF method)	/	/
5′-Nucleotidase Kit (Enzymatic Colorimetric Method)	/	/
Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	/	/
Cystatin C Kit (Turbidimetry Method)	/	/
β2-Microglobulin Kit (Turbidimetry Method)	/	/
5'-NT Calibrator	/	/
5'-NT Control	/	/
ADA Control	/	/
ADA Calibrator	/	/
AFU Control	/	/
ASO Calibrator	/	/
CysC Calibrator	/	/

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CysC Control	/	/
HbA1c Calibrator	/	/
HCY Calibrator	/	/
HS-CRP Calibrator	/	/
RF Calibrator	/	/
TBA Control	/	/
β2-MG Calibrator	/	/
β2-MG Control	/	/
Free Triiodothyronine（CLIA）	/	/
Free Thyroxine（CLIA）	/	/
Total Triiodothyronine（CLIA）	/	/
Total Thyroxine（CLIA）	/	/
Thyroid-stimulating Hormone（CLIA）	/	/
Follicle Stimulating Hormone（CLIA）	/	/
Luteinizing Hormone（CLIA）	/	/
Prolactin（CLIA）	/	/
Estradiol（CLIA）	/	/
Estriol（CLIA）	/	/
Testosterone（CLIA）	/	/
Progesterone（CLIA）	/	/
Total β Human Chorionic Gonadotropin（CLIA）	/	/
Free T3 Calibrators	/	/
Free T4 Calibrators	/	/
Total T3 Calibrators	/	/
Total T4 Calibrators	/	/
TSH Calibrators	/	/
FSH Calibrators	/	/
LH Calibrators	/	/
Prolactin Calibrators	/	/
Estradiol Calibrators	/	/
Estriol Calibrators	/	/
Testosterone Calibrators	/	/
Progesterone Calibrators	/	/
Total β HCG Calibrators	/	/

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Thyroid Function Multi Control	/	/
Reproductive Multi Control	/	/
Carcinoembryonic Antigen（CLIA）	/	/
Alpha-fetoprotein（CLIA）	/	/
Cancer Antigen 125（CLIA）	/	/
Cancer Antigen 15-3（CLIA）	/	/
Carbohydrate Antigen 19-9（CLIA）	/	/
CEA Calibrators	/	/
AFP Calibrators	/	/
CA125 Calibrators	/	/
CA15-3 Calibrators	/	/
CA19-9 Calibrators	/	/
Ferritin（CLIA）	/	/
Ferritin Calibrators	/	/
Wash Buffer	/	/
Substrate solution	/	/
Antistreptolysin "O" （ASO）Kit (Latex Immunoturbidimetric Method)	/	/
Antistreptolysin "O" Calibrator	/	/
ASO/CRP/RF triple Control	/	/
Cystatin C（CysC)Kit (Latex Immunoturbidimetric Method)	/	/
Cystatin C Calibrator	/	/
Cystatin C Control	/	/
Full Range C-Reactive Protein（FR-CRP）Kit(Latex Immunoturbidimetric Method)	/	/
C-reactive Protein Calibrator	/	/
Rheumatoid Factor（RF）Kit(Immunoturbidimetric Method）	/	/
Rheumatoid Factor Calibrator	/	/
β2-Microglobulin（β2-MG） Kit (Latex Immunoturbidimetric Method)	/	/
β2-Microglobulin Control	/	/
β2-Microglobulin Calibrator (for Serum)	/	/
β2-Microglobulin Calibrator (for Urine)	/	/
D-Dimer kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Angiotensin Converting Enzyme (ACE) Kit (Enzymatic Colorimetric Assay Method)	/	/

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Retinol Binding Protein (RBP) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Glucose-6-Phosphate Dehydrogenase (G6PD) Kit (UV Enzymatic Method)	/	/
Myoglobin (MYO) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
Immunoglobubin E (IgE) Kit (Particle-enhanced Immunoturbidimetric Assay Method)	/	/
β-Hydroxybutyrate (β-HB) Kit (Enzymatic Colorimetric Method)	/	/
High Sensitivity C-reaction Protein Kit （Particle-enhanced Immunoturbidimetric Assay Method）	/	/
HbA1c control N	/	/
HbA1c control P	/	/
Rheumatism Control N	/	/
Rheumatism Control P	/	/
HCY Control N	/	/
HCY Control P	/	/
FUN Control P	/	/
CO2 Control N	/	/
D-Dimer Calibrator	/	/
ACE Calibrator	/	/
RBP Calibrator	/	/
MYO Calibrator	/	/
IgE Calibrator	/	/
β-HB Calibrator	/	/
D-Dimer Control	/	/
ACE Control	/	/
RBP Control	/	/
G6PD Control	/	/
β-HB Control	/	/
Sample Processing System	SPL 1000	/
Troponin I(CLIA)	/	/
Troponin I Calibrators	/	/
B-type natriuretic peptide(CLIA)	/	/
BNP Calibrators	/	/
Myoglobin(CLIA)	/	/
MYO Calibrators	/	/

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

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

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America

CERTIFICATE

No. QS5 044751 0140 Rev. 06

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 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.: **SH2405501**

Effective Date: **2024-08-28**

Expiry Date: **2026-06-30**

Date of Issue: 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

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Overall Scope Statement:

Design and Development, Production, Service and Distribution of 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, Endoscope Light Source and Accessories, 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 Immunoassay 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, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer, Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Wireless Module, Wireless Device, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System

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Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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证书号： QS5 044751 0140 Rev. 06

证书持有者： **深圳迈瑞生物医疗电子股份有限公司**

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦 518057

组织机构代码: 914403007084678371

认 证 标 志:

认 证 范 围: 证书范围见第2页

认证标准: ISO 9001:2015

TÜV SÜD America Inc.认证机构证明上述公司已经建立并保持满足上述所列标准要求的质量管理体系。

报告号: SH2405501

生效期: 2024-08-28

到期时间: 2026-06-30

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日期， 2024-09-25

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深圳迈瑞生物医疗电子股份有限公司

中国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
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中国深圳市光明区南环大道1203号
邮编：518106

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日期， 2024-09-25

(Renee Walker)
Director, US Certification Body, MHS

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

TÜV SÜD Product Service

Certificate

No. Q5 044751 0164 Rev. 06

Holder of Certificate: **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 EN ISO 13485 tuvsud.com/ps-cert

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Report No.: SH2405501

Valid from: 2024-08-15
Valid until: 2026-08-31

Date, 2024-08-15

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

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

Design and Development, Production, Service and Distribution of:
Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments;
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Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Service and Distribution of:
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Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

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TÜV SÜD Product Service

认 证 证 书

证书号. Q5 044751 0164 Rev. 06

证书持有者： **深圳迈瑞生物医疗电子股份有限公司**

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦

518057

认证标志：

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

认证范围： **设计和开发、生产、服务和分销: 有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息范围见附件)**

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生效期： 2024-08-15

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发证日期, 2024-08-15

Christoph Dicks

Head of Certification/Notified Body

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证书号. Q5 044751 0164 Rev. 06

认证标准：

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
医疗器械 - 质量管理体系 - 用于法规的要求

生产场地：

深圳迈瑞生物医疗电子股份有限公司
中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
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深圳迈瑞生物医疗电子股份有限公司
中华人民共和国深圳市光明区南环大道1203号 518106

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All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

1) Use of this product is conducted as instructed in this operation manual by Mindray authorized personnel or skilled/trained clinical professionals.;
2) The product is stored and transported as instructed in the operation manual and the labeling;
3) The product is used only on the specified models.

Warranty

Free service will be provided to:

- Products that are covered by the warranty terms of Mindray.

Pay service will be provided to:

1) Expired products;
2) Products within the warranty period, but are damaged by improper use or human error, stored in improper environment, or damaged by force majeure or other reason not caused by the product itself.

Return Procedure

Follow the procedure below to return products to Mindray if needed.

Contact Mindray customer service department, inform them the product name and lot No. (the name and lot No. are labeled on the outer package of the product). If the name and lot No. are not legible, your return request will not be accepted. Please specify the product name, model, lot No. and the return reason.

M-52DIFF Lyse

[Product]

M-52DIFF Lyse

[Model]

M-52DIFF

[Specification]

500mL×4

[Intended use]

M-52DIFF Lyse dissolves RBCs and differentiates WBCs.

[Principle]

M-52DIFF lyse dissolves RBCs in the blood cell analysis process, it processes WBCs to intensify the difference of the WBC sub-populations, and incorporates laser scatter and flow cytometry to realize DIFF channel WBC analysis.

[Ingredients]

Surfactant..... .....<35g/L

[Storage condition and shelf life]

The product will be stable for 2 years when stored at 2℃ to 30℃(35℉ to 86℉), and the relative humidity must not exceed 90%. The working temperature range of the product is consistent with that of its applicable instruments. The open-vial validity is 60 days.

[Applicable analyzer models]

The product applies to BC-5000, BC-5150, BC-5120, BC-5130 and BC-5140 Auto Hematology Analyzers manufactured by Shenzhen Mindray Bio-Medical Electronics Co., Ltd..

[SAMPLE REQUIREMENT]

Fresh human whole blood anticoagulated. Do not use contaminated samples.

[MATERIALS REQUIRED BUT NOT PROVIDED]

The following materials are required but not provided with the product: Mindray-manufactured measurement instruments and matched reagents.

[Instructions for use]

1. Restore the M-52DIFF lyse to usage temperature;
2. Open the external packing and insert the pickup tube into the reagent container based on the matching color of the reagent cap and the connector of analyzer cap assembly;
3. Screw the cap assembly tight and replace the reagent according to the operator's manual of the analyzer;
4. Run a blank count and check the results. If the results meet the blank count requirements defined in the operator's manual of the analyzer, the newly installed reagent can be used for sample analysis. See the operator's manual of the analyzer for details.

[CUT-OFF VALUE/REFERENCE INTERVALS]

Not applicable.

[RESULT ELABORATION]
Not applicable.

[LIMITATIONS]
Not applicable.

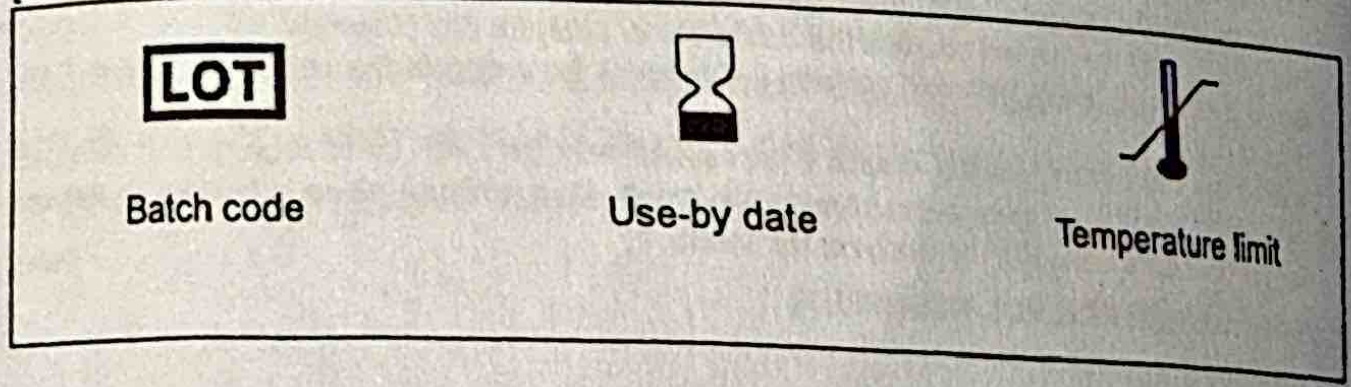
[PRODUCT SPECIFICATIONS]
1. Appearance: transparent liquid, no sediments, grains or flocculi.
2. Blank count results: the blank count results of M-52DIFF lyse tested on Mindray Analyzers meet the requirements in Table 1.

