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

Digitally signed by Poiata Vitalie
Date: 2024.01.18 16:11:13 EET
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

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

MD 0101250

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

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

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

Capitalul social: **5400** lei.

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

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

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

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

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

Registrator în domeniul înregistrării de stat

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

Rusu Diana

EB 0461494

Date cu caracter personal

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

Lista fondatorilor Biosistem-mld SRL

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

[State seal]
MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY

Agencia Española de Medicamentos y Productos Sanitarios
[Spanish State Agency of Medication and Sanitary Products]

S/REF
N/REF: PS/DP/MST
Date: 01/12/2015
Subject: Information to the addressee

DELTALAB, S.L
PLAZA DE LA VERNEDA, 1
POLIGONO INDUSTRIAL LA LLANA
081191 RUBÍ
(BARCELONA)

In response to your email dated 24/11/2015 requesting information on the products detailed below, which are included as items for general laboratory use in your company´s catalogue, and after having made the relevant inquiries, I can inform you that:

- Slides
- Uncoated cover slides
- Pasteur pipettes
- Tips for general purpose pipettes
- Sample cups and cuvettes
- Spreaders for extensions
- Calibrated loops
- Petri dishes
- Vials
- Caps
- Serological pipettes
- Cryovials
- Ritips
- Cassettes for biopsy
- Microtitre plates
- E.S.R. system stands
- Anticoagulants and preservatives in bulk
- Stains for microbiology.

[State seal]
MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY
SUPPORTING RECORD
AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
[SPANISH STATE AGENCY OF MEDICATION AND SANITARY PRODUCTS]
EXIT
Registration No: 26082/RG53761
Date; 14/12/2015 09:24:32

These products do not fall under the scope of Royal Decrees 1591/2009 of 16 October and 1662/2000 of 29 September, which regulate medical devices and medical devices for in vitro diagnostics respectively. These decrees transpose Directive 93/42/EEC on medical devices and Directive 98/79/EC of the European Parliament and of the Council dated 27 October 1998 on in vitro diagnostic medical devices to Spanish legislation, therefore their marketing falls under commercial legislation, consumer and user protection legislation and any applicable specific legislation.

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS
[Illegible signature]
Mª del Carmen Abad Luna
[Seal: Spanish State Agency of Medication and Sanitary Products]
Page 1/1

EMAIL
mpizarro@aemps.es

C/CAMPEZO, 1-EDIFICIO 8
28022 MADRID
TELEPHONE: 91 822 52 61
FAX: 91 822 52 89

Doña Marta Casanova Hernández, Traductora e Intérprete jurada de inglés nombrada por el Ministerio de Asuntos Exteriores y Cooperación certifica que la que antecede es traducción fiel y completa al inglés de un documento redactado en español. En Salamanca, a 15 de diciembre de 2015	I, Marta Casanova, Sworn Translator and Interpreter of English named by the Ministry of Foreign Affairs and Cooperation, hereby certify that the foregoing is a true and complete translation into English of a document written in Spanish. In Madrid, 15 December 2015

MARTA CASANOVA HERNANDEZ
Traductora-Intérprete Jurada de INGLÉS
Nº 9494

Declaración de Conformidad "CE"
"CE" Declaration of conformity

Directiva Productos Sanitarios para el Diagnóstico In Vitro 98/79/CE
In Vitro Diagnostic Medical Devices Directive 98/79/EC

Fabricante / *Manufacturer:* **AQUISEL, s.l.**
Dirección / *Address:* Autovía A-2 Km 585,1 08630 ABRERA (BARCELONA) - SPAIN

Declara bajo su responsabilidad que los productos listados debajo, han estado diseñados para la aplicación de diagnóstico In Vitro y cumplen todos los requisitos esenciales del anexo I del Real Decreto 1662/2000 transposición a la Legislación Española de la Directiva 98/79/CE sobre productos sanitarios para diagnóstico In Vitro.

Declares under their responsibility that the products listed below have been designed for In Vitro diagnostic application and that they comply with all essential requirements as laid out in Annex I of Real Decreto 1662/2000 transposition to the Spanish Legislation of the Directive 98/79/EC for In Vitro Diagnostic Medical Devices.

"Tubos AQUISEL"; contenedores para la recogida de muestras de sangre, variantes:

The "AQUISEL tube"; containers for blood sampling collection, kinds:

• K3E/EDTA 3K (anticoagulante)	• *K3E/EDTA 3K (anticoagulant)*
• K2E/EDTA 2K (anticoagulante)	• *K2E/EDTA 2K (anticoagulant)*
• 4NC/CITRATO 3Na (anticoagulante)	• *4NC/Citrate 3Na (anticoagulant)*
• 9NC/CITRATO 3Na (anticoagulante)	• *9NC/Citrate 3Na (anticoagulant)*
• LH/Heparina Li (anticoagulante)	• *LH/Li Heparin (anticoagulant)*
• LH/Heparina Li – Gel (anticoagulante)	• *LH/Li Heparin + Gel (anticoagulant)*
• MonoiodoAcetato Li +Gránulos PS activador (antiglicolítico)	• *IodoAcetate Li + Granules activator (antiglycolitic)*
• LH/Heparina Li + MonoiodoAcetato Li (anticoagulante + antiglicolítico)	• *LH/Li Heparin + IodoAcetate Li (anticoagulant + antiglycolitic)*
• FX/Fluoruro Na + Oxalato K (antiglicolítico + anticoagulante)	• *FX/Na Fluoride + K Oxalate (antiglycolitic + anticoagulant)*
• Z/Vacío (sin aditivos)	• *Z/Empty (non additive)*
• Z/ Tubo tratado (para suero)	• *Z/ Treatment Tube (for serum)*
• Z/ Tubo tratado con Gel separador (para suero)	• *Z/ Treatment Tube with Separator Gel (for serum)*
• Z/ Tubo tratado con Gránulos PS (para suero)	• *Z/ Treatment Tube with Granules PS (for serum)*
• Z/ Tubo con activador de la coagulación (para suero)	• *Z/ Tube with clotting activator (for serum)*
• Z/ Tubo con activador + Gel separador (para suero)	• *Z/ Tube with clotting activator + Separator Gel (for serum)*
• Z/ Tubo con activador + Gránulos PS (para suero)	• *Z/ Tube with clotting activator + Granules PS (for serum)*
Accesorios	***Accessories***
• CAP-GALET (Embudo para muestras de sangre)	• *CAP-GALET (Funnels for Blood Sampling)*

Abrera a 09 Octubre de 2014 , *Abrera 09th October 2014*

Firmado/Signed : Manel Sotelo y Sotelo
(Gerente / Manager)

file.:TF-1101-F _10-2014

AQUISEL, S.L. 08630 ABRERA (Barcelona) España Tf.: (93) 770 39 00 Fax: (93) 770 39 15

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer.*

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

SISTEMA INVASIVO ESTÉRIL DE TOMA DE MUESTRAS CON Y SIN MEDIO DE TRANSPORTE MARCA EUROTUBO
INVASIVE STERILE EUROTUBO COLLECTION SWAB FOR SAMPLE COLLECTION WITH AND WITHOUT TRANSPORT MEDIUM
(Códigos según Anexo 1 / *Codes in Annex 1)*

Tipo: Sistema invasivo estéril de recogida de muestras por contacto directo con el paciente
Type: *Invasive sterile collection system by direct contact with the patient*

Finalidad Prevista: Recogida y transporte de muestras biológicas para posteriores análisis microbiológicos
Intended Use: *Collection and transport of biological samples for subsequent microbiological analysis*

Código GMDN / *GMDN Code:* 33722

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

ESCOBILLON - *Swab*

Directiva 93/42/CEE Directiva Productos Sanitarios.
Transposición a la legislación española en **Real Decreto 1591/2009.**
Directive 93/42/ECC *Medical Devices Directive.*
Transposition to Spanish legislation in ***Real Decreto 1591/2009.***

Clasificación: Clase IIa
Classification: Class IIa

INFORMACIÓN ADICIONAL
En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005 06 0474 CP Epígrafe 1, de Garantía de Calidad de la Producción de acuerdo con los Anexos V y VII de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

OTHER INFORMATION:
Regarding the swabs, this documentation is supported by the CE Certificate number 2005 06 0474 CP Epigraph 1, Production Quality Assurance according to Annexes V and VII of Directive 93/42/EEC issued by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.

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TUBO CON MEDIO DE TRANSPORTE – *Tube with transport medium*

Directiva 98/79/CE Directiva Productos Sanitarios para Diagnóstico In Vitro.
Transposición a la legislación española en **Real Decreto 1662/2000.**
Directive 98/79/EC *In vitro Diagnostic Medical Devices Directive.*
Transposition to Spanish legislation in ***Real Decreto 1662/2000.***

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DELTALAB S.L.
Plaza de la Verneda 1, Pol. Ind. La Llana
08191 Rubi - Barcelona

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

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ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
300200	ESCOBILLON MAD.+ALGODON PEEL/1	SWAB I/W PEEL/1 WOOD+COTTON
300201	ESCOBILLON PS+ALGODON PEEL/1	SWAB I/W PEEL/1 PS+COTTON
300202	ESCOBILLON PS+VISCOSA PEEL/1	SWAB I/W PEEL/1 PS+VISCOSE
300203	ESCOBILLON ALU+ALGODON PEEL	SWAB I/W PEEL ALUM+COTTON
300210	ESCOBILLON MAD.+ALGOD.B/2 PEEL	SWAB B/2 PEEL/2 WOOD+COTTON
300250	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300251	ESCOBILLON ALU.+ALGODON TUBO	SWAB IN TUBE ALUM+COTTON
300252	ESCOBILLON PS+VISCOSA TUBO	SWAB IN TUBE PS+VISCOSE
300253	ESCOBILLON ALU.+VISCOSA TUBO	SWAB IN TUBE ALUM+VISCOSE
300254	ESC.ALUM.TRENZADO+VISCOSA TUBO	SWAB TWISTED ALUM+VISCOSE TUBE
300259	ESCOBILLON MAD.+VISCOSA TUBO	SWAB IN TUBE WOOD+VISCOSE
300261	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PP+COTTON
300263	ESCOBILLÓN 13X165MM PS C/POLIÉSTER	SWAB 13X165MM PS W/POLYESTER
300280	CARY BLAIR MADERA+ALGODON	CARY BLAIR SWAB WOOD+COTTON
300281	AMIES ALUMINIO+VISCOSA	AMIES SWAB ALUMINIUM+VISCOSE
300284	AMIES LIQUIDO PS+VISCOSA	AMIES SWAB LIQUID PS+VISCOSE
300285	AMIES CARBON PS+VISCOSA	AMIES+CHARCOAL SWAB PS+VISCOSE
300287	AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSE
300290	STUART MADERA+ALGODÓN	STUART SWAB WOOD+COTTON
300291	STUART ALUMINIO+ALGODÓN	STUART SWAB ALUM+COTTON
300292	STUART ALUMIN.TRENZADO+VISCOSA	STUART SWAB TWISTED ALU + VISC
300294	VIRUS ALUMINIO + POLIESTER	VIRUS SWAB ALUMINIUM POLYESTER
300295	STUART 13X165MM PS C/VISCOSA	STUART 13X165MM PS W/VISCOSE
300296	H. VIRUS ALUM. ALGODÓN	SWAB FOR VIRUS WIRE+COTTON TIP
300297	VIRUS PS+POLIESTER	VIRUS SWAB PS POLYESTER
300299	CHLAMYDIA PS+POLIESTER	CHLAMYDIA SWAB PS+POLYESTER
310200	ESCOBILLON MAD.+ALGODON FLOW	WOOD+COTTON SWAB FLOW
310202	ESCOBILLON PS+VISCOSA FLOW	PS+VISCOSE SWAB FLOW

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REF	DESCRIPCIÓN	*DESCRIPTION*
300211.1	ESCOBILLÓN PS+ALG. PACK PEEL/2	SWAB B/2 PS+COTTON PEEL/2
300212.1	ESCOBILLON PS+VISCOSA PEEL/2	SWAB PEEL/2 PS+VISCOSE
300250.1	ESCOBILLON MAD.+ALGOD. PURO TU	SWAB IN TUBE WOOD+PURE COTTON
300250.M	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300261.M	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON
300268.B	ESCOBILLON PS+POLIESTER PEEL PACK	SWAB PS+POLIESTER IND.WRAPPED
300280.2	CARY BLAIR PS+VISCOSA	CARY BLAIR SWAB PS+VISCOSE
300281/1	ESC. AMIES+CARBON ALUM.VISCOSA	AMIES CHARCOAL SWAB WIRE+VISCOSE
300281T	AMIES ALUMINIO TRENZADO+ VISCOS	AMIES SWAB TWIST.WIRE+VISCOSE
300281TC	AMIES+CARBON ALU.TRENZADO+ VISC	AMIES+CHARCOAL TWIS.WIRE+VISCO
300285.M	AMIES CARBON PS VISCOSA 6x100	AMIES CHARCOAL PS RAYON 6X100
300287.5	AMIES PS VISCOSA CAJAS 6x100	AMIES PS VISCOSE CASES 6X100
300287.A	ESCOB.AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSE
300295C	STUART CARBÓN PS + VISCOSA	STUART+CHARCOAL SWAB PS+VISCOS
310253.1	ESCOB. ALUM+VISCOSA FLOW	ALUM+VISCOSE SWAB FLOW
310211.1	ESCOBILLON PS+ALGODON B/2 FLOW	PS+COTTON SWAB B/2 FLOW
300250.MY	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300211.10	ESCOBILLÓN PS+ALG. PACK PEEL/10	SWAB PS+COTTON PEEL/10
300261AV	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, nº 1
Pol. Ind. La Llana
08191 Rubí (Barcelona) – España