Table 1 Requirements of M-52DIFF lyse blank count

Test parameter	Blank count requirements
WBC	$\leq 0.2\times10^9$/L
HGB	≤1g/L

[PRECAUTIONS]
1. For professional use in vitro diagnosis only.
2. Read the package insert carefully before using this product. It shall be used before the expiration date and disposed of properly when expired.
3. Do not use the reagent if it is frozen.
4. If the blank count is abnormal after the reagent is transported, place it still for 24 hours at room temperature before using it.
5. If the reagent is polluted or affected by other factors and becomes abnormal, stop using it and replace it with a normal one.
6. Dispose of the waste, residual and contaminated packing based on local regulations.
7. The following factors can affect the sample analysis: expired or ineffective reagent; reagent polluted by dust in the air; improper disposal of the sample; mixed with or used with reagents produced by other company; mixed use of residual from the old container and the newly-opened; used in condition other than specified.
8. Take the necessary precautions for the use of the product. Do not swallow. Avoid contact with skin and mucous membranes. If you accidentally take the reagent into your mouth, or the reagents accidentally spill on your skin or into your eyes, wash them off with plenty of water and go seek medical treatment if necessary.
9. Disposal of waste liquid and materials should be in accordance with local guidelines.
10. The Material Safety Data Sheet (SDS) is available upon request
11. All identified risks have been reduced as far as possible by generally acknowledged state of art, and the overall residual risk is acceptable.
12. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

[GRAPHICAL SYMBOLS]



HUMIDITY LIMITATION

Manufacturer

In vitro diagnostic medical device

CATALOGUE NUMBER

Authorized representative in the European Community

Consult instructions for use

European Conformity

Unique Device Identifier

[REFERENCES]

Not applicable.

[COMPANY CONTACT]

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680
EC-Representative:	Shanghai International Holding Corp. GmbH(Europe)
Address:	Eiffestraβe 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726

[Approval Date of the Operator's Manual]

2023.08.05

Lisante M-52DIFF

[Nombre del product]
Lisante M-52DIFF

[Modelo]

M-52DIFF
[Especificación del paquete]
500mL×4

[Uso previsto]
El lisante M-52DIFF disuelve los eritrocitos y diferencia los leucocitos.

[Principio]
El lisante M-52DIFF disuelve los eritrocitos en el proceso de análisis de glóbulos sanguíneos. Procesa los leucocitos para intensificar la diferencia entre sus subpoblaciones e incorpora la dispersión láser y la citometría de flujo para realizar el análisis de leucocitos en el canal DIFF.
6 Ingredientes

Tensoactivo..... <35 g/l

[Condición de almacenamiento y vida útil]
El producto es estable durante 2 años si se almacena a entre 2 ℃ y 30 ℃ (35 ℉ a 86 ℉); la humedad relativa no debe sobrepasar el 90 %. El intervalo de temperatura de funcionamiento del producto se corresponde con el de los instrumentos aplicables. La validez del vial abierto es de 60 días

[Modelos de analizador aplicables]
El producto se usa con los Analizadores automáticos para hematología BC-5000, BC-5150, BC-5120, BC-5130, BC-5140, BC-5160 y BC-5170 fabricados por Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

[REQUISITO DE LA MUESTRA]

Sangre humana completa reciente anticoagulada. No utilice muestras contaminadas.

[MATERIALES NECESARIOS PERO NO SUMINISTRADOS]
Los siguientes materiales son necesarios pero no se suministran con el producto: Instrumentos de medición fabricados por Mindray y reactivos compatibles.

[Instrucciones de uso]
1. Ponga el lisante M-52DIFF a temperatura de uso;
2. Abra el envase exterior e inserte el tubo de recogida en el envase de reactivo teniendo en cuenta el color de la tapa del reactivo y el del conector del conjunto del tapón del analizador;
3. Enrosque firmemente el conjunto del tapón y sustituya el reactivo siguiendo las instrucciones indicadas en el manual del operador del analizador;
4. Realice un recuento de blanco y compruebe los resultados. Si los resultados cumplen los requisitos del recuento de blanco definidos en el manual del operador del analizador, ya se puede utilizar el reactivo recién instalado para el análisis de muestras. Para obtener más detalles, consulte el manual del operador del analizador.

[VALOR DE CORTE/INTERVALOS DE REFERENCIA]
No procede.

[ELABORACIÓN DEL RESULTADO]
No procede.

[LIMITACIONES]
No procede.

[Características de rendimiento]
1. Aspecto: líquido transparente sin sedimentos, granos o flóculos.

2. Resultados del recuento de blanco: los resultados del recuento de blanco del lisante M-52DIFF probado en Mindray analizadores cumplen con los requisitos indicados en la tabla 1.

Tabla 1 Requisitos del recuento de blanco del lisante M-52DIFF

Parámetro de prueba	Requisitos del recuento de blanco
WBC	$\leq 0{,}2\times10^9$/l
HGB	≤1 g/l

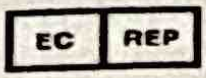
[PRECAUCIONES]

1. Para uso diagnóstico in vitro exclusivamente.
2. Leer detenidamente el prospecto antes de utilizar este producto. Se debe utilizar antes de su fecha de caducidad y desechar adecuadamente una vez caducado.
3. No utilizar el reactivo si está congelado.
4. Si el recuento de blanco no es normal tras el transporte del reactivo, déjelo reposar 24 horas a temperatura ambiente antes de usarlo.
5. Si el reactivo está contaminado o le afectan otros factores y se considera que es anómalo, no usarlo y sustituirlo con uno normal.
6. Eliminar los deshechos, residuos y envases contaminados según la normativa local.
7. Los siguientes factores pueden afectar al análisis de la muestra: reactivo caducado o ineficaz; reactivo contaminado por polvo en el aire; manipulación inadecuada de la muestra; mezclado o utilizado con reactivos producidos por otra compañía; mezcla de los restos de un envase antiguo con los del nuevo; utilización en condiciones distintas a las especificadas.
8. Tome las precauciones necesarias para el uso del producto. No los ingiera. Evite el contacto con la piel y las membranas mucosas. Si accidentalmente se lleva el reactivo a la boca o los reactivos se derraman accidentalmente en la piel o en los ojos, lávelos con abundante agua y busque tratamiento médico si es necesario.
9. El desecho de los residuos líquidos y materiales debe realizarse de acuerdo con las directrices locales.
10. La hoja de datos de seguridad de materiales (SDS) está disponible previa solicitud.
11. Todos los riesgos identificados se han reducido en la medida de lo posible por un estado de arte reconocido generalmente y el riesgo residual general es aceptable.
12. Cualquier incidente grave que se produzca en relación con el dispositivo se notificará al fabricante y a la autoridad competente del Estado miembro en el que se encuentren el usuario o el paciente.

[SÍMBOLOS GRÁFICOS]

		
CÓDIGO DE LOTE	Fecha de caducidad	LÍMITE DE TEMPERATURA
		
Límite de humedad	Fabricante	Dispositivo médico de diagnóstico in vitro

Número de catálogo



Representante autorizado en la Comunidad Europea

Consulte las instrucciones de uso

Conformidad con la legislación europea

Identificador único del dispositivo

[REFERENCIAS]

No procede.

[CONTACTO CON LA EMPRESA]

Fabricante: Dirección:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Dirección de correo electrónico:	service@mindray.com
Tel.:	+86 755 81888998
Fax:	+86 755 26582680
Representante de la CE:	Shanghai International Holding Corp. GmbH (Europa)
Dirección:	Eiffestraβe 80, Hamburgo 20537, Alemania
Tel.:	0049-40-2513175
Fax:	0049-40-255726

[FECHA DE APROBACIÓN DEL MANUAL DEL OPERADOR]

2022.06.06

Lyse M-52DIFF

[Nom du produit]

Lyse M-52DIFF

[Modèle]

M-52DIFF

[Spécification de conditionnement]

500 mL × 4

[Utilisation prevue]

Le réactif M-52DIFF Lyse dissout les globules rouges et permet de différencier les globules blancs.

[Principe]

Le réactif de lyse M-52DIFF dissout les globules rouges pendant le processus d'analyse des cellules sanguines, traite les globules blancs de manière à intensifier la différence entre les sous-populations de globules blancs et intègre une diffraction laser et une cytométrie de flux pour effectuer l'analyse des globules blancs dans le canal DIFF.

[Ingrédients]

Tensioactif ..... <35 g/l

[Conditions de stockage et durée de vie]

Le produit est stable pendant 2 ans s'il est stocké entre 2 °C et 30 °C (35 °F et 86 °F) à l'abri de la lumière, l'humidité relative ne doit pas dépasser 90 %. La plage de température de fonctionnement du produit est conforme à celle de ses instruments applicables. Un flacon ouvert est valide 60 jours.

[Modèles d'analyseur applicables]

Le produit convient aux automates d'hématologie BC-5000, BC-5150, BC-5120, BC-5130 et BC-5140 fabriqués par Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

[Exigences relatives aux échantillons]

Sang total humain frais anticoagulé. Ne pas utiliser d'échantillons contaminés.

[MATERIEL NECESSAIRE MAIS NON FOURNI]

Les éléments suivants sont requis mais ne sont pas fournis avec le produit : instruments de mesure fabriqués par Mindray et réactifs correspondants.

[Instructions d'utilisation]

1. Rétablissez la température d'utilisation du réactif de lyse M-52DIFF.
2. Ouvrez l'emballage extérieur et insérez le tube plongeur dans le conteneur du réactif en faisant correspondre la couleur du bouchon du réactif avec l'embout de l'analyseur.
3. Vissez complètement l'embout et replacez le réactif conformément au manuel d'utilisation de l'analyseur.
4. Effectuez un comptage à blanc et vérifiez les résultats. Si les résultats correspondent au comptage à blanc défini dans le manuel d'utilisation de l'analyseur, le tout nouveau réactif installé peut être utilisé pour l'analyse des échantillons. Consultez le manuel de l'opérateur pour en savoir plus.

[VALEUR SEUIL/INTERVALLE DE REFERENCE]

Non applicable.

[ELABORATION DES RESULTATS]

Non applicable.

[LIMITATIONS]

Non applicable.

[Caractéristiques de performances]

1. Aspect : liquide transparent, sans sédiments, cristaux ni flocules.
2. Résultats de comptage à blanc : le comptage à blanc du réactif de lyse M-52DIFF testé sur le BC-5000, BC-5150, BC-5120, BC-5130 et BC-5140 est conforme aux normes indiquées dans le Tableau 1.