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

SISTEMA INVASIVO ESTÉRIL, CON PUNTA ABSORBENTE, PARA TOMA DE MUESTRAS CON Y SIN MEDIO DE TRANSPORTE.
INVASIVE STERILE COLLECTION SWAB, WITH ABSORBENT TIPPED, FOR SAMPLE COLLECTION WITH AND WITHOUT TRANSPORT MEDIUM
(Códigos según Anexo 1 / *Codes in Annex 1)*

Tipo: Escobillón estéril con punta absorbente para la recogida de muestras.
Type: *Absorbent tipped sterile swab for samples collection.*

Finalidad Prevista: Recogida y transporte de muestras biológicas para posteriores análisis microbiológicos
Intended Use*: Collection and transport of biological samples for subsequent microbiological analysis*

Código GMDN / *GMDN Code:* 33722

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

ESCOBILLON - *Swab*

Directiva 93/42/CEE Directiva Productos Sanitarios.
Transposición a la legislación española en **Real Decreto 1591/2009.**
Directive 93/42/ECC *Medical Devices Directive.*
Transposition to Spanish legislation in ***Real Decreto 1591/2009.***

Clasificación: Clase I Estéril
Classification: Class I Sterile

INFORMACIÓN ADICIONAL
En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005 06 0475 CP Epígrafe 6, de Garantía de Calidad de la Producción de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). Organismo Notificado número 0318.

OTHER INFORMATION:
For the swabs, this documentation is supported by the CE Certificate number 2005 06 0475 CP Epigraph 6, according to Annexes VII section 5 and V section 3 of Directive 93/42/EEC issued by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.

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TUBO CON MEDIO DE TRANSPORTE – *Tube with transport medium*

Directiva 98/79/CE Directiva Productos Sanitarios para Diagnóstico In Vitro.
Transposición a la legislación española en **Real Decreto 1662/2000.**
Directive 98/79/EC *In vitro Diagnostic Medical Devices Directive.*
Transposition to Spanish legislation in ***Real Decreto 1662/2000.***

deltalab
DELTALAB S.L
Plaza de la Verneda 1, Pol. Ind. La Llana
08191 Rubí - Barcelona
T. +34 936 995 000, F. +34 936 994 512

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

deltalab

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS/ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
300265	ESCOBILLON PS+FLOCK EN TUBO	*SWAB / TUBE PS + FLOCK*
303806	ESCOB.FLOCK ULTRA PEEL P.	*FLOCKED SWAB PS STAND.NO/BP ST.PEEL P.*
304270	VICUM 2ML ESC.FLOCK NASOFAR. 100MM	*VICUM 2ML FLOCKED SWAB NASOPH.100MM*
304271	VICUM 1ML ESC.FLOCK ESTANDARD 80MM	*VICUM 1ML FLOCKED SWAB STANDARD 80MM*
304272	VICUM 1ML ESC.FLOCK URETRAL 80MM	*VICUM 1ML FLOCKED SWAB URETRAL 80MM*
304273	VICUM 3ML ESC.FLOCK ESTANDARD 100MM	*VICUM 3ML FLOCKED SWAB STANDARD 100MM*
304274	VICUM 3ML ESC.FLOCK URETRAL 100MM	*VICUM 3ML FLOCKED SWAB URETRAL 100MM*
304275	VICUM 3ML ESC.FLOCK NASOFARINGEO 100MM	*VICUM 3ML FLOCKED SWAB NASOPH.100MM*
304276	VICUM 2ML ESC.FLOCK URETRAL 100MM	*VICUM 2ML FLOCKED SWAB URETRAL 100MM*
304277	VICUM 1ML ESC.FLOCK NASOFARINGEO 100MM	*VICUM 1ML FLOCKED SWAB NASOPH.100MM*
304278	VICUM 2ML ESC.FLOCK ESTANDARD 80MM	*VICUM 2ML FLOCKED SWAB STANDARD 80MM*
304279	VICUM 2ML ESC.FLOCK MINITIP 100MM	*VICUM 2ML FLOCKED SWAB MINITIP 100MM*
304280	CARY BLAIR 2ML ESC.FLOCK ESTANDARD 80MM	*CARY BLAIR 2ML FLOCKED SWAB STANDARD 80MM*
304281	AMIES 1ML ESC.FLOCK ESTANDARD 80MM	*AMIES 1ML FLOCKED SWAB STANDARD 80MM*
304282	AMIES 1ML ESC.FLOCK URETRAL 80MM	*AMIES 1ML FLOCKED SWAB URETRAL 80MM*
304285	AMIES 1ML ESC.FLOCK NASOFARINGEO 100MM	*AMIES 1ML FLOCKED SWAB NASOPH. 100MM*
304286	AMIES 1ML ESC.FLOCK MINITIP 100MM	*AMIES 1ML FLOCKED SWAB MINITIP 100MM*
304287	AMIES 2ML ESC.FLOCK ESTANDARD 80MM	*AMIES 2ML FLOCKED SWAB STANDARD 80MM*
304291	VIRUS 1ML ESC.FLOCK ESTANDARD 80MM	*VIRUS 1ML FLOCKED SWAB STAND. 80MM*
304292	VIRUS 1ML ESC.FLOCK URETRAL 80MM	*VIRUS 1ML FLOCKED SWAB URETRAL 80MM*
304293	VIRUS 3ML ESC.FLOCK ESTANDARD 100MM	*VIRUS 3ML FLOCKED SWAB STANDARD 100M*
304294	VIRUS 3ML ESC.FLOCK URETRAL 100MM	*VIRUS 3ML FLOCKED SWAB URETRAL 100MM*
304295	VIRUS 3ML ESC.FLOCK NASOFARINGEO 100MM	*VIRUS 3ML FLOCK.SWAB NASOPH.100MM*
304297	VIRUS 1ML ESC.FLOCK NASOFARINGEO 100MM	*VIRUS 1ML FLOCK.SWAB NASOPH.100MM*
304296	VIRUS 2ML ESC.FLOCK NASOFARINGEO 2X100MM	*VIRUS 2ML FLOCK.SWAB NASOPH. 100MM*
304298	VIRUS 2ML ESC.FLOCK NASOF + ST. 100/80MM	*VIRUS 2ML FLOCK. SWAB NASOPH. + ST. 100/80MM*

deltalab

REF	DESCRIPCIÓN	*DESCRIPTION*
304288	AMIES 1ML 3 ESC.FLOCK MRSA	*AMIES 1ML 3 FLOCKED SWABS MRSA*
304212	LIM BROTH 2ML ESC.FLOCK ESTANDARD 80MM	*LIM BROTH 2ML FLOCKED SWAB STANDARD 80MM*

deltalab

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

CONTENEDORES PARA MUESTRAS NO ESTÉRILES
GENERAL SPECIMEN CONTAINER NON-STERILE
(Códigos según Anexo 1 / *Codes in Annex 1)*

Finalidad Prevista: Recogida y conservación y/o transporte, de cualquier tipo de muestra para diagnóstico (por ejemplo, orina, heces, esputo, mucosa, tejido) para análisis y/u otra investigación.
Intended Use: *Collection and preservation and/or transport, of any type of diagnostic specimen (e.g. urine, faeces, sputum, mucous, tissue) for analysis and/or other investigation.*

Código GMDN / *GMDN Code:* 47775

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

Directiva 98/79/CE: Directiva Productos Sanitarios para el Diagnostico "in vitro". Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive. Transposition to Spanish legislation in Real Decreto 1662/2000.*

Clasificación: Anexo 3, Clase: Otros
Classification: Annex 3, Class: Other

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

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ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
202840	FRASCO DE SEGURIDAD 20ML	*SECURITY CONTAINER 20ML*
202841	FRASCO DE SEGURIDAD 40ML	*SECURITY CONTAINER 40ML*
202842	FRASCO DE SEGURIDAD 60ML	*SECURITY CONTAINER 60ML*
202843	FRASCO DE SEGURIDAD 90ML (Ø48-h75)	*SECURITY CONTAINER 90ML (Ø48-h75)*
202844	FRASCO DE SEGURIDAD 120ML	*SECURITY CONTAINER 120ML*
202845	FRASCO DE SEGURIDAD 250ML	*SECURITY CONTAINER 250ML*
202846	FRASCO DE SEGURIDAD 500ML	*SECURITY CONTAINER 500ML*
202847	FRASCO DE SEGURIDAD 1000ML	*SECURITY CONTAINER 1000ML*
202848	FRASCO DE SEGURIDAD 90ML(Ø53-h68)	*SECURITY CONTAINER 90ML(Ø53-h68)*
300100	TUBO 17 ML PS 16X150 MM	*PS TUBE 16X150*
300101	TUBO PS 8ML 16X75MM GRADUADO C/BORDE	*PS TUBE 8ML 16X75MM GRADUATED WITH RIM*
300300	TUBO 4 ML PS 11X70 MM	*TUBE 11X70 PS*
300400	TUBO 6 ML PS 12X88 MM GRADUADO	*TUBE 12X88 PS GRADUATED*
300500	TUBO 3 ML PS 11X55 MM	*TUBE 11X55 PS*
300700	TUBO 13X75 PS	*TUBE 13X75 PS*
300702	TUBO 13X75 PS TAPADO	*TUBE 13X75 PS CAPPED*
300704	TUBO 13X75 PS TAPADO Y ETIQ	*TUBE 13X75 PS CAPPED&LABELLED*
300705	TUBO 10 ML PS 16X100 MM	*TUBE 16X100 PS*
300800	TUBO 5ML PS 12X75 MM GRADUADO	*TUBE 5ML PS 12X75MM GRADUATED*
300802	TUBO 12X75 PS + TAPON 305802	*PS TUBE 12X75 + CAP 305802*
300804	TUBO 12X75 PS TAPADO Y ETIQ	*TUBE 12X75 PS CAPPED LABELLED*
300900	TUBO 10ML PS 16X95MM GRADUADO	*TUBE 10ML PS 16X95MM GRADUATED*
300903	TUBO 16x95 PS TAPADO	*TUBE 16x95 POLYSTYRENE CAPPED*
300904	TUBO 10 ML PS 16X95 MM TAPADO ETIQUETADO	*TUBE 16X95 PS CAPPED LABELLED*
300907	TUBO 16X100 PS TAPADO	*TUBE 16X100 PS CAPPED*
300908	TUBO 16X100 PS TAPADO Y ETIQ	*TUBE 16X100 PS CAPPED LABELLED*
300911	TUBO 16X100 PS TAPADO C/308101	*TUBE 16x100 PS CAPPED W/308101*
300912	TUBO 16X95 PS TAPADO 305002	*16X95 TUBE PS CAPPED 305002*

REF	DESCRIPCIÓN	*DESCRIPTION*
300913	TUBO 16X95 PS TAPADO	*TUBE 16X95 PS CAPPED*
300914	TUBO 16x95 TAPADO 305002	*16x95 TUBE CAPPED 305002*
301200	TUBO CONICO 16X102 PS	*CONICAL TUBE 16X102 PS*
301201	TUBO CONICO 12ML PS 16X100 MM	*CONICAL TUBE 16X100 PS*
301202	TUBO CONICO 16X102 PS	*CONICAL TUBE 16X102 PS*
301205	TUBO CONICO 301200 TAP/305502	*PS TUBE 12ML CONICAL CAPPED*
301206	TUBO CONICO 16X102+TAP.305502	*PS CON. TUBE 16X102 + CAP305502*
301207	TUBO CONICO 16x102 PS TAPADO	*CONICAL TUBE 16x102 PS CAPPED*
301212	TUBO CONICO 12 ML PS 17X105 MM	*CONICAL TUBE 17X105 PS*
301213	TUBO CÓNICO 12ML PS 16X105MM	*CONICAL TUBE 12ML PS 16X105MM*
301403	TUBO 12ML PS 15X102 MM TAPADO FALDON	*TUBE 12ML PS CAPPED*
301700	TUBO 7 ML PS 13X100 MM	*TUBE 13X100 PS*
309201	FRASCO 30ML PS ETIQUETADO	*30ML UNIVERSAL LABELLED PS*
309202	FRASCO 30ML PS	*30ML CONTAINER PS*
309206	FRASCO 30ML PS TAPON ROJO	*30ML PS CONTAINER RED CAP*
309207	FRASCO 30ML PS TAP.CU SEPARADA	*PS 30ML CONTAINER SEPARATED CAP*
309222	FRASCO 30ML PS B/U	*30ML CONTAINER I/W PS*
309402	FRASCO 40ML PS	*PS 40ML CONTAINER*
309501	FRASCO 60ML PS ETIQUETADO	*PS 60 ML CONTAINER PRINTED LBL*
309502	FRASCO 60ML PS	*60ML CONTAINER PS*
309505	FRASCO 60ML PS T/AZUL	*CONTAINER PS 60ML BLUE CAP*
309552	FRASCO 60ML PS ESPATULA	*60ML CONTAINER WITH SPOON PS*
400400	TUBO 6 ML PP 12X88 MM GRADUADO	*TUBE 12X88 PP GRADUATED*
400500	TUBO 3 ML PP 11X55 MM	*TUBE 11X55 PP*
400700	TUBO 5 ML PP 13X75 MM	*TUBE 13X75 PP*
400705	TUBO 10 ML PP 16X100 MM	*TUBE 16X100 PP*
400800	TUBO 5ML PP 12X75 MM GRADUADO	*TUBE 5ML PP 12X75MM GRADUATED*
400806	TUBO 75X12 PP TAPADO T/ROJO	*TUBE 12x75 PP CAPPED 305806*
400900	TUBO 16X95 PP	*TUBE 16X95 PP*
400908	TUBO 16x95 TAPADO 305007	*16X95 PP TUBE CAPPED 305007*
401100	TUBO 5 ML PP 15X50 MM	*TUBE 15X50 PP*

REF	DESCRIPCIÓN	*DESCRIPTION*
401200	TUBO CONICO 12 ML PP 16X102 MM	*CONICAL TUBE 16X102 PP*
401201	TUBO CONICO 12 ML PP 16X100 MM	*CONICAL TUBE 16X100 PP*
401202	TUBO CONICO 16x102+TAPON 16MM	*CONICAL TUBE 16x102 + CAP 16MM*
401204	TUBO CÓNICO 12ML PP 16X100 MM	*CONICAL TUBE 12ML PP 16X100MM*
401307	TUBO CONICO 16X102 PP TAPADO	*CONICAL TUBE 16x102 PP CAPPED*
401403	TUBO 12ML PP 15X102 MM TAPADO FALDON	*PP 12 ML TUBE CAPPED*
401700	TUBO 7 ML PP 13X100 MM	*PP TUBE 13X100*
408702	FRASCO 150 ML PP AL VACÍO	*CUP F/VACUUM COLLECTION 150ml*
408726	FRASCO 150 ML PP B/U AL VACÍO	*CUP F/VACUUM COLLEC.150ml I/B*
409201	FRASCO 30ML PP ETIQUETADO	*30ML CONTAINER LABEL PP*
409202	FRASCO 30ML PP	*30ML CONTAINER PP*
409222	FRASCO 30ML PP BOLSA UNITARIA	*30ML CONTAINER I/W PP*
409402	FRASCO 40ML PP GRADUADO	*40ML CONTAINER PP GRADUATED*
409426	FRASCO 40ML PP B/U GRADUADO	*40ML CONTAINER I/W PP*
409501	FRASCO 60ML PP ETIQUETADO	*60ML CONTAINER LABELLED PP*
409502	FRASCO 60ML PP	*60ML CONTAINER PP*
409507	FRASCO 60ML PP ROSCADO T/VERDE	*60ML SCREW CAP CONT PP C/GREEN*
409511	FRASCO 60ML PP ETIQUETADO T/AZUL	*60ML BLUE CONTAINER LABEL PP*
409552	FRASCO 60ML PP C/ESPATULA	*60ML CONTAINER W/SPOON*
409556	FRASCO 60 ML. B/UNIT. CUCHARA	*60 ML PP CONTAINER WITH SPOON UNIT BAG*
409602	FRASCO 30ML PP C/CUCHARA	*30ML CONTAINER WITH SPOON PP*
409662	FRASCO 30ML.T/AZUL CUC S/ROSC	*SCREW CAP CONT.30ml PP*
409701	FRASCO 150ML PP ETIQUETADO	*150ML CONTAINER LABELLED PP*
409702	FRASCO 150ML PP	*150ML CONTAINER PP*
409703	FRASCO 150ML PP SIN ROSCAR	*150ML CONT SEPARATED CAP PP*
409707	FRASCO 150ML PP T/VERDE	*PP 150 ML CONTAINER GREEN CAP*
409711	FRASCO 150ML AZUL ETIQUETADO	*150ML BLUE CONTAINER LABEL PP*
409752	FRASCO 150ML PP C/CUCHARA	*150ML CONTAINER WITH SPOON PP*
409756	FRASCO 150ML B/U ESPATULA PP	*150ML CONTAINER I/W SPOON PP*
409802	FRASCO 50ML PP	*50ML CONTAINER PP*
409826	FRASCO 50ML PP B/U	*50ML CONTAINER I/W PP*

REF	DESCRIPCIÓN	*DESCRIPTION*
409852	FRASCO 50ML PP CON ESPATULA	*50ML CONTAINER WITH SPOON PP*
409902	FRASCO 200ML PP	*200ML CONTAINER PP*
409905	FRASCO 200ML PP AZUL TRANS. ETI	*CONTAINER 200 ML PP BLUE-PLAIN LBL*
409915	FRASCO 200ML PP AZUL TRANS S/E	*CONTAINER 200 ML PP BLUE*
409926	FRASCO 200ML PP B/U	*200ML CONTAINER PP I/W*
410046	FRASCO 50 ML PP T/PRECINTO	*TAMPER EVIDENT CONT.50ml H80mm*
410047	FRASCO T/BISAGRA 50ml H=80mm	*HINGED LID CONT.50ml H=80mm*
410056	FRASCO PRECINTO 50ml H80mm B/U	*HINGED LID CONT.50ml H80mm I/B*
419802	FRASCO 50ML PP T/PRECINTO	*50ML CONT SEALED CAP PP*
419805	FRASCO 50ML PP T/PRECI AZUL	*PP 50 ML CONT. SEALED CAP BLUE*
419825	FRASCO 50ML PP T/PREC.AZUL B/U	*50ML CONT SEAL.BLUE CAP I/W PP*
419826	FRASCO 50ML PP T/PRECINTO B/U	*50ML CONT SEALED CAP I/W PP*
429900	TUBO CONICO 50 ML PP TAPADO	*50ML CONICAL TUBE PP*
429901	TUBO CONICO 50ML PP FALDON TAPADO	*50ML CONICAL TUBE SKIRT PP*
429903	TUBO 50ML PP CON.FALDON S/TAP	*50ML CON.TUBE SKIRTE PP NO CAP*
429910	TUBO CONICO 15ML PP TAPADO	*15ML CONICAL TUBE PP*
444602801	FRASCO DE SEG. 60ML T/AZUL	*CHILD PROOF CONT 60ML BLUE LID*
444602802	ANTI-CHILD. SIN TAPON	*CHILD PROOF CONT.60ML NO CAP*
444602901	FRASCO SEGURIDAD 60ML T/AZUL	*CHILDPROOF CONT 60ML BLUE LID*
444602903	ANTI-CHILD BLANCO T/BLANCO 60	*CHILD PROOF WHITE CONTAINER 60*
444603202	FRASCO DE SEG. 30ML T/BLAN PRECINTO	*SECURITY CONT. 30ML WHITE CAP*
444603204	F.SEGURIDAD BLANCO 30ML T/BLANCO	*CHILDPROOF WH.CONT 30ML B/CAP*
444603300	FRASCO SEGURIDAD 60ML T/BLANCO	*CHILDPROOF CONT 60ML WHITE LID*
444603305	ANTI-CHILD.AZUL TAPON BLANCO	*CHILD PROOF BLUE CONT.WHITE CAP*
444603306	ANTI-CHILD. VERDE TAPON BLANCO	*CHILD PROOF GREEN CONT.WHITE CAP*
444603308	ANTI-CHILD.ROJO TAPON BLANCO	*CHILD PROOF RED CONT.WHITE CAP*
444603402	F. SEGURIDAD 125ML T/BLANCO	*CHILDPROOF CONT 125ML WHITE LID*
202845N	TARRO HISTOLOGIA 250ML NEGRO	*HISTOLOGY CONTAINER 250ML BLACK*
202846/T	FRASCO DE SEGURIDAD 500ML TAPADO	*SECURITY CONTAINER 500ML CAPPED*
202847/T	FRASCO DE SEGURIDAD 1000ML TAPADO	*SECURITY CONTAINER 1000ML CAPPED*

REF	DESCRIPCIÓN	*DESCRIPTION*
300500.8	TUBO 11X55 PS	*TUBE 11X55 PS*
300800.1	TUBO 5 ML PS 12X75 MM SIN ENRASES	*TUBE 12X75 PS*
300800.2	TUBO 12X75 PS REFORZADO	*TUBE 12X75 PS*
300900M	TUBO 16X95 PS GRAD.CAJA 5X100	*TUBE 16X95 PS GRAD.CASE 5X100*
309202.4	FRASCO 30ML PS	*PS 30 ML. UNIVERSAL PLAIN LBL*
309202.NR	FRASCO 30ML PS	*30ml CONTAINER PS NO SCREW*
309202V	FRASCO 30ML PS TAPÓN VERDE	*30ML CONTAINER PS GREEN CAP*
309202.WO	FRASCO 30ML PS SIN TAPÓN	*CONT.30ML PS NO CAP*
309222.1	FRASCO 30ML PS B/U ETIQUETADO	*CONTAINER 30 ML. UNIT BAG LABEL*
309501BE	FRASCO 60ML PS B/50 CÓD. BARRAS	*60ML PS CONTAINER B/50 BAR COD*
309502.10	FP-60 S/ROSCAR C/600 T/ROJO	*CONT.60ML C/600 RED CAP*
309502.6	FRASCO 60 ML. PS ETIQUETA BLANC	*PS 60 ML. CONTAINER PLAIN LABEL*
309602E	FRASCO 30ML PS CON ESPATULA ETIQUETADO	*30ML CONTAINER WITH SPOON PS*
309622.1	FCO.30 CUCH. ETIQ. ESP. B/UNIT.	*PS 30ML SPOON+LABEL+UNIT BAG CONT.*
400004.1	FRASCO 125ML PP 57X73	*125ML CONTAINER PP*
400500.B	TUBO 11x55 PP B/400	*TUBE 11x55 PP B/400*
400706E	TUBO 10ML C/A.BORICO TAP.ETIQ.B/U	*100ML TUBE W/BORIC A. CAP.LAB. I/W*
400800.1	TUBO 5 ML PP 12X75 MM SIN ENRASES	*TUBE 12X75 WITHOUT RINGS PP*
400906BOR	TUBO 16X100 TAP- 308106 AC. BOR	*TUBE 16X100 PP CAP ACID BORIC*
400906MD	TUBO 16x100 PP TAPADO 308106	*16x100 TUBE PP CAPPED 308106*
409201.S	FRASCO 30ML PP ETIQUETADO	*30ML CONTAINER LABEL PP*
409201.SE	FRASCO 30ML PP ETIQUETADO B100	*30ML CONTAINER LABEL PP B/100*
409202.8	FRASCO 30 ML TAPADO TAPON AZUL	*30ML CONTAINER PP BLUE CAP*
409202.WO	FRASCO 30ML PP SIN TAPÓN	*CONT. 30ML PP NO CAP*
409203.2	FRASCO 30ML PP T/BLAN ENV. SEP	*PP 30 ML+ WHITE CAP SEPARAT.C/1800*
409203.2A	FR.30ML PP T/BL.ENV.SEP.C/ANO	*PP 30ML WHITE CAP SEP.PLAIN BO*
409502.2B	FR.60ML ETIQ.T/ROJO 10X50	*CONT.60ML LABEL RED C.10X50*
409502.2C	FR. 60ML PP ETIQ.T/ROJO 16X50	*60ML CONT. PP LABEL RED CAP 16X50*
409502.4	FRASCO 60ML S/ROSCAR 38X65 PP	*60ML CONT. UNCAPPED 38X65MM PP*
409502.4Y	FRASCO 60ml S/ROSCAR PP T/AMA	*60ml CONT.UNCAPPED PP YEL/LID*
409502G	FRASCO 60ML GRADUADO	*60ML CONTAINER GRADUATED PP*