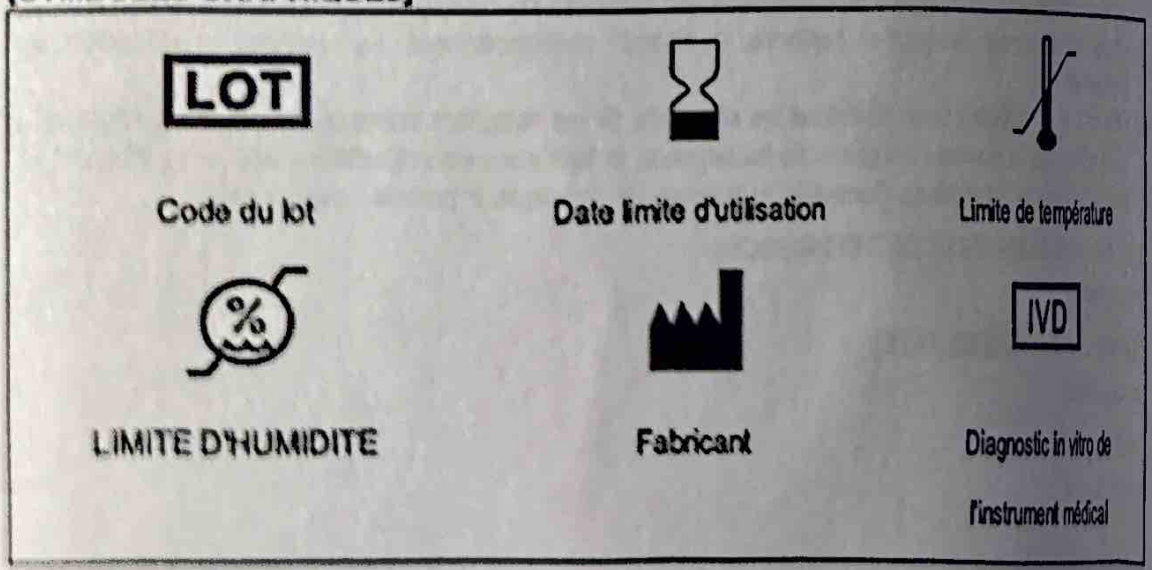
Tableau 1 Normes en matière de comptage à blanc du réactif de lyse M-52DIFF

Paramètre testé	Normes de comptage à blanc
GB	≤0,2 ×10^9/l
HGB	≤1 g/l

[PRECAUTIONS]

1. Destiné au diagnostic in vitro à usage professionnel uniquement.
2. Lisez attentivement la notice qui figure sur l'emballage du produit avant de l'utiliser. Utilisez le produit avant la date de péremption et, une fois périmé, procédez à sa mise au rebut.
3. N'utilisez pas le réactif s'il est congelé.
4. Si le comptage à blanc est anormal une fois que le réactif est transporté, laissez-le immobile pendant 24 heures à température ambiante avant de l'utiliser.
5. Si le réactif est pollué ou affecté par d'autres facteurs et devient anormal, cessez de l'utiliser et remplacer-le par un réactif normal.
6. Procédez à la mise au rebut des déchets, des résidus et de l'emballage contaminé en suivant la réglementation locale.
7. Les facteurs suivants peuvent affecter l'analyse de l'échantillon : réactif périmé ou inefficace, réactif pollué par la poussière présente dans l'air, mise au rebut inadéquate de l'échantillon, réactif mélangé ou utilisé avec des réactifs produits par une autre entreprise, mélange de résidu de l'ancien et du nouvel emballage, réactif utilisé dans des conditions autres que celles spécifiées.
8. Prenez les précautions nécessaires pour l'utilisation du produit. Ne pas avaler. Eviter le contact avec la peau et les muqueuses. Si le réactif pénètre accidentellement dans la bouche, ou en cas de contact accidentel des réactifs avec la peau ou les yeux, laver abondamment à l'eau et consulter un médecin si nécessaire.
9. L'élimination du matériel et des déchets liquides doit être effectuée en conformité avec les directives locales.
10. La fiche de données de sécurité (FDS) est disponible sur demande.
11. Tous les risques identifiés ont été réduits autant que possible à l'aide d'une méthode de pointe communément reconnue et le risque résiduel global est acceptable.
12. Tout incident grave survenu en lien avec le dispositif doit être signalé au fabricant et à l'autorité compétente de l'Etat membre dans lequel l'utilisateur et/ou le patient est établi.

[SYMBOLES GRAPHIQUES]



REFERENCE CATALOGUE

Représentant agréé pour la Communauté européenne

Consulter les instructions d'utilisation

Conformité européenne

Identifiant unique du dispositif

[REFERENCES]

Non applicable.

[COORDONNEES DE LA SOCIETE]

Fabricant:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Adresse:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Adresse de courriel:	service@mindray.com
Tél. :	+86 755 81888998
Télécopie:	+86 755 26582680
Représentant pour l'UE:	Shanghai International Holding Corp. GmbH (Europe)
Adresse:	Eiffestraβe 80, Hamburg 20537, Allemagne
Tél. :	0049-40-2513175
Télécopie:	0049-40-255726

[DATE D'APPROBATION DU MANUEL D'UTILISATION]

2022.06.06

Lise M-52DIFF

[Nome do produto]
Lise M-52DIFF

[Modelo]
M-52DIFF

[Especificação da Embalagem]
500mL×4

[Uso pretendido]
A lise M-52DIFF dissolve os RBCs e diferencia os WBCs.

[Princípio]
A lise M-52DIFF dissolve os RBCs no processo de análise de células sanguíneas. Ele processa WBCs para intensificar a diferença entre as subpopulações de WBC e incorpora dispersão a laser e citometria de fluxo para realizar a análise de WBC do canal DIFF.

[Composição]

Surfactante.....<35g/L

[Condições de armazenamento e prazo de validade]
O produto ficará estável durante 2 anos quando armazenado a 2 ℃ a 30 ℃(35°F a 86°F) e a humidade relativa não deve exceder%. A faixa de temperatura de trabalho do produto é consistente com a dos instrumentos aplicáveis. A validade do frasco aberto é de 60 dias.

[Modelos de analisadores aplicáveis]
O produto se aplica aos analisadores automáticos de hematologia BC-5000, BC-5150, BC-5120, BC-5130 e BC-5140 fabricados por Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

[Requisitos da amostra]
Anticoagulante de sangue total humano fresco. Não use amostras contaminadas.

[MATERIAIS NECESSÁRIOS, MAS NÃO FORNECIDOS]
Os seguintes materiais são necessários, mas não são fornecidos com o produto: Instrumentos de medição fabricados pela Mindray e reagentes correspondentes.

[Instruções de uso]
1. Retorne a lise M-52DIFF à temperatura de uso;
2. Abra a embalagem externa e insira o tubo de coleta no recipiente de reagente com base na cor correspondente da tampa do reagente e no conector do conjunto de tampas do analisador;
3. Feche bem o conjunto de tampas e substitua o reagente de acordo com o manual do operador do analisador;
4. Realize uma contagem em branco e verifique os resultados. Se os resultados atenderem aos requisitos de contagem em branco definidos no manual do operador do analisador, o reagente recém-instalado pode ser usado para análise de amostra. Consulte o manual do operador do analisador para obter detalhes.

[VALOR DE CORTE/INTERVALOS DE REFERÊNCIA]
Não aplicável.

[ELABORAÇÃO DO RESULTADO]
Não aplicável.

[LIMITAÇÕES]
Não aplicável.

[Características de desempenho]
1. Aparência: líquido transparente, sem sedimentos, grãos ou flocos.
2. Resultados de contagem em branco: os resultados de contagem em branco da lise M-52DIFF

testada em BC-5000, BC-5150, BC-5120, BC-5130 e BC-5140 atende às exigências na Tabela 1.

Tabela 1 Exigências de contagem em branco da lise M-52DIFF

Parâmetro de teste	Requisitos de contagem em branco
GB	≤0,2×10⁹/L
Hb	≤1g/L

[PRECAUÇÕES]

1. Somente para diagnóstico in vitro de uso profissional.
2. Leia o encarte da embalagem atentamente antes de usar o produto. Ele deve ser usado antes da data de validade e descartado adequadamente quando vencido.
3. Não use o reagente se ele estiver congelado.
4. Se a contagem de branco estiver anormal após o transporte do reagente, coloque-o ainda por 24 horas em temperatura ambiente antes de usá-lo.
5. Se o reagente estiver poluído ou for afetado por outros fatores e ficar anormal, pare de usá-lo e substitua-o por um normal.
6. Descarte os resíduos, resíduos e embalagens contaminadas com base nas regulamentações locais.
7. Os seguintes fatores podem afetar a análise da amostra: Reagente vencido ou ineficaz; reagente poluído por pó no ar; eliminação inadequada da amostra; misturado com ou utilizado com reagentes produzidos por outra empresa; utilização mista de resíduos do recipiente antigo e do recém-aberto; usado em condição diferente da especificada.
8. Tome as precauções necessárias para a utilização do produto. Não engolir. Evite o contato com a pele e membranas mucosas. Se os reagentes forem levados à boca ou derramados na pele ou nos olhos acidentalmente, lave-os com bastante água e procure tratamento médico, se necessário.
9. O descarte de resíduos líquidos e materiais deve estar de acordo com as diretrizes locais.
10. A Folha de dados de segurança (SDS) do material está disponível mediante solicitação
11. Todos os riscos identificados foram reduzidos tanto quanto possível pelo em geral reconhecido estado da arte, e o risco residual total é aceitável.
12. Qualquer incidente grave que tenha ocorrido em relação ao dispositivo deve ser comunicado ao fabricante e à autoridade competente do país em que o utilizador e/ou o paciente está estabelecido.

[SÍMBOLOS GRÁFICOS]

Código do lote

Data de validade

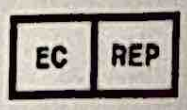
Limite de temperatura

LIMITAÇÃO DA UMIDADE

Fabricante

Diagnóstico in vitro dispositivo médico

NÚMERO DE CATÁLOGO



Representante autorizado na Comunidade Europeia

Consulte as instruções de uso

CE

Conformidade com a Europa

UDI

Identificador exclusivo do dispositivo

[REFERÊNCIAS]

Não aplicável.

[CONTATO DA EMPRESA]

Fabricante:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Endereço:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Endereço de e-mail:	service@mindray.com
Tel.:	+86 755 81888998
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Representantes na UE:	Shanghai International Holding Corp. GmbH (Europa)
Endereço:	Eiffestraße 80, Hamburgo 20537, Alemanha
Tel.:	0049-40-2513175
Fax:	0049-40-255726

[DATA DE APROVAÇÃO DO MANUAL DO OPERADOR]

2022.06.06

Лизирующий реагент M-52DIFF

[Наименование изделия]
Лизирующий реагент M-52DIFF

[Модель]

M-52DIFF

[Спецификации упаковки]

500 мл × 4

[Предусмотренное применение]
Лизирующий реагент M-52DIFF растворяет RBC и служит для дифференцировки WBC.