REF	DESCRIPCIÓN	*DESCRIPTION*
409502G.4	FR.60 GRAD.S/ROSCAR TAP.SEPARA	*CONT.60 GRAD.UNCAPPED SEP.CAP*
409507G	FRASCO 60ml PP GRAD.T/VERDE	*60ml CONT.PP GRAD.GREEN CAP*
409511.4	FR.60ML AZUL CLARO S/ETIQUETA	*60ML LIGHT BLUE CONTAINER*
409511.5	FR.60ML AZUL TRANSL. ETIQ. BLANC	*60ML CONTAINER TRANS.BLUE LBL*
409552.Y	FRASCO 60ml PP C/ESPÁTULA T/AM	*60ml CONTAINER W/SPOON YEL/LID*
409552G	FRASCO 60ML PP GRADUADO C/ESPA	*60ML CONTAINER W/SPOON GRADUAT*
409552.TA	FRASCO 60ML PP C/ESPATULA T.AZUL	*60ML CONTAINER PP W/SPOON BLUE CAP*
409702.3	FRASCO 150ml PP TAPÓN BLANCO	*PP CONTAINER 150ml WHITE CAP*
409702.P	FRASCO 150ML PP ROSCADO	*150ML PP CUPPED CONTAINER*
409702.PB	FRASCO 150ML PP ROSCADO T.BLA	*150ML PP CUPPED CONT.WHITE C.*
409703.5	FRASCO 150 ML. T/AZUL S/ROSCAR	*150ML CONT SEPARATED BLUE CAP*
409703WC	FRASCO 150ML PP SIN ROSCAR T/BLANCO	*150ML PP CONT.SEPAR.CAP WHITE*
409711.4	FR.150ML AZUL CLARO S/ETIQUETA	*150ML LIGHT BLUE CONTAINER*
409711.5	FR.150ML AZUL TRANS. ETIQ. BLANC	*150ML CONTAINER BLUE TRANSL.LB*
409805.6	FRASCO 50ML PP T/ROJO SEPARADO	*50ML PP CONTAINER SEP. RED CAP*
410046.5	FRASCO T/PREC.50ml H80mm C/500	*HINGED LID CONT.50ml H80 C/500*
410046A.5	FRASCO T/PREC.50ml 500UD AZUL	*HINGED LID CONT.500U BLUE*
410046R.5	FRASCO T/PREC.50ml 500UD ROSA	*HINGED LID CONT.500U PINK*
420900E	TUBO 12ML PP S/TAPON C/FALDON	*PP 12ML TUBE W/SKIRT W/OUT CAP*
429900.25	TUBO CONICO 50ml PP B/25	*50ml CONICAL TUBE PP B/25*
429900SP	TUBO 50ML PP CONICO SIN ROSCAR	*50ML CONICAL TUBE PP SEP.CAP*
429901.25	TUBO CON.50ml PP C/FALDON B/2	*50ml CONICAL TUBE W/SKIRT B/25*
429910SP	TUBO 15ml PP CONICO SIN ROSCAR	*15ml CONICAL TUBE PP SEP.CAP*
429927S/E	TUBO CONICO 50ML C/FALDON B/U	*50ML CONICAL TUBE SKIRT I/W PP*
44462903M	ANTI-CHILD BLANCO T/BLANCO 60	*CHILDPROOF WHIE CONT.60ML WC*
309202.O	FRASCO 30ML PS ST. EO	*CONTAINER 30ML PS ST.EO*
429930	TUBO 50ML PP CONICO IMPRESO B/25	*50ML TUBE PP CONICAL PRINT 25/B*
429940	TUBO 15 ML PP CONICO IMPRESO GRANEL	*15ML TUBE PP CONICAL PRINTED IN BULK*
429945	TUBO 15 ML PP CONICO IMPRESO B/25	*15ML TUBE PP CONICAL PRINT 25/B*

REF	DESCRIPCIÓN	*DESCRIPTION*
429950	TUBO 50 ML PP CONICO IMPRESO C/F B/25	*50ML TUBE PP CONICAL PRINT SKIRTED 25/B*
300500MI	TUBO 11X55 PS	*TUBE 11X55 PS*
175723	TUBO 5ML PS 13X75 TAPADO ROJO	*TUBE 5ML PS 13X75 CAPPED RED*
175724	TUBO 10ML PS 16X95 TAPADO ROJO	*10ML TUBE PS 16X95 CAPPED RED*
400903	TUBO 10ML PP 16X95 TAPADO ROJO	*10ML TUBE PP 16X95 CAPPED RED*
661035	TUBO 10ML PS 16X95 TAPADO NATURAL	*10ML TUBE PS 16X95 CAPPED NATURAL*
408702C	FRASCO VACÍO 120ml LOTE IMPRESO	*VACUUM CONT.120ML CML*
408726.A	FRASCO P/VACÍO 120ml B/I C/AN.	*CUP F/VACUUM 120ml I/B PLAIN/C*
400805	TUBO 75X12 PP TAPADO T/AZUL	*TUBE 75X12 PP CAPPED C/BLUE*
202844/T	FRASCO DE SEGURIDAD 120ML TAPADO	*SECURITY CONTAINER 120ML CAPPED*
409557	FRASCO 60ML PP C/ESPATULA T/VERDE	*CONTAINER 60ML PP W/SPOON GREEN CAP*
419802.T	FRASCO 50ML PP T/PREC. DESTAPADO	*CONTAINER 50ML PP C/TAMPER EVID. UNCOVERED*
409502.4B	FRASCO 60ML PP T/AZUL NO TAPADO	*60ML CONTAINER PP BLUE CAP UNCOVERED*
409702B	FRASCO 150ML PP B/50	*150ML CONTAINER PP B/50*
309205	FRASCO 30ML PS T/AZUL ETIQ.	*30ML CONTAINER PS BLUE CAP LABEL*
429906SP	TUBO 50ML PP CONICO T/ROJO SIN ROSCAR	*50ML CONICAL TUBE PP SEP.CAP RED*
429901SP	TUBO CONICO 50ML PP FALDON SIN ROSCAR	*TUBE 50ML PP SKIRTED SEP. CAP*
175725	TUBO 3ML PS 11X55 TAPADO ROJO	*TUBE 3ML PS 11X55 CAPPED RED*
409511.4TA	FRASCO 60ML PP C/CUCHARA T/AZUL	*CONTAINER 60ML PP W/SPOON BLUE CAP*
202842A	FRASCO SEGURIDAD 60ML T/AZUL	*CONTAINER 60ML BLUE CAP*
202844A	FRASCO DE SEGURIDAD 120ML T/AZUL	*SECURITY CONTAINER 120ML BLUE CAP*
409512	FRASCO 60ML PP T/ROJO C/GRIS	*CONT. 60ML PP RED C. GREY B.*
301201CA	TUBO CONICO 12ML PS 16X100 MM	*CONICAL TUBE 16X100 PS*

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

TUBOS DE EXTRACCIÓN – CITRATO TAMPONADO
BLOOD CONTAINERS – SODIUM CITRATE
(Códigos según Anexo 1 / *Codes in Annex 1)*

Finalidad Prevista: Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (p.ej. para estudios de coagulación del plasma)
Intended Use: *Collection and preservation and/or transport, of blood for analysis and/or other (e.g. for plasma coagulation studies)*

Código GMDN / *GMDN Code:* 58139

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

Directiva 98/79/CE: Directiva Productos Sanitarios para el Diagnostico "in vitro". Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive. Transposition to Spanish legislation in Real Decreto 1662/2000.*

Clasificación: Anexo 3, Clase: Otros
Classification: Annex 3, Class: Other

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
601102	TUBO CITRATO PP 4 ML	CITRATE TUBE 4ML PP
601103	TUBO CITRATO PP 2,5ML	CITRATE TUBE 2.5ML PP
601203	TUBO CITRAT TAMP 3,2% PP 2,5ML	CITRATE TUBE 3.2% 2.5ML PP
621101	TUBO CITRATO 1ML PERFORABLE	CITRATE TUBE 1ML PIERCEABLE
621102	TUBO CITRATO 2ML PERFORABLE	CITRATE TUBE 1ML PIERCEABLE
601103.2	TUBO CITRATO 2.5ML RETRACTIL	CITRATE TUBE 2.5ML WRAPPEDRACK
601203.1	TUBO CITRATO 3.2% 2.5ML GRANEL	CITRATE TUBE 3.2% 2.5ML BULK

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

TUBOS DE EXTRACCIÓN – K3EDTA
BLOOD CONTAINERS – K3EDTA
(Códigos según Anexo 1 / *Codes in Annex 1)*

Finalidad Prevista: Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, hematología de sangre como conteo sanguíneo completo (SCS), y determinación cuantitativa de drogas.
Intended Use: *Collection and preservation and/or transport of blood for analysis and/or other investigation (e.g.whole blood hematology such as complete blood count (CBC) and quantitative drug assay determinations.*

Código GMDN / GMDN *Code:* 58143

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

Directiva 98/79/CE: Directiva Productos Sanitarios para el Diagnostico "in vitro".
Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive.*
Transposition to Spanish legislation in Real Decreto 1662/2000.

Clasificación: Anexo 3, Clase: Otros
Classification: Annex 3, Class: Other

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

deltalab

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
601603	TUBO EDTA TRIPOTASICO 2,5ML PP 13X75MM	EDTA TUBE TRI-K R/BOT 2.5ML PP
601612	TUBO EDTA TRI-K PP 4ML	EDTA TUBE TRI-K 4ML PP
601613	TUBO EDTA TRI-K PP 2,5ML	EDTA TUBE TRI-K 2.5ML PP
601702	TUBO EDTA TRI-K PP 4ML	EDTA TUBE TRI-K 4ML PP
611604	TUBO EDTA TRI-K 3ML PP 13X80 T/GOMA PERF.	EDTA TRI-K TUBE 3ML PP 13X80 RUBBER CAP PERF.
621610	TUBO EDTA TRI.1ML PP 12X55MM T/PRE PERF.	EDTA TUBE TRI-K 1ML PP 12X55MM C/PRE-PERF.
621611	TUBO EDTA TRI-K 2ML 16X55 FALDON T/PRE-PERF.	EDTA TUBE TRI-K 2ML 16X55 SKIRTED C/PRE-PERF.
621613	TUBO EDTA TRI 2,5ML PP 13X80MM T/PERFOR.	EDTA TUBE TRI-K 2.5ML PP 13X80MM T/PRE-PERF.
601603.2	TUBO EDTA TRI-K 2.5ML RETRACTILADO	EDTA TRI-K TUBE 2.5ML WRAP/RAC
601702.2	TUBO EDTA TRI-K 4ML RETRACTILADO	EDTA TRI-K TUBE 4ML WRAPP/RACK
611603.1	TUBO EDTA TRI-K PULV. 3ML 13X75 T/PERFO	EDTA TUBE PUL.K3 3ML PIERC.CAP

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:
Declares under its responsibility that the product:

TUBOS DE EXTRACCIÓN – SEROTUB
BLOOD CONTAINERS – SEROTUBE
(Códigos según Anexo 1 / *Codes in Annex 1)*

Finalidad Prevista: Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, determinación química del suero sanguíneo).
Intended Use: *Collection and preservation and/or transport, of blood for analysis and/or other investigation (e.g. blood serum chemistry determinations)*

Código GMDN / GMDN *Code:* 58138

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

Directiva 98/79/CE: Directiva Productos Sanitarios para el Diagnostico "in vitro".
Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive.*
Transposition to Spanish legislation in Real Decreto 1662/2000.

Clasificación: Anexo 3, Clase: Otros
Classification: Annex 3, Class: Other

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

deltalab

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	*DESCRIPTION*
600300	TUBO SUERO PP 9ML GRANULOS	SEROTUBE W/GRANULES PP 9ML
600400	TUBO SUERO PP 4ML GRANULOS	SEROTUBE W/GRANULES PP 4ML
600602	SEROTUB GLUCOSA PP 4ML	SERUM GLUCOSE 4ML GRANULES PP
600610	SEROTUB GLUCOSA PP 10ML	PP SERUM GLUCOSE 10ML GRANULES
600800	TUBO SUERO PP 9ML GEL	SERUM TUBE W/GEL 9ML PP
600801	TUBO SUERO PP 4ML GEL	SERUM TUBE W/GEL 4ML PP
620200	TUBO SUERO 2ML PERF GRANULOS	SERUM TUBE 2ML PIER W/GRANULES
620300	TUBO SUERO 10ML PERF GRANULOS	SERUM TUBE 10ML PIER W/GRANULE
620400	TUBO SUERO 4ML PERF GRANULOS	SERUM TUBE 4ML PIER W/GRANULES
620800	TUBO SUERO 10ML PERF GEL	SERUM TUBE 10ML PIERCEABLE GEL

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60131743 0001

Report No.: 10042449 010

Manufacturer:
Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

Products:
In-vitro diagnostic Medical Devices for self-testing

(see attachment for products included)

Replaces Approval, Registration No.: HL 60088590 0001

Expiry Date: 2023-09-17

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2018-10-19

Date: 2018-10-19

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Allen Chen
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60131743 0001
Report No.: 10042449 010

Manufacturer:
Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

Products:

- Blood Glucose Monitoring Systems
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Triglyceride Monitoring System
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Triglyceride Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin/ Triglyceride Monitoring Systems
- Blood Pressure/Glucose/Cholesterol Monitoring Systems (assessment limited to Glucose/Cholesterol Monitoring)

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Allen Chen

Date: 2018-10-19

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

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

Design and development, manufacture and distribution of Medical devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2018-10-19
Certificate Registration No.:	SX 60131746 0001
An audit was performed. Report No.:	50145079 001
This Certificate is valid until:	2021-09-17

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-10-19

Allen Chen

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60131746 0001
Report No.: 50145079 001

Organization:
Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

Scope:

Products:

- In vitro diagnostic medical devices used in blood analytes and blood glucose monitoring including meter, test strips and control solutions for self-testing, near patient/point of care.
- Blood Pressure/Glucose/Cholesterol Monitoring System (assessment limited to Blood Pressure Monitoring)

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Allen Chen

Date: 2018-10-19

Annex to certificate

Standard **ISO 9001:2015**

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

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

2022-12-15

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

TÜVRheinland®
Precisely Right.

Certificate

Standard **ISO 9001:2015**

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

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

including the locations according to annex

Scope: Design, development, manufacture, distribution, installation and service of instruments and reagents for:
- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Reagent labelling and assembly.
Storage of raw materials for instruments, instruments and reagents for:
- Clinical diagnostics.
- Agri-food analysis.
- Veterinary diagnostics.

Dispatched of stored product.

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

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

2022-12-15

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1695779-1

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

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

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

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1695779-1

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

The scope of certification includes the following additional sites:

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

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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

BioSystems
REAGENTS & INSTRUMENTS

EC DECLARATION OF CONFORMITY

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

Hereby DECLARES

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

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

under the specifications declared by BioSystems S.A.

It means that the products:

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

Barcelona, November 6th, 2012

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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

AUTOIMMUNITY – ELISA:

ANA Screening
Anti-Annexin V IgG/IgM (ANX)
Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)
Anti-Cardiolipin Antibodies (ACA-IgG/IgM)
Anti-Centromere B Antibodies (CENP-B)
Anti-Citrullinated Protein Antibodies (ACPA)
Anti-Deamidated Gliadin Peptides IgA (DGP IgA)
Anti-Deamidated Gliadin Peptides IgG (DGP IgG)
Anti-dsDNA Antibodies
Anti-GBM Antibodies - EIA (GBM)
Anti-Gliadin Antibodies (AGA-IgG/IgA)
Anti-Histones Antibodies (HIST)
Anti-Insulin Antibodies (INS)
Anti-Jo1 Antibodies
Anti-M2 Antibodies (M2)
Anti-MPO Antibodies
Anti-Nucleosome Antibodies (NCL)
Anti-Phospholipid IgG/IgM (APLA)
Anti-PR3 Antibodies
Anti-Ribosomal P Antibodies (Rib P)
Anti-Scl70 Antibodies
Anti-Sm Antibodies
Anti-Sm/RNP Antibodies
Anti-SSA (Ro) Antibodies
Anti-SSB (La) Antibodies
Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Thyroid Peroxidase Antibodies (Anti-TPO)
Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA)
Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG)
ASCA-IgG/IgA (ASCA)
ENA 4-Profile
ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS:
AUTOIMMUNITY – INSTRUMENTS:

iPRO

RAPID TESTS – LATEX AGGLUTINATION:

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

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon
TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening
Febrile Serodiagnostics Salmonella
Brucella abortus
Brucella abortus, Rose Bengal
Proteus Ox19
Salmonella paratyphi AH
Salmonella paratyphi AO
Salmonella paratyphi BH
Salmonella paratyphi BO
Salmonella paratyphi CH
Salmonella paratyphi CO
Salmonella typhi H
Salmonella typhi O
Brucella Positive Control
Proteus Positive Control
Salmonella Positive Control
Serology Negative Control

TEST IT
for healthy generations

in vitro diagnostic test

Fecal Occult Blood (FOB) Test

CE

TEST IT
for healthy generations

in vitro diagnostic test

INSTRUCTION FOR USE
Fecal Occult Blood (FOB) Test
For hHB (human hemoglogin)
Detection in Feces

Only for professional *in vitro* diagnostic use

Product Code: TIHHB02

BACKGROUND INFORMATION
The presence of fecal occult blood in the stool is associated with gastrointestinal disorders such as diverticulitis, polyps, and Crohn's disease, that may lead to colorectal cancer if not treated. Early diagnosis by fecal occult blood screening and treatment of these problems has been shown to significantly reduce mortality from colorectal cancer. Detection of occult blood in feces is a recommended examination method by many organization such as WHO (World Health Organization) for large intestine cancer diagnosis.
Immunochromatographic test methods have superior clinical specificity when compared to a chemical based test (e.g. guaiac) as well as do not required any dietary restrictions.

INTENDED USE
Fecal Occult (Hidden) Blood Test is a qualitative immunochromatographic test for detection of human hemoglobin (hHb) in human feces for professional use.

REAGENTS
Mouse monoclonal anti-hemoglobin antibody-A, goat anti-mouse (IgG) polyclonal antibody and monoclonal anti-hemoglobin antibody B conjugated with colloidal colored particles.

METHOD
Fecal Occult Blood Test uses solid-phase immunochromatographic technology for the qualitative detection of hHb in human feces. The test is a two-site immunometric assay in which a combination of monoclonal and polyclonal antibodies is used to selectively detect hHb in samples with a high degree of sensitivity. Mouse monoclonal anti-hemoglobin antibody A was immobilized on the test area "T" and goat anti-mouse (IgG) polyclonal antibodies were immobilized on the control area "C" of the nitrocellulose membrane. Monoclonal anti-hemoglobin antibody B conjugated with colored particles was dried on a conjugate pad.
Sample is introduced from sampling pad. If there is hHb at detectable level in the sample, hHb binds to the mobile monoclonal anti-hemoglobin antibody B conjugated with colored particles. Together they move to the test area "T". hHB molecules bind to the immobilized mouse monoclonal anti-hemoglobin antibody and as a result of this, hHb molecules that have already bound to mobile monoclonal anti-hemoglobin antibody A (conjugated with colored particles) become immobilized in the test area "T" thus creating a visible colored signal in the test area "T" (a colored test line), indicating positive test result. If there is no hHb at detectable level in the sample then sample moves to the test area "T" together with unbound (free) monoclonal anti-hemoglobin antibody B conjugated with colored particles. Immobilized mouse monoclonal anti-hemoglobin antibody A can not bind to mobilized monoclonal anti-hemoglobin antibody B conjugated with colored particles, therefore no visible colored signal in test area "T" (no colored test line) can be obtained, indicating negative test result. Regardless of hHb content of the liquid sample monoclonal anti-hemoglobin antibody B conjugated with colloidal particles mobile bind immobilized goat anti-mouse (IgG) polyclonal antibodies while liquid sample is passing through the control area "C". Therefore accumulation of colloidal colored particles produces a visible colored signal in the control area "C" (a colored control line), indicating a valid test result. Colored line should be visible in the control area "C" in every case; if no visible colored line in control area "C", test result should be indicated as invalid.

PRECAUTIONS AND LIMITATIONS
1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
4. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
5. Wear disposable gloves while performing the test.
6. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
7. Blood detection can not be realized if the very little amount of blood is not evenly spread across the feces. For this reason, it is recommended that feces sampling should be done from different areas of the feces. In this way sampling possibility of blood in feces increases.
8. Repeating the test every six months is recommended, as there is no continuous bleeding in case of large intestine cancer. Accordingly, detection possibility of periodically bleeding tumor increases.

9. Below are illnesses that cause bleeding, where the test gives a positive result although the patient is not suffering from a large intestine cancer.
- Ruptures in the digestive system
- Oesophageal varices
- Medication that causes gastric irritation e.g. aspirin
- Gastric tumor or malignant tumor
- Meckels diverticulum
- Ulcerative colitis
- Polyps of large intestine
- Hemorrhoids

10. All patient samples should be handled as if they are capable of transmitting disease. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
11. This test will indicate only the selectively total human hemoglobin (hHb) in the sample, and should not be used as the only basis for the diagnosis.
As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources.Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.
Kit components : Test cassettes, sample collection tubes with dilution buffer, instructions for use.
Additional materials required but not provided : Collection cup and timer.
Additional materials recommended but not provided : Negative and positive control materials.

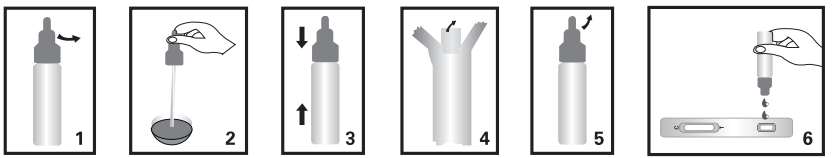
SAMPLE COLLECTION AND PREPARATION

- The test can be performed using feces samples. Feces samples can be stored at 2 - 8 °C until they are being tested in a period of 3 days after collection if not tested within 6 hours. Sample prepared in the sample collection tube can be stored for 6 months at - 20°C if not tested within 1 hour after preparation.
- Sample should not be collected during or within three days of a menstrual period, or if the patient suffers from bleeding hemorrhoids or blood in the urine, false positive test results may be obtained.
- Dietary restrictions are not necessary. Test is a convenient test method that employs anti-human hemoglobin antibodies that causes recognize only human hemoglobin with high sensitivity.

TEST PROCEDURE

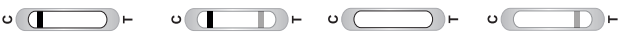
1. Open the sampling test tube by turning the lid (Figure 1).
2. Insert and twist the rod into the sample feces in at least 3 different parts of the sample (Figure 2).
3. Insert the rod with the collected sample into the test tube and close it firmly. Shake the sampling test tube well up and low direction for 2 minutes (Figure 3).
   * Please make sure that dilution buffer with fecal sample in tube is homogeneous and it has low solid density .
4. Remove the test kit from its protective aluminum pouch and place the test on a flat surface (Figure 4).
5. Open the cap on the tip of the sampling test tube (Figure 5).
6. Draw 2 drops of sample into sample well of the test cassette (Figure 6).
7. Results should be read within 10 minute as shown below. Do not interpret results beyond 20 minutes, results forming after 20 minutes should be regarded as invalid .

NOTE: If the extracted sample does not migrate in the test because of the particles, centrifuge the extracted sample in the sample collection tube. Then collect 80 µl supernatant and dispense it to the sample well of a new test device and follow the instruction from step 4.



INTERPRETATION OF RESULTS

Negative : Only one colored band is visible in "C" area.
Positive : Two colored bands are visible in "C" and "T" areas.
Low concentration of hHb may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid : No colored band is visible or only one colored band is visible in "T" area; test should be repeated using a new test device.



QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

Cut off value : 50 ng hHb/ml

Sensitivity : 99 % Specificity : 99,9 %
+ Predictive Value : 99,9 % - Predictive Value : 96,7 %

Test		Reference + Result	Reference - Result
	+ Result	99	0
	- Result	1	30

There is no hook effect (Measurement rage up to 100.000 ng/ml).

Cross Reactivity : There is no any cross reaction interactions with the hemoglobin as follows:
1000 mg/L Cattle Hb
1000 mg/L Sheep Hb
1000 mg/L Horse Hb
1000 mg/L Pig Hb
1000 mg/L Goat Hb
1000 mg/L Rabbit Hb
1000 mg/L Dog Hb

Internal Quality Control: Following substances were used for internal quality control: h Hemoglobin, h Albumin, h Haptoglobin, h Myoglobin, h Transferrin.

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CE

Manufacturer

Consult instruction for use

Attention, see instruction for use

IVD *In vitro* diagnostic medical device

For single use only

Number of test

Storage temperature

REF Catalog number

LOT Lot number

Expiry date

TEST IT
for healthy generations

GEBRAUCHSANWEISUNG
Test auf okkultes Blut im Stuhl (FOB)
Für hHB (humanes Hämogoglean)
Nachweis in Fäkalien

in vitro-diagnostik

Nur für die professionelle *In-vitro*-Diagnostik

Produktcode: TIHHB02

ALLGEMEINE INFORMATIONEN

Das Vorhandensein von okkultem Blut im Stuhl wird mit Magen-Darm-Erkrankungen wie Divertikulitis, Polypen und Morbus Crohn in Verbindung gebracht, die unbehandelt zu Darmkrebs führen können. Es hat sich gezeigt, dass eine frühzeitige Diagnose durch ein Screening auf okkultes Blut im Stuhl und die Behandlung dieser Probleme die Darmkrebssterblichkeit signifikant senkt. Der Nachweis von okkultem Blut im Stuhl ist eine Untersuchungsmethode, die von vielen Organisationen wie der WHO (Weltgesundheitsorganisation) zur Diagnose von Dickdarmkrebs empfohlen wird.
Immunchromatographische Testmethoden haben im Vergleich zu einem chemischen Test (z. B. Gaiaic) eine überlegene klinische Spezifität und erfordern keine diätetischen Einschränkungen.