[Принцип работы]
Лизирующий реагент M-52DIFF растворяет RBC в процессе анализа клеток крови. Он служит для обработки WBC с целью усиления разницы между субпопуляциями WBC, а также применяется в анализе методом рассеяния лазерного излучения и проточной цитометрии для дифференцировки WBC в канале DIFF.

[Активные ингредиенты]

Поверхностно-активное вещество .....<35 г/л

[Условия хранения и срок годности при хранении]
Продукт будет оставаться стабильным в течение 2 лет при хранении при температуре от 2 до 30 °C (от 35 до 86 °F) при относительной влажности не более 90%. Диапазон рабочих температур продукта соответствует диапазону для применимых аппаратов. Срок годности в открытом флаконе составляет 60 дней.

[Вещество используется со следующими моделями анализаторов]
Вещество применяется с автоматизированными гематологическими анализаторамиBC-5000, BC-5150, BC-5120, BC-5130 и BC-5140 компании Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

[Требование к пробе]
Свежая цельная крови человека с антикоагулянтом. Не используйте загрязненные образцы.

[НЕОБХОДИМЫЕ МАТЕРИАЛЫ, НЕ ВХОДЯЩИЕ В КОМПЛЕКТ ПОСТАВКИ]
Следующие материалы необходимы, но не входят в комплект поставки: измерительные приборы и соответствующие реагенты производства компании Mindray.

[Инструкции по эксплуатации]
1. Доведите лизирующий реагент M-52DIFF до температуры эксплуатации.
2. Откройте внешнюю упаковку и вставьте приемную трубку в контейнер с реагентом в соответствии с цветом крышки контейнера и соединителя сопловой крышки анализатора.
3. Закрутите сопловую крышку до отказа и замените реагент в соответствии с руководством пользователя реагента.
4. Выполните холостой подсчет и проверьте результаты. Если результаты соответствуют требованиям к результатам холостого подсчета, указанным в руководстве пользователя анализатора, новый реагент может быть использован для анализа образцов. Для получения более подробной информации см. руководство пользователя анализатора.

[ЗНАЧЕНИЕ ОТСЕЧКИ/РЕФЕРЕНСНЫЕ ИНТЕРВАЛЫ]
Неприменимо.

[РАСШИФРОВКА РЕЗУЛЬТАТОВ]
Неприменимо.

[ОГРАНИЧЕНИЯ]
Неприменимо

[Эксплуатационные свойства]
1. Внешний вид: прозрачная жидкость, без осадка, гранул или хлопьев осадка

2. Результаты холостого подсчета: результаты холостого подсчета лизирующего реагента M-52DIFF анализаторовBC-5000, BC-5150, BC-5120, BC-5130 и BC-5140 соответствуют требованиям, указанным в Таблице 1.

Таблица 1. Требования к холостому подсчету лизирующего реагента M-52DIFF

Тестируемый параметр	Требования к холостому подсчету
WBC	≤0.2×10⁹/л
HGB	≤1 г/л

[МЕРЫ ПРЕДОСТОРОЖНОСТИ]

1. Только для профессиональной диагностики in vitro.
2. Перед использованием данного продукта внимательно прочитайте вкладыш. Его необходимо использовать до истечения срока годности и утилизировать надлежащим образом по истечении срока годности.
3. Не используйте реагент, если он заморожен.
4. Если после транспортировки реагента результат холостого подсчета не соответствует норме, перед использованием оставьте его на 24 часа при комнатной температуре.
5. Если реагент загрязнен или был подвержен воздействию других факторов и стал непригодным, прекратите использование и замените его.
6. Утилизируйте отходы, остатки и загрязненную упаковку в соответствии с местными нормативными требованиями.
7. На анализ проб могут влиять следующие факторы: просроченный или недействительный реагент; загрязнение реагента пылью в воздухе; неправильное обращение с пробой; смешивание или использование с реагентами других производителей; смешивание нового реагента с остатками предыдущего из другого контейнера во время использования; использование в условиях, отличных от указанных.
8. Примите необходимые меры предосторожности при использовании продукта. Не проглатывайте. Избегайте контакта с кожей и слизистыми оболочками. Если реагент случайно попал в рот, на кожу или в глаза, промойте большим количеством воды и при необходимости обратитесь за медицинской помощью.
9. Утилизация отработанной жидкости и материалов должна осуществляться в соответствии с местными правилами.
10. Паспорт безопасности материала (SDS) доступен по запросу.
11. Продукт отвечает современным требованиям, и все выявленные риски были сведены к минимуму, а общий остаточный риск является приемлемым.
12. О любом серьезном происшествии, связанным с устройством, следует сообщить производителю и компетентному органу государства-члена, в котором находятся пользователь и/или пациент.

[ГРАФИЧЕСКИЕ СИМВОЛЫ]

НОМЕР ПО КАТАЛОГУ

ПОЛНОМОЧЕННЫЙ ПРЕДСТАВИТЕЛЬ В ЕВРОПЕЙСКОМ СООБЩЕСТВЕ

ИНСТРУКЦИИ ПО ЭКСПЛУАТАЦИИ

Соответствие европейским стандартам

Уникальный идентификатор устройства

[СПИСОК ЛИТЕРАТУРЫ]

Неприменимо.

[КОНТАКТНАЯ ИНФОРМАЦИЯ КОМПАНИИ]

Изготовитель:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Адрес:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Электронная почта:	service@mindray.com
Телефон:	+86 755 81888998
Факс:	+86 755 26582680
Представительство в ЕС:	Shanghai International Holding Corp. GmbH(Europe)
Адрес:	Eiffestraβe 80, 20537 Hamburg, Germany
Телефон:	0049-40-2513175
Факс:	0049-40-255726

[ДАТА УТВЕРЖДЕНИЯ РУКОВОДСТВА ОПЕРАТОРА]

2022.06.06

M-52DIFF Lizi

[Ürün adı]

M-52DIFF Lizi

[Model]

M-52DIFF

[Ambalaj Spesifikasyon]

500mL×4

[Kullanım amacı]

M-52DIFF Lizi, RBC'leri çözer ve WBC'leri farklılaştırır.

[Prensip]

M-52DIFF lizi, kan hücresi analiz sürecinde RBC'leri çözer. WBC alt popülasyonları arasındaki farkı yoğunlaştırmak için WBC'leri işler ayrıca DIFF kanalı WBC analizini gerçekleştirmek için lazer dağılımı ve akış sitometrisini içerir.

[İçerik]

Yüzey aktif madde..... .....<35g/L

[Saklama koşulları ve raf ömrü]

Ürün, 2℃ ila 30℃ (35℉ ila 86℉) aralığında saklandığında 2 yıl boyunca stabil kalır, ayrıca bağıl nem %90'ı geçmemelidir. Ürünün çalışma sıcaklığı aralığı, geçerli aletlerinin çalışma sıcaklığı aralığıyla tutarlıdır. Açık flakon geçerliliği 60 gündür.

[Uygun analizör modelleri]

Ürün, Shenzhen Mindray Bio-Medical Electronics Co., Ltd. tarafından üretilen BC-5000, BC-5150, BC-5120, BC-5130 ve BC-5140 Otomatik Hematoloji Analizörlerine uygundur.

[Numune Gerekliliği]

Antikoagülasyonlu taze insan tam kanı. Kontamine olmuş numuneleri kullanmayın.

[ÜRÜNLE BİRLİKTE VERİLMEYEN ANCAK GEREKLİ OLAN MALZEMELER]

Şu malzemeler gereklidir ancak ürünle birlikte verilmez: Mindray tarafından üretilen ölçüm cihazları ve eşleşen reaktifler.

[Kullanım talimatları]

1. M-52DIFF lyse'i kullanım sıcaklığına getirin;
2. Dış ambalajı açın ve pikup tüpünü, eşleşen reaktif kapağı rengine ve analizör kapağı tertibatının konektörüne dayalı olarak reaktif kabına yerleştirin;
3. Kapak grubunu sıkıca vidalayın ve reaktifi analizörün kullanıcı el kitabına göre değiştirin;
4. Boş sayım yapın ve sonuçları kontrol edin. Sonuçların, analizörün kullanıcı el kitabında tanımlanan boş sayıp gerekliliğini karşılaması halinde yeni oluşturulan reaktif numune analizi için kullanılabilir. Ayrıntılar için analizörün kullanıcı el kitabını inceleyin.

[KESME DEĞERİ/REFERANS ARALIKLARI]

Geçerli değildir.

[SONUÇ DETAYLANDIRMASI]

Geçerli değildir.

[SINIRLAMALAR]

Geçerli değildir.

[Performans özellikleri]

1. Görünüş: şeffaf sıvı, tortusuz, taneciksiz veya topaklanmasız.
2. Boş sayım sonuçları: Mindray Analizörlerinde test edilen M-52DIFF lyse'in boş sayım sonuçları Tablo

1'de belirtilen gereklilikleri karşılamaktadır.

Tablo 1 M-52DIFF İzi boş sayımı gereklilikleri

Test parametresi	Boş sayım gereklilikleri
WBC	≤0,2×10⁹/L
HGB	≤1g/L

[ÖNLEMLER]

1. Yalnızca uzmanların in vitro tanısal kullanımına yöneliktir.
2. Bu ürünü kullanmadan önce prospektüsü dikkatlice okuyun. Son kullanma tarihinden önce kullanılmalı ve süresi dolduğunda uygun şekilde atılmalıdır.
3. Reaktif donmuşsa kullanmayın.
4. Reaktif taşındıktan sonra boş sayım anormalse kullanmadan önce oda sıcaklığında 24 saat bekletin.
5. Reaktifin kirlenmesi veya diğer faktörlerden etkilenmesi ve anormal hale gelmesi durumunda reaktifi kullanmayı bırakın ve normal bir reaktif ile değiştirin.
6. Atıkları, artıkları ve kontamine olmuş ambalajları yerel düzenlemelere uygun olarak atın.
7. Aşağıdaki faktörler numune analizini etkileyebilir: Son kullanma tarihi geçmiş veya etkisiz reaktif; havadaki tozla kirlenmiş reaktif; numunenin yanlış şekilde kullanılması; başka bir şirket tarafından üretilen reaktiflerle karıştırılması veya kullanılması; eski kaptan kalan artıkların ve yeni açılan kabın karışık kullanımı; belirtilenden farklı bir şekilde kullanılması.
8. Ürünün kullanımı için gerekli önlemleri alın. Yutmayın. Cilt ve mukoz membranları ile temasından kaçının. Reaktifi yanlışlıkla ağzınıza alırsanız veya reaktifler yanlışlıkla cildinize veya gözlerinize dökülürse bol suyla yıkayın ve gerekirse tıbbi tedavi alın.
9. Atık sıvı ve malzemeler, yerel yönetmeliklere uygun olarak bertaraf edilmelidir.
10. Malzeme Güvenlik Veri Formu (SDS) istek üzerine mevcuttur.
11. Tanımlanan tüm riskler, genel olarak kabul gören son teknoloji ile mümkün olduğunca azaltılmıştır ve geriye kalan riskler kabul edilebilirdir.
12. Cihaz ile ilgili olarak meydana gelen tüm ciddi olaylar, üreticiye ve kullanıcının ve/veya hastanın bulunduğu Üye Devletin yetkili makamına bildirilmelidir.

[GRAFİK SEMBOLLER]

Seri kodu

Son kullanma tarihi

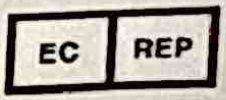
Sıcaklık sınırı

NEM LİMİTİ

Üretici

İn vitro tanısal tıbbi cihaz

KATALOG NUMARASI



Avrupa Topluluğundaki yetkili temsilci

Kullanım talimatlarına başvurun

CE	UDI
Avrupa Uyumluluğu	Benzersiz cihaz tanımlayıcısı

[REFERANSLAR]

Geçerli değildir.

[ŞİRKET İLETİŞİM]

Üretici:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Adres:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
E-Posta Adresi:	service@mindray.com
Tel:	+86 755 81888998
Faks:	+86 755 26582680
AB-Temsilcisi:	Shanghai International Holding Corp. GmbH(Europe)
Adres:	Eiffestraße 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Faks:	0049-40-255726

[KULLANIM KILAVUZUNUN ONAY TARİHİ]

2022.06.0

CE

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Contents of this manual are subject to change without prior notice.

All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

1) Use of this product is conducted as instructed in this operation manual by Mindray authorized personnel or skilled/trained clinical professionals;
2) The product is stored and transported as instructed in the operation manual and the labeling;
3) The product is used only on the specified models.

Warranty

Free service will be provided to:

- Products that are covered by the warranty terms of Mindray.

Pay service will be provided to:

1) Expired products;
2) Products within the warranty period, but are damaged by improper use or human error, stored in improper environment, or damaged by force majeure or other reason not caused by the product itself.

Return Procedure

Follow the procedure below to return products to Mindray if needed.

Contact Mindray customer service department, inform them the product name and lot No. (the name and lot No. are labeled on the outer package of the product). If the name and lot No. are not legible, your return request will not be accepted. Please specify the product name, model, lot No. and the return reason.

M-52LH Lyse

1 Product
M-52LH Lyse
2 Model
M-52LH
3 Specification
100mL×4
4 Intended use
M-52LH Lyse dissolves RBCs, realizes WBC counting, basophil differential and hemoglobin measurement.
5 Principle
M-52LH lyse further processes the blood cells that have been processed by M-52DIFF lyse, it turns hemoglobin into methemoglobin, which then measured by the colorimetric method. It also processes WBCs to intensify the difference between basophils and other WBC sub-populations, and incorporates laser scatter and flow cytometry to realize basophil analysis.
6 Ingredients
Quaternary ammonium salts.....<50g/L
Isopropanol.....2-10g/L
7 Storage condition and shelf life
The product must be stored in the temperature of 2℃–30℃, and the relative humidity must not exceed 90%. The storage room must be well ventilated and without corrosive gas. The shelf life is 2 years. The product must be used in the temperature of 10℃–30℃, and it stays valid for 60 days after being opened.
8 Applicable analyzer models
The product applies to BC-5000, BC-5150, BC-5120, BC-5130 and BC-5140 Auto Hematology Analyzers manufactured by Shenzhen Mindray Bio-Medical Electronics Co., Ltd..
9 SAMPLE REQUIREMENT
Fresh human whole blood anticoagulated. Do not use contaminated samples.
10 MATERIALS REQUIRER BUT NOT PROVIDED
The following materials are required but not provided with the product: Mindray-manufactured measurement instruments and matched reagents.
11 Instructions for use
1) Restore the M-52LH lyse to usage temperature;
2) Open the external packing and insert the pickup tube into the reagent container based on the matching color of the reagent cap and the connector of analyzer cap assembly;
3) Screw the cap assembly tight and replace the reagent according to the operator's manual of the analyzer;
4) Run a blank count and check the results. If the results meet the blank count requirements defined in the operator's manual of the analyzer, the newly installed reagent can be used for sample analysis. See the operator's manual of the analyzer for details.
12 CUT-OFF VALUE/REFERENCE INTERVALS
Not applicable.
13 RESULT ELABORATION
Not applicable.
14 LIMITATIONS
Not applicable.
15 PRODUCT SPECIFICATIONS
1) Appearance: transparent liquid, no sediments, grains or flocculi.

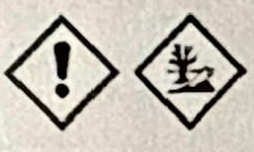
2) Blank count results: the blank count results of M-52LH lyse tested on Mindray Analyzers meet the requirements in Table 1.

Table 1 Requirements of M-52LH lyse blank count

Test parameter	Blank count requirements
WBC	≤0.2×10⁹/L
HGB	≤1g/L

16 PRECAUTIONS

1) For professional use in vitro diagnosis only.
2) Read the package insert carefully before using this product. It shall be used before the expiration date and disposed of properly when expired.
3) Do not use the reagent if it is frozen.
4) If the blank count is abnormal after the reagent is transported, place it still for 24 hours at room temperature before using it.
5) If the reagent is polluted or affected by other factors and becomes abnormal, stop using it and replace it with a normal one.
6) Dispose of the waste, residual and contaminated packing based on local regulations.
7) The following factors can affect the sample analysis: expired or ineffective reagent; reagent polluted by dust in the air; improper disposal of the sample; mixed with or used with reagents produced by other company; mixed use of residual from the old container and the newly-opened; used in condition other than specified.
8) Take the necessary precautions for the use of the product. Do not swallow. Avoid contact with skin and mucous membranes. If you accidentally take the reagent into your mouth, or the reagents accidentally spill on your skin or into your eyes, wash them off with plenty of water and go seek medical treatment if necessary.
9) Disposal of waste liquid and materials should be in accordance with local guidelines.
10) The Material Safety Data Sheet (SDS) is available upon request
11) All identified risks have been reduced as far as possible by generally acknowledged state of art, and the overall residual risk is acceptable.
12) Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
13) This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



Warning

H411	Toxic to aquatic life with long lasting effects.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
Prevention	
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P264	Wash all exposed external body areas thoroughly after handling.
Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313	If eye irritation persists: Get medical advice/attention.
P391	Collect spillage.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation

17 GRAPHICAL SYMBOLS

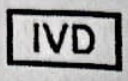
Batch code

Use-by date

Temperature limit

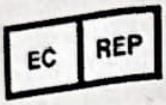
HUMIDITY LIMITATION

Manufacturer



In vitro diagnostic medical device

CATALOGUE NUMBER



Authorized representative in the European Community

Consult instructions for use

European Conformity

Unique Device Identifier

18 REFERENCES

Not applicable.

19 COMPANY CONTACT

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680
EC-Representative:	Shanghai International Holding Corp. GmbH(Europe)
Address:	Eiffestraβe 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726

20 Approval Date of the Operator's Manual

2022.06.06

Lisante M-52LH

1 Nombre del producto

Lisante M-52LH

2 Modelo

M-52LH

3 Especificación del paquete

100mL×4

4 Uso previsto

El lisante M-52LH disuelve los eritrocitos, efectúa el recuento de leucocitos, la diferenciación de basófilos y la medición de la hemoglobina.

5 Principio

El lisante M-52LH hace un análisis más profundo de las células sanguíneas que ha procesado el lisante M-52DIFF, convierte la hemoglobina en metahemoglobina, que luego se mide con el método colorimétrico. También procesa WBC para intensificar la diferencia entre basófilos y otras subpoblaciones de WBC, además, incorpora dispersión láser y citometría de flujo para realizar el análisis de basófilos.

6 Ingredientes

Sales de amonio cuaternario ..... <50 g/l

Isopropanol ..... 2-10 g/l

7 Condición de almacenamiento y vida útil

El producto se debe almacenar a una temperatura de entre 2 °C y 30 °C y la humedad relativa no debe superar el 90 %. La habitación de almacenamiento debe estar bien ventilada y sin gases corrosivos.
Su vida útil es de 2 años.
El intervalo de temperatura de funcionamiento del producto se corresponde con el de los instrumentos aplicables. La validez del vial abierto es de 60 días

8 Modelos de analizador aplicables

Este producto se usa con analizadores automáticos para hematología BC-5000, BC-5150, BC-5120, BC-5130 y BC-5140 fabricados por Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

9 REQUISITO DE LA MUESTRA

Sangre humana completa reciente anticoagulada. No utilice muestras contaminadas.

10 MATERIALES NECESARIOS PERO NO SUMINISTRADOS

Los siguientes materiales son necesarios pero no se suministran con el producto: Instrumentos de medición fabricados por Mindray y reactivos compatibles.

11 Instrucciones de uso

1) Ponga el lisante M-52LH a temperatura de uso;
2) Abra el envase exterior e inserte el tubo de recogida en el envase de reactivo teniendo en cuenta el color de la tapa del reactivo y el del conector del conjunto del tapón del analizador;
3) Enrosque firmemente el conjunto del tapón y sustituya el reactivo siguiendo las instrucciones indicadas en el manual del operador del analizador;
4) Realice un recuento de blanco y compruebe los resultados. Si los resultados cumplen los requisitos del recuento de blanco definidos en el manual del operador del analizador, ya se puede utilizar el reactivo recién instalado para el análisis de muestras. Para obtener más detalles, consulte el manual del operador del analizador.

12 VALOR DE CORTE/INTERVALOS DE REFERENCIA

No procede.

13 ELABORACIÓN DEL RESULTADO

No procede.

14 LIMITACIONES

No procede.

15 Características de rendimiento

1) Aspecto: líquido transparente sin sedimentos, granos o flóculos.
2) Resultados del recuento de blanco: los resultados del recuento de blanco del lisante M-52LH probado en Mindray analizadores cumplen con los requisitos indicados en la tabla 1.

Tabla 1 Requisitos del recuento de blanco del lisante M-52LH

Parámetro de prueba	Requisitos del recuento de blanco
WBC	≤0,2×10⁹/l
HGB	≤1 g/l

16 PRECAUCIONES

1) Para uso diagnóstico in vitro exclusivamente.
2) Leer detenidamente el prospecto antes de utilizar este producto. Se debe utilizar antes de su fecha de caducidad y desechar adecuadamente una vez caducado.
3) No utilizar el reactivo si está congelado.
4) Si el recuento de blanco no es normal tras el transporte del reactivo, déjelo reposar 24 horas a temperatura ambiente antes de usarlo.
5) Si el reactivo está contaminado o le afectan otros factores y se considera que es anómalo, no usarlo y sustituirlo con uno normal.
6) Eliminar los deshechos, residuos y envases contaminados según la normativa local.
7) Los siguientes factores pueden afectar al análisis de la muestra: reactivo caducado o ineficaz; reactivo contaminado por polvo en el aire; manipulación inadecuada de la muestra; mezclado o utilizado con reactivos producidos por otra compañía; mezcla de los restos de un envase antiguo con los del nuevo; utilización en condiciones distintas a las especificadas.
8) Tome las precauciones necesarias para el uso del producto. No los ingiera. Evite el contacto con la piel y las membranas mucosas. Si accidentalmente se lleva el reactivo a la boca o los reactivos se derraman accidentalmente en la piel o en los ojos, lávelos con abundante agua y busque tratamiento médico si es necesario.
9) El desecho de los residuos líquidos y materiales debe realizarse de acuerdo con las directrices locales.
10) La hoja de datos de seguridad de materiales (SDS) está disponible previa solicitud.
11) Todos los riesgos identificados se han reducido en la medida de lo posible por un estado de arte reconocido generalmente y el riesgo residual general es aceptable.
12) Cualquier incidente grave que se produzca en relación con el dispositivo se notificará al fabricante y a la autoridad competente del Estado miembro en el que se encuentren el usuario o el paciente
13) Este producto contiene componentes clasificados según el Reglamento (CE) n.º 1272/2008:

Aviso	
H411	Tóxico para los organismos acuáticos, con efectos nocivos duraderos
H315	Provoca irritación cutánea.
H319	Provoca irritación ocular grave.
Prevención	
P273	No dispersar en el medio ambiente.
P280	Llevar guantes/prendas/gafas/máscara de protección.