VERWENDUNGSZWECK

Der Test auf okkultes Blut im Stuhl ist ein qualitativer immunchromatographischer Test zum Nachweis von humanem Hämoglobin (hHb) inmenschlichen Fäkalien für den professionellen Gebrauch.

REAGENZIEN

Monoklonaler Anti-Hämoglobin-Antikörper der Maus A, polyklonaler Anti-Maus-Antikörper gegen Maus (IgG) und monoklonaler Anti-Hämoglobin-Antikörper B konjugiert mit kolloidal gefärbten Partikeln.

METHODE

Der Test auf okkultes Blut im Stuhl verwendet die immunchromatographische Festphasentechnologie zum qualitativen Nachweis von hHb in menschlichen Fäkalien. Bei dem Test handelt es sich um einen immunmetrischen Zwei-Standort-Test, bei dem eine Kombination aus monoklonalen und polyklonalen Antikörpern verwendet wird, um hHb selektiv in Proben mit hoher Sensitivität nachzuweisen. Der monoklonale Anti-Hämoglobin-A-Antikörper der Maus wurde auf dem Testareal "T" und die polyklonalen Antikörper (IgG) der Ziege auf dem Kontrollareal "C" der Nitrozellulosemembran immobilisiert. Der monoklonale Anti-Hämoglobin-B-Antikörper, der an farbige Partikel konjugiert war, wurde auf einem konjugierten Puffer getrocknet.
Die Probe wird aus einem Probenahmepuffer eingebracht. Wenn hHb in einer nachweisbaren Menge in der Probe vorhanden ist, bindet hHb an den mobilen monoklonalen Anti-Hämoglobin-B-Antikörper, der mit farbigen Partikeln konjugiert ist. Gemeinsam bewegen sie sich in den Testbereich "T". Die hHB-Moleküle binden an den immobilisierten monoklonalen Antihämoglobin-Antikörper der Maus und daher immobilisieren sich die hHb-Moleküle, die bereits an den mobilen monoklonalen Anti-Hämoglobin-A-Antikörper (konjugiert mit farbigen Partikeln) gebunden haben, im Testbereich "T" und erzeugen ein sichtbares farbiges Signal im Testbereich "T" (eine farbige Testlinie). ein positives Testergebnis anzeigen. Wenn kein hHb in der Probe nachweisbar ist , bewegt sich die Probe in den Testbereich "T" mit dem ungebundenen (freien) monoklonalen Anti-Hämoglobin-B-Antikörper, der an farbige Partikel konjugiert ist. Der monoklonale Anti-Hämoglobin-A-Antikörper von immobilisierten Mäusen kann nicht an den an gefärbte Partikel konjugierten monoklonalen Anti-Hämoglobin-B-Antikörper binden, so dass im Testbereich "T" (keine farbige Testlinie) kein sichtbares farbiges Signal erhalten werden kann , das auf ein negatives Testergebnis hinweist. Unabhängig vom hHb-Gehalt der flüssigen Probe bindet der monoklonale Anti-Hämoglobin-B-Antikörper, der an mobile kolloidale Partikel konjugiert ist, die polyklonalen Antikörper der immobilisierten Ziegenmaus (IgG), während die flüssige Probe den Kontrollbereich "C" passiert. Daher erzeugt die Anhäufung kolloidaler farbiger Partikel ein sichtbares Farbsignal im Kontrollbereich "C" (eine farbige Kontrolllinie), das ein gültiges Testergebnis anzeigt. Die farbige Linie muss in jedem Fall im Kontrollbereich "C" sichtbar sein; wenn im Kontrollbereich "C" keine sichtbare farbige Linie zu sehen ist, ist das Prüfergebnis als ungültig zu kennzeichnen.

VORSICHTSMASSNAHMEN UND EINSCHRÄNKUNGEN

1.Nur für den professionellen Gebrauch und *In-vitro*-Diagnostika .
2.Lesen Sie diese Packungsbeilage vollständig und sorgfältig durch, bevor Sie den Test verwenden. Der Test muss in strikter Übereinstimmung mit diesen Anweisungen durchgeführt werden, um genaue Ergebnisse zu erhalten.
3.Verwenden Sie das Testkit nicht über das Verfallsdatum hinaus. Das Testgerät ist für den einmaligen Gebrauch bestimmt. Nicht wiederverwenden.
4.Das Prüfgerät muss bis zu seiner Verwendung in seinem versiegelten Originalbeutel verbleiben. Verwenden Sie den Test nicht, wenn das Siegel gebrochen oder der Beutel beschädigt ist.
5.Tragen Sie während der Prüfung Einweghandschuhe.

6.Dieses Testkit sollte nur von entsprechend qualifiziertem Personal gehandhabt werden, das in Laborverfahren geschult und mit deren potenziellen Gefahren vertraut ist. Tragen Sie geeignete Schutzkleidung, Handschuhe sowie Augen- und Gesichtsschutz und handhaben Sie diese gemäß den erforderlichen guten Laborpraktiken.
7.Eine Blutdetektion kann nicht durchgeführt werden, wenn die sehr geringe Blutmenge nicht gleichmäßig im Kot verteilt ist. Aus diesem Grund wird empfohlen, Kotproben aus verschiedenen Bereichen des Kots zu nehmen. Auf diese Weise erhöht sich die Möglichkeit einer Blutentnahme im Kot.
8.Es wird empfohlen, den Test alle sechs Monate zu wiederholen, da es bei Dickdarmkrebs zu keinen kontinuierlichen Blutungen kommt. Dadurch erhöht sich die Wahrscheinlichkeit, einen periodischen hämorrhagischen Tumor zu erkennen.
9.Im Folgenden sind Krankheiten aufgeführt, die Blutungen verursachen, bei denen der Test ein positives Ergebnis liefert, obwohl der Patient nicht an Dickdarmkrebs leidet.
-Risse im Verdauungssystem
-Ösophagusvarizen
-Medikamente, die Magenreizungen verursachen, wie z. B. Aspirin
-Magentumor oder bösartiger Tumor
-Meckels-Divertikel
-Kolitis
-Polypen des Dickdarms
-Hämorrhoiden
10.Alle Patientenproben sollten so behandelt werden, als ob sie in der Lage wären, die Krankheit zu übertragen. Beachten Sie bei allen Verfahren die festgelegten Vorsichtsmaßnahmen gegen mikrobiologische Gefahren und befolgen Sie die Standardverfahren für die ordnungsgemäße Entsorgung der Proben.
11.Dieser Test zeigt nur das selektive humane Gesamthämoglobin (hHb) in der Probe an und sollte nicht als alleinige Grundlage für die Diagnose verwendet werden.
Wie bei allen diagnostischen Tests ist zu beachten, dass eine Identifikationsdiagnose nicht auf einem einzigen Testergebnis basieren kann. Die Diagnose kann von einem Experten erst nach Auswertung aller klinischen und Laborergebnisse gestellt werden.

LAGERUNG

Die Prüfvorrichtung ist von direkter Sonneneinstrahlung, Feuchtigkeit, Wärme- und Strahlungsquellen fernzuhalten. Zwischen 4 °C und 30 °C (39 °F und 86 °F) lagern. Nicht einfrieren.
Der Test in der Originalverpackung bleibt bis zum Verfallsdatum unter Lagerbedingungen stabil. Das Prüfgerät darf nicht später als eine Stunde nach dem Öffnen des Blattes verwendet werden.
Bestandteile des Kits : Testkassetten, Probensammelröhrchen mit Verdünnungspad, Gebrauchsanweisung.
Zusätzliche Ausrüstung erforderlich, aber nicht im Lieferumfang enthalten : Auffangbecher und Zeitschaltuhr.
Zusätzliches Material empfohlen, aber nicht im Lieferumfang enthalten : Negativ- und Positivkontrollmaterialien.

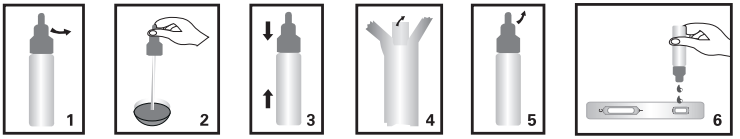
PROBENAHME UND AUFBEREITUNG

- Der Test kann mit Kotproben durchgeführt werden. Kotproben können bis zur Untersuchung innerhalb von 3 Tagen nach der Entnahme bei 2 °C bis 8 °C gelagert werden, wenn sie nicht innerhalb der folgenden Fristen getestet werden:
6 Stunden. Die im Probenröhrchen vorbereitete Probe kann 6 Monate bei -20°C gelagert werden, wenn sie nicht innerhalb von 1 Stunde nach der Vorbereitung getestet wird.
-Die Probe sollte nicht während oder innerhalb von drei Tagen nach einer Menstruation entnommen werden, oder wenn die Patientin an blutenden Hämorrhoiden oder Blut im Urin leidet, können falsch positive Testergebnisse erzielt werden.
-Diätetische Einschränkungen sind nicht erforderlich. Bei dem Test handelt es sich um eine praktische Testmethode, bei der Anti-Human-Hämoglobin-Antikörper verwendet werden, die nur humanes Hämoglobin mit hoher Sensitivität erkennen.

TESTVERFAHREN

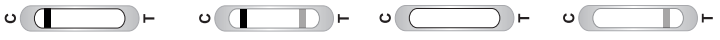
1.Öffnen Sie das Probenahmereagenzglas, indem Sie den Deckel drehen (Abbildung 1).
2.Führen Sie den Stiel in den Kot der Probe ein und drehen Sie ihn in mindestens 3 verschiedene Teile der Probe (Abbildung 2).
3.Führen Sie den Stab mit der Probe in das Reagenzglas ein und verschließen Sie es fest. Schütteln Sie das Probenreagenzglas 2 Minuten lang nach oben und unten (Abbildung 3).
* Bitte achten Sie darauf, dass der Verdünnungspuffer mit der Stuhlprobe im Röhrchen homogen ist und eine geringe Feststoffdichte aufweist.
4.Nehmen Sie das Testkit aus der schützenden Aluminiumtasche und legen Sie den Test auf eine ebene Fläche (Abbildung 4).
5.Öffnen Sie die Kappe am Ende des Probenahmereagenzglases (Abbildung 5).
6.Nehmen Sie 2 Tropfen der Probe aus der Probenvertiefung der Testkassette (Abbildung 6).

7.Die Ergebnisse sollten innerhalb von 10 Minuten abgelesen werden, wie unten gezeigt. Interpretieren Sie Ergebnisse nicht nach 20 Minuten, Ergebnisse, die nach 20 Minuten gebildet werden, sollten als ungültig betrachtet werden. Anmerkungen: Wenn die entnommene Probe aufgrund von Partikeln nicht in den Test migriert, zentrifugieren Sie die extrahierte Probe in das Probensammelröhrchen. Nehmen Sie dann 80 µl Überstand und verteilen Sie ihn in der Probenahmevertiefung eines neuen Testers und befolgen Sie die Anweisungen in Schritt 4.



INTERPRETATION DER ERGEBNISSE

Negativ : Im Bereich "C" ist nur ein farbiger Streifen sichtbar.
Positiv : In den Bereichen "C" und "T" sind zwei farbige Streifen sichtbar.
Eine niedrige hHb-Konzentration kann zu einer schwachen Linie in der "T"-Zone führen. Selbst eine solche schwache Linie im "T"-Bereich sollte als "positiv" angesehen werden.
Ungültig : Im Bereich "T" ist kein farbiger Streifen oder nur ein farbiger Streifen sichtbar; Die Prüfung ist mit einem neuen Prüfgerät zu wiederholen.



QUALITÄTSKONTROLLE

Die Tests enthielten verfahrenstechnische Qualitätskontrollfunktionen. Wenn der Test abgeschlossen ist, sieht der Benutzer eine farbige Linie im Bereich "C" des Tests bei negativen Proben und eine farbige Linie im Bereich "T" und "C" bei positiven Proben. Das Erscheinungsbild der "C"-Kontrolllinie wird als interne Verfahrenskontrolle betrachtet. Diese Zeile zeigt an, dass ein ausreichendes Probenvolumen sowie ein gültiges Testergebnis hinzugefügt wurden. Es wird empfohlen, eine Negativkontrolle und eine Positivkontrolle zu verwenden, um die gute Leistung des Tests als externe Kontrolle zu überprüfen. Benutzer müssen die entsprechenden Richtlinien auf Bundes-, Landes- und lokaler Ebene in Bezug auf externe Qualitätskontrollen befolgen.

LEISTUNGSBEWERTUNG

Cut-off-Wert : 50 ng hHb/ml

Sensitivität : 99 % Spezifität : 99,9 %
+Vorhersagewert : 99,9 % - Vorhersagewert : 96,7 %

		Referenz	
		+ Ergebnis	- Ergebnis
Test	+ Ergebnis	99	0
	- Ergebnis	1	30

Es gibt keinen Hakeneffekt (Messwut bis 100.000 ng /ml).