P264	Lavarse todas las áreas corporales externas expuestas después de la manipulación.
Respuesta	
P305+P351+P338	EN CASO DE CONTACTO CON LOS OJOS: Aclarar cuidadosamente con agua durante varios minutos. Quitar las lentes de contacto, si lleva y resulta fácil. Seguir aclarando.
P337+P313	Si persiste la irritación ocular: Consultar a un médico.
P391	Recoger el vertido.
P302+P352	EN CASO DE CONTACTO CON LA PIEL: Lavar con abundante agua.
P332+P313	En caso de irritación cutánea: Consultar a un médico.
P362+P364	Quitar las prendas contaminadas y lavarlas antes de volver a usarlas.
Desecho	
P501	Eliminar el contenido/recipiente en el punto de recogida de residuos peligrosos o especiales autorizados conforme a la reglamentación local.

17 SÍMBOLOS GRÁFICOS

CÓDIGO DE LOTE

Fecha de caducidad

LÍMITE DE TEMPERATURA

HUMIDITY LIMITATION

Fabricante

Dispositivo médico de diagnóstico in vitro

Número de catálogo

Representante autorizado en la Comunidad Europea

Consulte las instrucciones de uso

Conformidad con la legislación europea

Identificador único del dispositivo

18 REFERENCIAS

No procede.

19 CONTACTO CON LA EMPRESA

Fabricante:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Dirección:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Dirección de correo electrónico:	service@mindray.com
Tel.:	+86 755 81888998
Fax:	+86 755 26582680
Representante de la CE:	Shanghai International Holding Corp. GmbH (Europa)
Dirección:	Eiffestraβe 80, Hamburgo 20537, Alemania
Tel.:	0049-40-2513175
Fax:	0049-40-255726

20 FECHA DE APROBACIÓN DEL MANUAL DEL OPERADOR

2022.06.06

Lyse M-52LH

1 Nom du produit
Lyse M-52LH
2 Modèle
M-52LH
3 Spécification de conditionnement
100 mL× 4
4 Utilisation prévue
La lyse M-52LH dissout les globules rouges, réalise le comptage des globules blancs, ainsi que la mesure différentielle des basophiles et la mesure du taux d'hémoglobine.
5 Principe
Le réactif de lyse M-52LH réalise un autre traitement des cellules sanguines ayant été traitées par le réactif de lyse M-52DIFF. Il transforme l'hémoglobine en methémoglobine, qui est ensuite mesurée par une méthode colorimétrique. Il réalise également un traitement sur les globules blancs afin d'intensifier la différence entre les basophiles et d'autres sous-populations de globules blancs, et intègre une diffraction laser et une cytométrie de flux permettant l'analyse des basophiles.
6 Ingrédients
Sels d'ammonium quaternaire .....<50 g/l
Isopropanol.....2 à 10 g/l
7 Conditions de stockage et durée de vie
Le produit doit être stocké à une température comprise entre 2 ℃ et 30 ℃ et l'humidité relative ne doit pas dépasser 90 %. La salle de stockage doit être bien ventilée et exempte de gaz corrosif. La durée de stockage est de 2 ans.
La plage de température de fonctionnement du produit est conforme à celle de ses instruments applicables. Un flacon ouvert est valide 60 jours.
8 Modèles d'analyseur applicables
Le produit convient aux automates d'hématologie BC-5000, BC-5150, BC-5120, BC-5130 et BC-5140 fabriqués par Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
9 Exigences relatives aux échantillons
Sang total humain frais anticoagulé. Ne pas utiliser d'échantillons contaminés.
10 MATERIEL NECESSAIRE MAIS NON FOURNI
Les éléments suivants sont requis mais ne sont pas fournis avec le produit : instruments de mesure fabriqués par Mindray et réactifs correspondants.
11 Instructions d'utilisation
1) Rétablissez la température d'utilisation du réactif de lyse M-52LH.
2) Ouvrez l'emballage extérieur et insérez le tube plongeur dans le conteneur du réactif en faisant correspondre la couleur du bouchon du réactif avec l'embout de l'analyseur.
3) Vissez complètement l'embout et replacez le réactif conformément au manuel d'utilisation de l'analyseur.
4) Effectuez un comptage à blanc et vérifiez les résultats. Si les résultats correspondent au comptage à blanc défini dans le manuel d'utilisation de l'analyseur, le tout nouveau réactif installé peut être utilisé pour l'analyse des échantillons. Consultez le manuel de l'opérateur pour en savoir plus.

12 VALEUR SEUIL/INTERVALLE DE REFERENCE
Non applicable.
13 ELABORATION DES RESULTATS
Non applicable.
14 LIMITATIONS
Non applicable.
15 Caractéristiques de performances
1) Aspect : liquide transparent, sans sédiments, cristaux ni flocules.
2) Résultats de comptage à blanc : le comptage à blanc du réactif de lyse M-52LH testé sur le BC-5000, BC-5150, BC-5120, BC-5130 et BC-5140 est conforme aux normes indiquées dans le Tableau 1.

Tableau 1 Normes en matière de comptage à blanc du réactif de lyse M-52LH

Paramètre testé	Normes de comptage à blanc
GB	≤0.2×10⁹/l
HGB	≤1 g/l

16 PRECAUTIONS

1. Destiné au diagnostic in vitro à usage professionnel uniquement.
2. Lisez attentivement la notice qui figure sur l'emballage du produit avant de l'utiliser. Utilisez le produit avant la date de péremption et, une fois périmé, procédez à sa mise au rebut.
3. N'utilisez pas le réactif s'il est congelé.
4. Si le comptage à blanc est anormal une fois que le réactif est transporté, laissez-le immobile pendant 24 heures à température ambiante avant de l'utiliser.
5. Si le réactif est pollué ou affecté par d'autres facteurs et devient anormal, cessez de l'utiliser et remplacer-le par un réactif normal.
6. Procédez à la mise au rebut des déchets, des résidus et de l'emballage contaminé en suivant la réglementation locale.
7. Les facteurs suivants peuvent affecter l'analyse de l'échantillon : réactif périmé ou inefficace, réactif pollué par la poussière présente dans l'air, mise au rebut inadéquate de l'échantillon, réactif mélangé ou utilisé avec des réactifs produits par une autre entreprise, mélange de résidu de l'ancien et du nouvel emballage, réactif utilisé dans des conditions autres que celles spécifiées.
8. Prenez les précautions nécessaires pour l'utilisation du produit. Ne pas avaler. Eviter le contact avec la peau et les muqueuses. Si le réactif pénètre accidentellement dans la bouche, ou en cas de contact accidentel des réactifs avec la peau ou les yeux, laver abondamment à l'eau et consulter un médecin si nécessaire.
9. L'élimination du matériel et des déchets liquides doit être effectuée en conformité avec les directives locales.
10. La fiche de données de sécurité (FDS) est disponible sur demande.
11. Tous les risques identifiés ont été réduits autant que possible à l'aide d'une méthode de pointe communément reconnue et le risque résiduel global est acceptable.
12. Tout incident grave survenu en lien avec le dispositif doit être signalé au fabricant et à l'autorité compétente de l'Etat membre dans lequel l'utilisateur et/ou le patient est établi.
13. Ce produit contient des composants classés comme suit conformément au règlement (CE) n° 1272/2008 :

Avertissement	
H411	Toxique pour les organismes aquatiques, entraîne des effets à long terme.
H315	Provoque une irritation cutanée.
H319	Provoque une sévère irritation des yeux.
Prévention	
P273	Eviter le rejet dans l'environnement.
P280	Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.
P264	Se laver soigneusement toutes les parties externes du corps exposées après manipulation.
Réponse	
P305+P351+P338	EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en

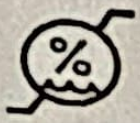
	porte et si elles peuvent être facilement enlevées. Continuer à rincer.
P337+P313	Si l'irritation oculaire persiste : consulter un médecin.
P391	Recueillir le produit répandu.
P302+P352	EN CAS DE CONTACT AVEC LA PEAU : laver abondamment à l'eau.
P332+P313	En cas d'irritation cutanée : consulter un médecin.
P362+P364	Enlever les vêtements contaminés et les laver avant réutilisation.
Mise au rebut	
P501	Eliminer le contenu/récipient dans un point de collecte des déchets dangereux ou spéciaux agréé conformément à la réglementation locale en vigueur.

17 SYMBOLES GRAPHIQUES

Code du lot

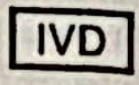
Date limite d'utilisation

Limite de température



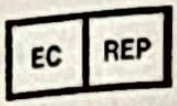
LIMITE D'HUMIDITE

Fabricant



Diagnostic in vitro de l'instrument médical

REFERENCE CATALOGUE



Représentant agréé pour la Communauté européenne

Consulter les instructions d'utilisation

Conformité européenne

Identifiant unique du dispositif

18 REFERENCES

Non applicable.

19 COORDONNEES DE LA SOCIETE

Fabricant:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Adresse:	Mindray Building, Keji 12th Road South, High-tech Industrial park, Nanshan, Shenzhen 518057, P.R.China
Adresse de courriel:	service@mindray.com
Tél. :	+86 755 81888998
Télécopie:	+86 755 26582680
Représentant pour l'UE:	Shanghai International Holding Corp. GmbH (Europe)
Adresse:	Eiffestraβe 80, Hamburg 20537, Allemagne
Tél. :	0049-40-2513175
Télécopie:	0049-40-255726

20 DATE D'APPROBATION DU MANUEL D'UTILISATION

2022.06.06

Lise M-52LH

1 Nome do produto
Lise M-52LH

2 Modelo
M-52LH

3 Especificação da Embalagem
100mL×4

4 Uso pretendido
A lise M-52LH dissolve RBCs, realiza contagem de WBC, diferencial de basófilos e medição de hemoglobina.

5 Princípio
A lise M-52LH também processa as células sanguíneas que foram processadas por lise M-52DIFF, ela transforma hemoglobina em meta-hemoglobina, que é, então, medida pelo método colorimétrico. Ela também processa os leucócitos (GB) para intensificar a diferença entre basófilos e outras subpopulações de leucócitos, e incorpora disseminação por laser e citometria de fluxo para realizar a análise de basófilos.

6 Composição

Sais quaternários de amônio ..... <50g/L

Isopropanol 2-10g/L

7 Condições de armazenamento e prazo de validade
O produto deve ser armazenado na temperatura de 2 ℃ a 30 ℃ e a umidade relativa não deve exceder 90%. A sala de armazenamento deve ser bem ventilada e sem gás corrosivo. A vida de prateleira é de 2 anos.
A faixa de temperatura de trabalho do produto é consistente com a dos instrumentos aplicáveis. A validade do frasco aberto é de 60 dias.

8 Modelos de analisadores aplicáveis
O produto se aplica aos analisadores automáticos de hematologia BC-5000, BC-5150, BC-5120, BC-5130 e BC-5140 fabricados por Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

9 Requisitos da amostra
Anticoagulante de sangue total humano fresco. Não use amostras contaminadas.

10 MATERIAIS NECESSÁRIOS, MAS NÃO FORNECIDOS
Os seguintes materiais são necessários, mas não são fornecidos com o produto: Instrumentos de medição fabricados pela Mindray e reagentes correspondentes.

11 Instruções de uso
1) Retorne a lise M-52LH à temperatura de uso;
2) Abra a embalagem externa e insira o tubo de coleta no recipiente de reagente com base na cor correspondente da tampa do reagente e no conector do conjunto de tampas do analisador;
3) Feche bem o conjunto de tampas e substitua o reagente de acordo com o manual do operador do analisador;
4) Realize uma contagem em branco e verifique os resultados. Se os resultados atenderem aos requisitos de contagem em branco definidos no manual do operador do analisador, o reagente recém-instalado pode ser usado para análise de amostra. Consulte o manual do operador do analisador para obter detalhes.

12 VALOR DE CORTE/INTERVALOS DE REFERÊNCIA
Não aplicável.

13 ELABORAÇÃO DO RESULTADO
Não aplicável.

14 LIMITAÇÕES

Não aplicável.

15 Características de desempenho

1) Aparência: líquido transparente, sem sedimentos, grãos ou flocos.

3) Resultados de contagem em branco: os resultados de contagem em branco da lise M-52LH testada em BC-5000, BC-5150, BC-5120, BC-5130 e BC-5140 atende às exigências na Tabela 1.

Tabela 1 Exigências de contagem em branco da lise M-52LH

Parâmetro de teste	Requisitos de contagem em branco
GB	$\leq 0.2\times10^9$/L
Hb	≤1g/L

16 PRECAUÇÕES

1. Somente para diagnóstico in vitro de uso profissional.
2. Leia o encarte da embalagem atentamente antes de usar o produto. Ele deve ser usado antes da data de validade e descartado adequadamente quando vencido.
3. Não use o reagente se ele estiver congelado.
4. Se a contagem de branco estiver anormal após o transporte do reagente, coloque-o ainda por 24 horas em temperatura ambiente antes de usá-lo.
5. Se o reagente estiver poluído ou for afetado por outros fatores e ficar anormal, pare de usá-lo e substitua-o por um normal.
6. Descarte os resíduos, resíduos e embalagens contaminadas com base nas regulamentações locais.
7. Os seguintes fatores podem afetar a análise da amostra: Reagente vencido ou ineficaz; reagente poluído por pó no ar; eliminação inadequada da amostra; misturado com ou utilizado com reagentes produzidos por outra empresa; utilização mista de resíduos do recipiente antigo e do recém-aberto; usado em condição diferente da especificada.
8. Tome as precauções necessárias para a utilização do produto. Não engolir. Evite o contato com a pele e membranas mucosas. Se os reagentes forem levados à boca ou derramados na pele ou nos olhos acidentalmente, lave-os com bastante água e procure tratamento médico, se necessário.
9. O descarte de resíduos líquidos e materiais deve estar de acordo com as diretrizes locais.
10. A Folha de dados de segurança (SDS) do material está disponível mediante solicitação
11. Todos os riscos identificados foram reduzidos tanto quanto possível pelo em geral reconhecido estado da arte, e o risco residual total é aceitável.
12. Qualquer incidente grave que tenha ocorrido em relação ao dispositivo deve ser comunicado ao fabricante e à autoridade competente do país em que o utilizador e/ou o paciente está estabelecido.
13. Este produto contém componentes classificados da seguinte forma, de acordo com a Norma (CE) nº 1272/2008:

Aviso	
H411	Tóxico para a vida aquática com efeitos duradouros.
H315	Causa irritação na pele.
H319	Causa irritação grave nos olhos.
Prevenção	
P273	Evite liberar no meio ambiente.
P280	Use luvas, roupas, óculos de proteção e proteção para o rosto.
P264	Lave bem todas as áreas externas expostas do corpo após o manuseio.
Resposta	

P305+P351+P338	SE ESTIVER NOS OLHOS: Lave cuidadosamente com água por vários minutos. Remova as lentes de contato, se presentes, e caso sejam de fácil remoção. Continue a enxaguar.
P337+P313	Se a irritação dos olhos persistir: Procure assistência médica.
P391	Colete o derramamento.
P302+P352	SE ESTIVER NA PELE: Lave com água em abundância.
P332+P313	Se ocorrer irritação na pele: Procure assistência médica.
P362+P364	Retire as roupas contaminadas e lave-as antes de reutilizá-las.
Descarte	
P501	Descarte o conteúdo/recipiente em um ponto de coleta de resíduos perigosos ou especiais autorizado de acordo com todos os regulamentos locais.

17 SÍMBOLOS GRÁFICOS

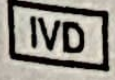
Código do lote

Data de validade

Limite de temperatura

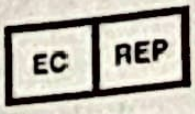
LIMITAÇÃO DA UMIDADE

Fabricante



Diagnóstico in vitro dispositivo médico

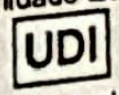
NÚMERO DE CATÁLOGO



Representante autorizado na Comunidade Europeia

Consulte as instruções de uso

Conformidade com a Europa



Identificador exclusivo do dispositivo

18 REFERÊNCIAS

Não aplicável.

19 CONTATO DA EMPRESA

Fabricante:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Endereço:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Endereço de e-mail:	service@mindray.com
Tel.:	+86 755 81888998
Fax:	+86 755 26582680
Representantes na UE:	Shanghai International Holding Corp. GmbH (Europa)
Endereço:	Eiffestraβe 80, Hamburgo 20537, Alemanha
Tel.:	0049-40-2513175
Fax:	0049-40-255726

20 DATA DE APROVAÇÃO DO MANUAL DO OPERADOR

2022.06.06

Лизирующий реагент M-52LH

1 Наименование изделия
Лизирующий реагент M-52LH

2 Модель
M-52LH

3 Спецификации упаковки
100 мл × 4

4 Предусмотренное применение
Лизирующий реагент M-52LH растворяет RBC и используется при подсчете WBC, дифференцировке базофилов и измерении уровня гемоглобина.

5 Принцип работы
Лизирующий реагент M-52LH производит дальнейшую обработку кровяных телец, обработанных реагентов M-52DIFF, преобразовывая гемоглобин в метгемоглобин, измерение которого осуществляется посредством колориметрического метода. Данный реагент также обрабатывает лейкоциты для усиления различий между базофилам и другими субпопуляциями лейкоцитов и использует метод рассеивания лазерного излучения и проточной цитометрии для выполнения анализа базофилов.

6 Активные ингредиенты

Четвертичная аммонийная соль.....<50 г/л

Изопропиловый спирт .....2-10 г/л

7 Условия хранения и срок годности при хранении
Продукт должен храниться при температуре 2–30 °C, а относительная влажность не должна превышать 90%. Помещение для хранения должно быть хорошо вентилируемым, без коррозионных газов. Срок хранения составляет 2 года.
Диапазон рабочих температур продукта соответствует диапазону для применимых аппаратов.
Срок годности в открытом флаконе составляет 60 дней.

8 Вещество используется со следующими моделями анализаторов
Вещество применяется с автоматизированными гематологическими анализаторамиBC-5000, BC-5150, BC-5120, BC-5130 и BC-5140 компании Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

9 Требование к пробе
Свежая цельная крови человека с антикоагулянтом. Не используйте загрязненные образцы.

10 НЕОБХОДИМЫЕ МАТЕРИАЛЫ, НЕ ВХОДЯЩИЕ В КОМПЛЕКТ ПОСТАВКИ
Следующие материалы необходимы, но не входят в комплект поставки: измерительные приборы и соответствующие реагенты производства компании Mindray.

11 Инструкции по эксплуатации
1) Доведите лизирующий реагент M-52LH до температуры эксплуатации.
2) Откройте внешнюю упаковку и вставьте приемную трубку в контейнер с реагентом в соответствии с цветом крышки контейнера и соединителя сопловой крышки анализатора.
3) Закрутите сопловую крышку до отказа и замените реагент в соответствии с руководством пользователя реагента.
4) Выполните холостой подсчет и проверьте результаты. Если результаты соответствуют требованиям к результатам холостого подсчета, указанным в руководстве пользователя анализатора, новый реагент может быть использован для анализа образцов. Для получения более подробной информации см. руководство пользователя анализатора.

12 ЗНАЧЕНИЕ ОТСЕЧКИ/РЕФЕРЕНСНЫЕ ИНТЕРВАЛЫ
Неприменимо.

13 РАСШИФРОВКА РЕЗУЛЬТАТОВ
Неприменимо.

14 ОГРАНИЧЕНИЯ

Неприменимо

15 Эксплуатационные свойства

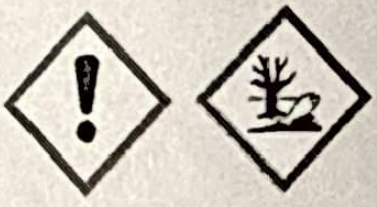
1) Внешний вид: прозрачная жидкость, без осадка, гранул или хлопьев осадка
2) Результаты холостого подсчета: результаты холостого подсчета лизирующего реагента M-52LH анализаторовBC-5000, BC-5150, BC-5120, BC-5130 и BC-5140 соответствуют требованиям, указанным в Таблице 3.

Таблица 3. Требования к холостому подсчету лизирующего реагента M-52LH

Тестируемый параметр	Требования к холостому подсчету
WBC	$\leq 0.2\times10^9$/л
HGB	≤1 г/л

16 МЕРЫ ПРЕДОСТОРОЖНОСТИ

1. Только для профессиональной диагностики in vitro.
2. Перед использованием данного продукта внимательно прочитайте вкладыш. Его необходимо использовать до истечения срока годности и утилизировать надлежащим образом по истечении срока годности.
3. Не используйте реагент, если он заморожен.
4. Если после транспортировки реагента результат холостого подсчета не соответствует норме, перед использованием оставьте его на 24 часа при комнатной температуре.
5. Если реагент загрязнен или был подвержен воздействию других факторов и стал непригодным, прекратите использование и замените его.
6. Утилизируйте отходы, остатки и загрязненную упаковку в соответствии с местными нормативными требованиями.
7. На анализ проб могут влиять следующие факторы: просроченный или недействительный реагент; загрязнение реагента пылью в воздухе; неправильное обращение с пробой; смешивание или использование с реагентами других производителей; смешивание нового реагента с остатками предыдущего из другого контейнера во время использования; использование в условиях, отличных от указанных.
8. Примите необходимые меры предосторожности при использовании продукта. Не проглатывайте. Избегайте контакта с кожей и слизистыми оболочками. Если реагент случайно попал в рот, на кожу или в глаза, промойте большим количеством воды и при необходимости обратитесь за медицинской помощью.
9. Утилизация отработанной жидкости и материалов должна осуществляться в соответствии с местными правилами.
10. Паспорт безопасности материала (SDS) доступен по запросу.
11. Продукт отвечает современным требованиям, и все выявленные риски были сведены к минимуму, а общий остаточный риск является приемлемым.
12. О любом серьезном происшествии, связанным с устройством, следует сообщить производителю и компетентному органу государства-члена, в котором находятся пользователь и/или пациент.
13. Данный продукт содержит компоненты, классифицированные следующим образом в соответствии с Регламентом (ЕС) № 1272/2008:



Осторожно!