Kreuzreaktivität: Es gibt keine Kreuzreaktionen mit Hämoglobin wie folgt:

1000 mg/L Hb Rinder
1000 mg/L Schaf Hb
1000 mg/L Hb für Pferde
1000 mg/L Hb Schweinefleisch
1000 mg/L Hb Ziege
1000 mg/L Hb Kaninchen
1000 mg/L Hb für Hunde

Interne Qualitätskontrolle: Für die interne Qualitätskontrolle wurden folgende Substanzen verwendet: h-Hämoglobin, h-Albumin, h-Haptoglobin, h-Myoglobin, h-Transferrin.

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Hersteller


Gebrauchsanweisung hinzuziehen


Achtung, bitte beachten Sie die Gebrauchsanweisung

IVD
In-vitro-diagnostisches Medizinprodukt


Nur für den Einmalgebrauch


Anzahl der Tests


Lagertemperatur

REF Katalognummer

LOT Lotnummer


Haltbarkeitsdatum

TEST IT
for healthy generations

MODE D'EMPLOI
Test de sang occulte dans les selles (FOB)
Pour l'hHB (hémogogrégine humaine)
Détection dans les matières fécales

Test de diagnostic *in vitro*

Uniquement pour un usage professionnel de diagnostic *in vitro*

Code de produit : TIHHB02

INFORMATIONS GÉNÉRALES

La présence de sang occulte fécal dans les selles est associée à des troubles gastro-intestinaux tels que la diverticulite, les polypes et la maladie de Crohn, qui peuvent entraîner un cancer colorectal s'ils ne sont pas traités. Il a été démontré que le diagnostic précoce par dépistage du sang occulte dans les selles et le traitement de ces problèmes réduisent considérablement la mortalité due au cancer colorectal. La détection du sang occulte dans les fèces est une méthode d'examen recommandée par de nombreuses organisations telles que l'OMS (Organisation mondiale de la santé) pour le diagnostic du cancer du gros intestin.
Les méthodes de test immunochromatographique ont une spécificité clinique supérieure par rapport à un test chimique (par exemple, le gaïaïque) et ne nécessitent aucune restriction alimentaire.

UTILISATION PRÉVUE

Le test de sang occulte (caché) fécal est un test immunochromatographique qualitatif pour la détection de l'hémoglobine humaine (hHb) dans les matières fécales humaines à usage professionnel.

RÉACTIFS

Anticorps monoclonal anti-hémoglobine-A de souris, anticorps polyclonal anti-souris de chèvre (IgG) et anticorps monoclonal anti-hémoglobine B conjugué à des particules de couleur colloïdale.

MÉTHODE

Le test de sang occulte dans les selles utilise la technologie immun chromatographique en phase solide pour la détection qualitative de hHb dans les fèces humaines. Le test est un test immunométrique à deux sites dans lequel une combinaison d'anticorps monoclonaux et polyclonaux est utilisée pour détecter sélectivement hHb dans des échantillons présentant un degré élevé de sensibilité. L'anticorps monoclonal anti-hémoglobine A de souris a été immobilisé sur la zone d'essai « T » et des anticorps polyclonaux anti-souris (IgG) de chèvre ont été immobilisés sur la zone témoin « C » de la membrane de nitrocellulose. L'anticorps monoclonal anti-hémoglobine B conjugué à des particules colorées a été séché sur un tampon conjugué.
L'échantillon est introduit à partir d'un tampon d'échantillonnage. S'il y a hHb à un niveau détectable dans l'échantillon, hHb se lie à l'anticorps monoclonal mobile anti-hémoglobine B conjugué avec des particules colorées. Ensemble, ils se déplacent vers la zone d'essai « T ». Les molécules hHB se lient à l'anticorps monoclonal anti-hémoglobine de souris immobilisé et, par conséquent, les molécules hHb qui se sont déjà liées à l'anticorps monoclonal anti-hémoglobine mobile A (conjugué avec des particules colorées) s'immobilisent dans la zone d'essai « T », créant ainsi un signal coloré visible dans la zone d'essai « T » (une ligne de test colorée), indiquant un résultat de test positif. S'il n'y a pas de hHb au niveau détectable dans l'échantillon, l'échantillon se déplace vers la zone d'essai « T » avec l'anticorps monoclonal anti-hémoglobine B non lié (libre) conjugué à des particules colorées. L'anticorps monoclonal anti-hémoglobine A de souris immobilisé ne peut pas¬se lier à l'anticorps monoclonal anti-hémoglobine B mobilisé conjugué à des particules colorées, de sorte qu'aucun signal coloré visible dans la zone d'essai « T » (pas de ligne d'essai colorée) ne peut être obtenu, indiquant un résultat de test négatif. Quelle que soit la teneur en hHb de l'échantillon liquide, l'anticorps monoclonal anti-hémoglobine B conjugué à des particules colloïdales mobiles lie les anticorps polyclonaux anti-souris (IgG) de chèvre immobilisés pendant que l'échantillon liquide traverse la zone de contrôle « C ». Par conséquent, l'accumulation de particules colorées colloïdales produit un signal coloré visible dans la zone de contrôle « C » (une ligne de contrôle colorée), indiquant un résultat de test valide. La ligne colorée doit être visible dans la zone de contrôle « C » dans tous les cas; si aucune ligne colorée visible n'est visible dans la zone de contrôle « C », le résultat de l'essai doit être indiqué comme non valide.

PRÉCAUTIONS ET LIMITES

1.Pour usage professionnel et diagnostique *in vitro* uniquement.
2.Lisez cet encart complètement et attentivement avant d'utiliser le test. Le test doit être effectué en stricte conformité avec ces instructions pour obtenir des résultats précis.
3.N'utilisez pas la trousse de test au-delà de la date de péremption. L'appareil de test est à usage unique. Ne pas réutiliser.
4.Le dispositif d'essai doit rester dans sa pochette scellée d'origine jusqu'à son utilisation. N'utilisez pas le test si le sceau est brisé ou si la poche est endommagée.
5.Portez des gants jetables pendant l'examen.
6.Cette trousse d'essai ne doit être manipulée que par du personnel dûment qualifié, formé aux procédures de laboratoire et familiarisant avec leurs dangers potentiels. Porter des vêtements de protection, des gants et une protection oculaire et faciale appropriés et manipuler de manière appropriée conformément aux bonnes pratiques de laboratoire requises.

7.La détection du sang ne peut pas être réalisée si la très petite quantité de sang n'est pas répartie uniformément dans les matières fécales. Pour cette raison, il est recommandé que l'échantillonnage des matières fécales soit effectué à partir de différentes zones des matières fécales. De cette façon, la possibilité d'échantillonnage de sang dans les matières fécales augmente.
8.Il est recommandé de répéter le test tous les six mois, car il n'y a pas de saignement continu en cas de cancer du gros intestin. En conséquence, la possibilité de détection d'une tumeur hémorragique périodique augmente.
9.Vous trouverez ci-dessous les maladies qui causent des saignements, où le test donne un résultat positif bien que le patient ne souffre pas d'un cancer du gros intestin.
-Ruptures dans le système digestif
-Varices œsophagiennes
-Médicaments qui provoquent une irritation gastrique, par exemple l'aspirine
-Tumeur gastrique ou tumeur maligne
-Diverticule de Meckels
-Colite ulcéreuse
-Polypes du gros intestin
-Hémorroïdes
10.Tous les échantillons de patients doivent être manipulés comme s'ils étaient capables de transmettre la maladie. Observer les précautions établies contre les dangers microbiologiques dans toutes les procédures et suivre les procédures standard pour l'élimination appropriée des échantillons.
11.Ce test indiquera uniquement l'hémoglobine humaine sélectivement totale (hHb) dans l'échantillon et ne doit pas être utilisé comme seule base pour le diagnostic.
Comme pour tous les tests de diagnostic, il faut garder à l'esprit qu'un diagnostic d'identification ne peut pas être basé sur un seul résultat de test. Le diagnostic ne peut être atteint par un expert qu'après l'évaluation de tous les résultats cliniques et de laboratoire.

STOCKAGE

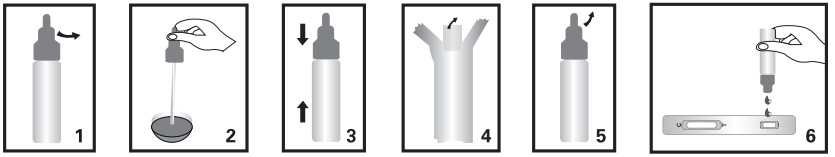
L'appareil d'essai doit être tenu à l'écart de la lumière directe du soleil, de l'humidité, de la chaleur et des sources de rayonnement. Conserver entre 4 et 30 °C (39 et 86 °F). Ne pas congeler.
Le test dans l'emballage d'origine reste stable jusqu'à la date de péremption dans les conditions de stockage. Le dispositif d'essai doit être utilisé au maximum une heure après l'ouverture de la feuille.
Composants du kit : Cassettes d'essai, tubes de prélèvement d'échantillons avec tampon de dilution, mode d'emploi.
Matériel supplémentaire requis mais non fourni : Gobelet de collecte et minuterie.
Matériel supplémentaire recommandé mais non fourni : Matériaux témoins négatifs et positifs.

PRÉLÈVEMENT ET PRÉPARATION D'ÉCHANTILLONS

- Le test peut être effectué à l'aide d'échantillons de matières fécales. Les échantillons de matières fécales peuvent être conservés entre 2 et 8 °C jusqu'à ce qu'ils soient testés dans un délai de 3 jours après le prélèvement s'ils ne sont pas testés dans les délais suivants : 6 heures. L'échantillon préparé dans le tube de prélèvement peut être conservé pendant 6 mois à - 20°C s'il n'est pas testé dans l'heure 1 suivant la préparation.
-L'échantillon ne doit pas être prélevé pendant ou dans les trois jours suivant une période menstruelle, ou si la patiente souffre de saignements hémorroïdes ou de sang dans l'urine, des résultats de test faussement positifs peuvent être obtenus.
-Les restrictions alimentaires ne sont pas nécessaires. Le test est une méthode de test pratique qui utilise des anticorps anti-hémoglobine humaine qui ne reconnaissent que l'hémoglobine humaine avec une sensibilité élevée.

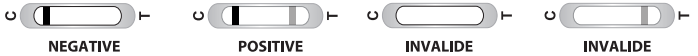
PROCÉDURE D'ESSAI

1.Ouvrez le tube à essai de prélèvement en tournant le couvercle (figure 1).
2.Insérez et tordez la tige dans les matières fécales de l'échantillon dans au moins 3 parties différentes de l'échantillon (Figure 2).
3.Insérez la tige avec l'échantillon prélevé dans le tube à essai et fermez-la fermement. Bien agiter le tube à essai de prélèvement vers le haut et dans le sens bas pendant 2 minutes (figure 3).
* Veuillez-vous assurer que le tampon de dilution avec échantillon fécal dans le tube est homogène et qu'il a une faible densité solide.
4.Retirez la trousse de test de sa pochette protectrice en aluminium et placez l'essai sur une surface plane (Figure 4).
5.Ouvrez le capuchon situé à l'extrémité du tube à essai de prélèvement (figure 5).
6.Prélever 2 gouttes d'échantillon dans le puits d'échantillon de la cassette d'essai (figure 6).
7.Les résultats doivent être lus dans les 10 minutes comme indiqué ci-dessous. N'interprétez pas les résultats au-delà de 20 minutes, les résultats se formant après 20 minutes doivent être considérés comme invalides.
REMARQUE : Si l'échantillon extrait ne migre pas dans l'essai à cause des particules, centrifuger l'échantillon extrait dans le tube de prélèvement de l'échantillon. Prélever ensuite 80 µl de surnageant et le distribuer dans le puits d'échantillonnage d'un nouvel appareil d'essai et suivre les instructions de l'étape 4.



INTERPRÉTATION DES RÉSULTATS

Négatif: Une seule bande colorée est visible dans la zone « C ».
Positive : Deux bandes colorées sont visibles dans les zones « C » et « T ».
Une faible concentration de hHb peut provoquer une faible ligne dans la zone « T ». Même une ligne aussi faible dans la zone « T » doit être considérée comme « positive ».
Non valide: Aucune bande colorée n'est visible ou une seule bande colorée est visible dans la zone « T »; L'essai doit être répété à l'aide d'un nouveau dispositif d'essai.



CONTRÔLE QUALITÉ

Les tests ont intégré des fonctionnalités de contrôle de la qualité procédurale. Lorsque le test est terminé, l'utilisateur verra une ligne colorée dans la zone « C » du test sur les échantillons négatifs et une ligne colorée dans la zone « T » et « C » sur les échantillons positifs. L'apparition de la ligne de contrôle « C » est considérée comme un contrôle procédural interne. Cette ligne indique qu'un volume suffisant d'échantillon a été ajouté ainsi qu'un résultat d'analyse valide. Il est recommandé d'utiliser un contrôle négatif et un témoin positif pour vérifier la bonne performance du test en tant que contrôle externe. Les utilisateurs doivent suivre les directives fédérales, étatiques et locales appropriées concernant les contrôles de qualité externes.