H411	Токсично для водной жизни с долго длящимся воздействием.

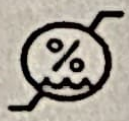
H315	Вызывает раздражение кожи.
H319	При попадании в глаза вызывает выраженное раздражение.
Меры предосторожности	
P273	Избегайте попадания в окружающую среду.
P280	Используйте защитные перчатки, защитную одежду, средства защиты глаз и лица.
P264	После работы тщательно промойте все открытые участки тела.
Ответные меры	
P305+P351+P338	ПРИ ПОПАДАНИИ В ГЛАЗА: осторожно промойте водой в течение нескольких минут. Снимите контактные линзы, если они есть и их легко снять. Продолжайте промывать.
P337+P313	Если раздражение глаз сохраняется: обратитесь за медицинской помощью.
P391	Соберите разлитую жидкость.
P302+P352	ПРИ ПОПАДАНИИ НА КОЖУ: промойте большим количеством воды.
P332+P313	При появлении раздражения на коже: обратитесь за медицинской помощью.
P362+P364	Снимите загрязненную одежду и постирайте ее перед повторным использованием.
Утилизация	
P501	Утилизируйте содержимое/контейнер в авторизованном пункте сбора опасных или специальных отходов в соответствии с местными нормативными требованиями.

17 ГРАФИЧЕСКИЕ СИМВОЛЫ]

НОМЕР ПАРТИИ

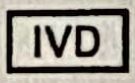
СРОК ГОДНОСТИ

ТЕМПЕРАТУРНОЕ ОГРАНИЧЕНИЕ



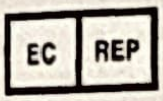
ПРЕДЕЛЫ ВЛАЖНОСТИ

ИЗГОТОВИТЕЛЬ



ДЛЯ ДИАГНОСТИКИ IN VITRO

НОМЕР ПО КАТАЛОГУ



ПОЛНОМОЧЕННЫЙ ПРЕДСТАВИТЕЛЬ В ЕВРОПЕЙСКОМ СООБЩЕСТВЕ

ИНСТРУКЦИИ ПО ЭКСПЛУАТАЦИИ

Соответствие европейским стандартам

Уникальный идентификатор устройства

18 СПИСОК ЛИТЕРАТУРЫ]

Неприменимо.

19 КОНТАКТНАЯ ИНФОРМАЦИЯ КОМПАНИИ

Изготовитель:

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Факс: 0049-40-255726

20 ДАТА УТВЕРЖДЕНИЯ РУКОВОДСТВА ОПЕРАТОРА

2022.06.06

M-52LH LİZİ

1 Ürün adı
M-52LH LİZİ

2 Model
M-52LH

3 Ambalaj Spesifikasyon
100mL×4

4 Kullanım amacı
M-52LH Lizi, RBC'leri çözer, WBC sayımı, bazofil diferansiyeli ve hemoglobin ölçümünü gerçekleştirir.

5 Prensip
M-52LH LİZİ, M-52DIFF LİZİ ile işlenmiş kan hücrelerini ilaveten işler, ardından kolorimetrik yöntemle ölçülen hemoglobini metamoglobine dönüştürür. Ayrıca bazofillerle diğer WBC alt popülasyonları arasındaki farkı artırmak için WBC'leri de işler ve bazofil analizini gerçekleştirmek için lazer dağıtma ve akış sitometrisini içerir.

6 İçerik

Kuvaterner amonyum tuzları.....<50g/L

İzopropanol.....2-10g/L

7 Saklama koşulları ve raf ömrü
Ürün 2℃~30℃ sıcaklıkta saklanmalı ve bağıl nem %90'ı geçmemelidir. Depolama odası iyi havalandırılmalı ve aşındırıcı gaz içermemelidir. Raf ömrü 2 yıldır.
Ürünün çalışma sıcaklığı aralığı, geçerli aletlerinin çalışma sıcaklığı aralığıyla tutarlıdır. Açık flakon geçerliliği 60 gündür.

8 Uygun analizör modelleri
Ürün, Shenzhen Mindray Bio-Medical Electronics Co., Ltd. tarafından üretilen BC-5000, BC-5150, BC-5120, BC-5130 ve BC-5140 Otomatik Hematoloji Analizörlerine uygundur.

9 Numune Gerekliliği
Antikoagülasyonlu taze insan tam kanı. Kontamine olmuş numuneleri kullanmayın.

10 ÜRÜNLE BİRLİKTE VERİLMEYEN ANCAK GEREKLİ OLAN MALZEMELER
Şu malzemeler gereklidir ancak ürünle birlikte verilmez: Mindray tarafından üretilen ölçüm cihazları ve eşleşen reaktifler.

11 Kullanım talimatları
1) M-52LH LİZİ'i kullanım sıcaklığına getirin;
2) Dış ambalajı açın ve pikup tüpünü, eşleşen reaktif kapağı rengine ve analizör kapağı grubunun konektörüne dayalı olarak reaktif kabına yerleştirin;
3) Kapak grubunu sıkıca vidalayın ve reaktifi analizörün kullanıcı el kitabına göre değiştirin;
4) Boş sayım yapın ve sonuçları kontrol edin. Sonuçların, analizörün kullanıcı el kitabında tanımlanan boş sayıp gerekliliğini karşılaması halinde yeni oluşturulan reaktif numune analizi için kullanılabilir. Ayrıntılar için analizörün kullanıcı el kitabını inceleyin.

12 KESME DEĞERİ/REFERANS ARALIKLARI
Geçerli değildir.

13 SONUÇ DETAYLANDIRMASI
Geçerli değildir.

14 SINIRLAMALAR
Geçerli değildir.

15 Performans özellikleri

1) Görünüş: şeffaf sıvı, tortusuz, taneciksiz veya topaklanmasız.
2) Boş sayım sonuçları: Mindray Analizörlerinde test edilen M-52LH LİZİ'in boş sayım sonuçları, Tablo 1'teki gerekliliklerı karşılamaktadır.

Tablo 1 M-52LH LİZİ boş sayım gerekliliklerı

Test parametresi	Boş sayım gerekliliklerı
WBC	≤0.2×10⁹/L
HGB	≤1g/L

16 ÖNLEMLER

1) Yalnızca uzmanların in vitro tanısal kullanımına yöneliktir.
2) Bu ürünü kullanmadan önce prospektüsü dikkatlice okuyun. Son kullanma tarihinden önce kullanılmalı ve süresi dolduğunda uygun şekilde atılmalıdır.
3) Reaktif donmuşsa kullanmayın.
4) Reaktif taşındıktan sonra boş sayım anormalse kullanmadan önce oda sıcaklığında 24 saat bekletin.
5) Reaktifin kirlenmesi veya diğer faktörlerden etkilenmesi ve anormal hale gelmesi durumunda reaktifi kullanmayı bırakın ve normal bir reaktif ile değiştirin.
6) Atıkları, artıkları ve kontamine olmuş ambalajları yerel düzenlemelere uygun olarak atın.
7) Aşağıdaki faktörler numune analizini etkileyebilir: Son kullanma tarihi geçmiş veya etkisiz reaktif; havadaki tozla kirlenmiş reaktif; numunenin yanlış şekilde kullanılması; başka bir şirket tarafından üretilen reaktiflerle karıştırılması veya kullanılması; eski kaptan kalan artıkların ve yeni açılan kabın karışık kullanımı; belirtilenden farklı bir şekilde kullanılması.
8) Ürünün kullanımı için gerekli önlemleri alın. Yutmayın. Cilt ve mukoz membranları ile temasından kaçının. Reaktifi yanlışlıkla ağzınıza alırsanız veya reaktifler yanlışlıkla cildinize veya gözlerinize dökülürse bol suyla yıkayın ve gerekirse tıbbi tedavi alın.
9) Atık sıvı ve malzemeler, yerel yönetmeliklere uygun olarak bertaraf edilmelidir.
10) Malzeme Güvenlik Veri Formu (SDS) istek üzerine mevcuttur.
11) Tanımlanan tüm riskler, genel olarak kabul gören son teknoloji ile mümkün olduğunca azaltılmıştır ve geriye kalan riskler kabul edilebilirdir.
12) Cihaz ile ilgili olarak meydana gelen tüm ciddi olaylar, üreticiye ve kullanıcının ve/veya hastanın bulunduğu Üye Devletin yetkili makamına bildirilmelidir.
13) Bu ürün, Yönetmelik (EC) No. 1272/2008'e uygun olarak aşağıdaki şekilde sınıflandırılmış bileşenleri içerir:

Uyarı	
H411	Sucul ortamda uzun süre kalıcı, toksik etki.
H315	Ciltte tahrişe neden olur.
H319	Gözde ciddi tahrişe neden olur.
Önleme	
P273	Çevreye salınmasını önleyin.
P280	Koruyucu eldiven, koruyucu giysi, göz koruyucu ve yüz koruyucu kullanın.
P264	Temas ettikten sonra açıkta kalan tüm dış vücut bölgelerini iyice yıkayın.
Yanıt	
P305+P351+P338	GÖZLE TEMASI HALİNDE: Su ile birkaç dakika dikkatlice durulayın. Varsa ve çıkarması kolaysa kontakt lensleri çıkarın. Durulamaya devam edin.
P337+P313	Göz tahrişinin geçmemesi halinde: Tıbbi tavsiye

	alın/doktorunuza başvurun.
P391	Dökülmüleri toplayın.
P302+P352	CİLT İLE TEMASI HALİNDE: Bol suyla yıkayın.
P332+P313	Cilt tahrişi oluşması halinde: Tıbbi tavsiye alın/doktorunuza başvurun.
P362+P364	Kontamine olmuş giysileri çıkarın ve yeniden kullanmadan önce yıkayın.
Atma	
P501	İçeriği/kabı yerel yönetmeliklere uygun olarak yetkili tehlikeli veya özel atık toplama noktasına atın

17 GRAFİK SEMBOLLERİ

LOT Seri kodu	Son kullanma tarihi	Sıcaklık sınırı
NEM LİMİTİ	Üretici	IVD İn vitro tanısal tıbbi cihaz
REF KATALOG NUMARASI	EC REP Avrupa Topluluğundaki yetkili temsilci	Kullanım talimatlarına başvurun
CE Avrupa Uyumluluğu	UDI Benzersiz cihaz tanımlayıcısı	

18 REFERANSLAR

Geçerli değildir.

19 ŞİRKET İLETİŞİM

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Tel:	0049-40-2513175
Faks:	0049-40-255726

20 KULLANIM KILAVUZUNUN ONAY TARİHİ

2022.06.06