ÉVALUATION DU RENDEMENT

Valeur de coupure : 50 ng hHb/ml

Sensibilité : 99 %
Spécificité : 99,9 %
+ Valeur prédictive : 99,9 %
- Valeur prédictive : 96,7 %

		Référence + Résultat	Référence - Résultat
Test	+ Résultat	99	0
	- Résultat	1	30

Il n'y a pas d'effet crochet (Rage de mesure jusqu'à 100.000 ng / ml).

Réactivité croisée : Il n'y a pas d'interactions de réaction croisée avec l'hémoglobine comme suit:

1000 mg/L de bovins Hb
1000 mg/L de mouton Hb
1000 mg/L Hb pour chevaux
1000 mg/L Hb porcin
1000 mg/L d'Hb caprine
1000 mg/L Hb de lapin
1000 mg/L d'Hb pour chien

Contrôle interne de la qualité : Les substances suivantes ont été utilisées pour le contrôle interne de la qualité: h hémoglobine, h albumine, h haptoglobine, h myoglobine, h transferrine.

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Se reporter aux instructions d'utilisation

Attention, lire les instructions d'utilisation

IVD Dispositif médical de diagnostic *in vitro*

À usage unique

Nombre de tests

Température de conservation

REF Numéro de référence

LOT Numéro de lot

Date d'expiration

TEST IT
for healthy generations

ISTRUZIONI PER L'USO
Test del Sangue Occulto Fecale (FOB)
Per hHB (emoglobina umana)
Rilevazione nelle Feci

test diagnostico *in vitro*

Solo per uso professionale nella diagnostica *in vitro*

Codice del Prodotto: TIHHB02

INFORMAZIONI DI BASE

La presenza di sangue occulto fecale nelle feci è associata a disturbi gastrointestinali come la diverticolite, i polipi e il morbo di Crohn, che se non trattati possono portare al cancro del colon-retto. È stato dimostrato che la diagnosi precoce mediante screening del sangue occulto nelle feci e il trattamento di questi problemi riducono significativamente la mortalità per cancro del colon-retto. Il rilevamento del sangue occulto nelle feci è un metodo di esame raccomandato da molte organizzazioni come l'OMS (Organizzazione Mondiale della Sanità) per la diagnosi del cancro dell'intestino crasso.
I metodi di test immunocromatografici hanno una specificità clinica superiore rispetto a un test a base chimica (ad esempio guaiaco) e non richiedono alcuna restrizione dietetica.

USO PREVISTO

Il Test del Sangue Occulto nelle Feci (nascosto) è un test immunocromatografico qualitativo per il rilevamento dell'emoglobina umana (hHb) nelle feci umane per uso professionale.

REAGENTI

Anticorpo monoclonale anti-emoglobina di topo-A, anticorpo policlonale di capra anti-topo (IgG) e anticorpo monoclonale anti-emoglobina B coniugato con particelle colloidali colorate.

METODO

Il Test del Sangue Occulto nelle Feci utilizza la tecnologia immunocromatografica in fase solida per il rilevamento qualitativo di hHb nelle feci umane. Il test è un test immunometrico a due siti in cui viene utilizzata una combinazione di anticorpi monoclonali e policlonali per rilevare selettivamente l'hHb in campioni con un elevato grado di sensibilità. Gli anticorpi monoclonali anti-emoglobina di topo A sono stati immobilizzati sull'area del test "T" e gli anticorpi policlonali anti-topo (IgG) di capra sono stati immobilizzati sull'area di controllo "C" della membrana di nitrocellulosa. L'anticorpo monoclonale anti-emoglobina B coniugato con particelle colorate è stato essiccato su un tampone coniugato.
Il campione viene introdotto dal tampone di campionamento. Se nel campione è presente un livello rilevabile di hHb, l'hHb si lega all'anticorpo mobile monoclonale anti-emoglobina B coniugato con particelle colorate. Insieme si spostano nell'area test "T". Le molecole di hHB si legano all'anticorpo monoclonale anti-emoglobina di topo immobilizzato e, di conseguenza, le molecole di hHb che si sono già legate all'anticorpo mobile monoclonale anti-emoglobina A (coniugato con particelle colorate) vengono immobilizzate nell'area del test "T" creando così un segnale colorato visibile nell'area del test "T" (una linea di test colorata), che indica un risultato positivo del test. Se nel campione non è presente un livello rilevabile di hHb, il campione si sposta nell'area del test "T" insieme all'anticorpo monoclonale anti-emoglobina B non legato (libero) coniugato con particelle colorate. L'anticorpo monoclonale anti-emoglobina di topo immobilizzato non può legarsi all'anticorpo monoclonale anti-emoglobina B mobilizzato coniugato con particelle colorate, pertanto non è possibile ottenere alcun segnale colorato visibile nell'area del test "T" (nessuna linea colorata del test), indicando un risultato negativo del test. Indipendentemente dal contenuto di hHb del campione liquido, l'anticorpo B monoclonale anti-emoglobina coniugato con particelle colloidali si lega agli anticorpi policlonali anti-topo (IgG) di capra immobilizzati mentre il campione liquido passa attraverso l'area di controllo "C". Pertanto l'accumulo di particelle colloidali colorate produce un segnale colorato visibile nell'area di controllo "C" (una linea di controllo colorata), indicando un risultato valido del test. La linea colorata dovrebbe essere visibile nell'area di controllo "C" in ogni caso; se nessuna linea colorata visibile nell'area di controllo "C", il risultato del test deve essere indicato come non valido.

PRECAUZIONI E LIMITAZIONI

1.Solo per uso professionale e diagnostico *in vitro*.
2.Leggere completamente e attentamente questo inserto prima di utilizzare il test. Il test deve essere eseguito in stretta conformità con queste istruzioni per ottenere risultati accurati.
3.Non utilizzare il kit di test oltre la data di scadenza. Il dispositivo di prova è monouso. Non riutilizzare.
4.Il dispositivo di test deve rimanere nella sua busta sigillata originale fino al momento dell'uso. Non utilizzare il test se il sigillo è rotto o la busta è danneggiata.
5.Indossare guanti monouso durante l'esecuzione del test.

6.Questo kit di test deve essere maneggiato solo da personale adeguatamente qualificato addestrato nelle procedure di laboratorio e che abbia familiarità con i potenziali pericoli. Indossare indumenti protettivi, guanti e protezioni per occhi/viso adeguati e maneggiare in modo appropriato con le Buone Pratiche di Laboratorio richieste.
7.Il rilevamento del sangue non può essere realizzato se la piccolissima quantità di sangue non è distribuita uniformemente sulle feci. Per questo motivo, si raccomanda di prelevare campioni di feci da diverse aree delle feci. In questo modo il campionamento del sangue nelle feci aumenta la possibilità.
8.Si consiglia di ripetere il test ogni sei mesi, in quanto non vi è sanguinamento continuo in caso di cancro dell'intestino crasso. Possibilità di rilevamento, aumento periodico del tumore sanguinante.
9.Di seguito sono riportate le malattie che causano sanguinamento, in cui il test dà un risultato positivo sebbene il paziente non sia affetto da un cancro dell'intestino crasso.
-Rotture nel sistema digestivo
-Varici esofagee
-Farmaci che causano irritazione gastrica, ad es. aspirina
-Tumore gastrico o tumore maligno
-Diverticolo di Meckels
-Colite ulcerosa
-Polipi dell'intestino crasso
-Emorroidi
10.Tutti i campioni dei pazienti devono essere maneggiati come se fossero in grado di trasmettere malattie. Osservare le precauzioni stabilite contro i rischi microbiologici durante tutte le procedure e seguire le procedure standard per il corretto smaltimento dei campioni.
11.Questo test indicherà solo l'emoglobina umana totale selettiva (hHb) nel campione e non dovrebbe essere utilizzato come unica base per la diagnosi.
Come per tutti i test diagnostici, va tenuto presente che una diagnosi di identificazione non può essere basata su un singolo risultato del test. La diagnosi può essere raggiunta solo da un esperto dopo la valutazione di tutti i risultati clinici e di laboratorio.

IMMAGAZZINAMENTO

Il dispositivo di test deve essere tenuto lontano dalla luce solare diretta, dall'umidità, dal calore e da fonti di radiazioni. Conservare a 4 - 30°C (39 - 86°F). Non congelare.
Il test nella confezione originale si mantiene stabile fino alla data di scadenza nelle condizioni di conservazione. Il dispositivo di test deve essere utilizzato al massimo un'ora dopo l'apertura della pellicola.
Componenti del Kit: Cassette per test, provette per la raccolta dei campioni con tampone di diluizione, istruzioni per l'uso.
Materiali aggiuntivi richiesti ma non forniti: Bicchiere di raccolta e timer.
Materiali aggiuntivi consigliati ma non forniti: Materiali di controllo negativi e positivi.

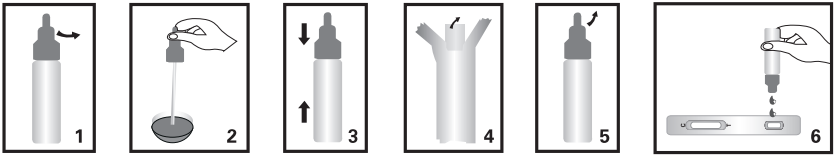
COLLEZIONE E PREPARAZIONE DEL CAMPIONE

-Il test può essere eseguito utilizzando campioni di feci. I campioni di feci possono essere conservati a 2 - 8 °C fino a quando non vengono testati in un periodo di 3 giorni dopo la raccolta se non vengono testati entro 6 ore. Il campione preparato nella provetta di raccolta del campione può essere conservato per 6 mesi a -20°C se non testato entro 1 ora dalla preparazione.
-Il campione non deve essere raccolto durante o entro tre giorni dal ciclo mestruale, o se il paziente soffre di emorroidi sanguinanti o sangue nelle urine, si possono ottenere risultati falsi positivi del test.
-Non sono necessarie restrizioni dietetiche. Il test è un metodo di test conveniente che impiega anticorpi anti-emoglobina umana che fa riconoscere solo l'emoglobina umana con alta sensibilità.

PROCEDURA DEL TEST

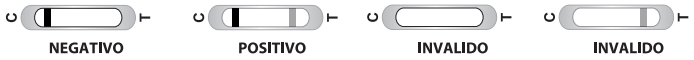
1.Aprire la provetta di campionamento ruotando il coperchio (Figura 1).
2.Inserire e torcere l'asta nelle feci del campione in almeno 3 diverse parti del campione (Figura 2).
3.Inserire l'asta con il campione raccolto nella provetta e chiuderla saldamente. Agitare bene la provetta di campionamento verso l'alto e verso il basso per 2 minuti (Figura 3).
* Assicurarsi che il tampone di diluizione con campione fecale nella provetta sia omogeneo e abbia una bassa densità solida.
4.Rimuovere il kit del test dalla busta protettiva in alluminio e posizionare il test su una superficie piana (Figura 4).
5.Aprire il tappo sulla punta della provetta di campionamento (Figura 5).
6.Aspirare 2 gocce di campione nel pozzetto del campione della cassetta del test (Figura 6).
7.I risultati devono essere letti entro 10 minuti come mostrato di seguito. Non interpretare i risultati oltre i 20 minuti, i risultati che si formano dopo i 20 minuti devono essere considerati non validi.

NOTA: Se il campione estratto non migra nel test a causa delle particelle, centrifugare il campione estratto nella provetta di raccolta del campione. Quindi raccogliere 80 µl di surnatante e dispensarlo nel pozzetto del campione di un nuovo dispositivo di test e seguire le istruzioni dal passaggio 4.



INTERPRETAZIONE DEI RISULTATI

Negativo : Nell'area "C" è visibile solo una banda colorata.
Positivo : Due bande colorate sono visibili nelle aree "C" e "T".
Una bassa concentrazione di hHb può causare una linea debole nell'area "T". Anche una linea così debole nell'area "T" dovrebbe essere considerata "positiva".
Invalido : Nessuna banda colorata è visibile o solo una banda colorata è visibile nell'area "T"; il test deve essere ripetuto utilizzando un nuovo dispositivo di test.



CONTROLLO DI QUALITÀ

I test hanno incorporato funzionalità di controllo della qualità procedurale. Al termine del test, l'utente vedrà una linea colorata nell'area "C" del test sui campioni negativi e una linea colorata nell'area "T" e "C" sui campioni positivi. La comparsa della linea "C" di controllo è considerata un controllo procedurale interno. Questa riga indica che è stato aggiunto un volume sufficiente di campione e un risultato del test valido. Si consiglia di utilizzare un controllo negativo e un controllo positivo per verificare la corretta esecuzione del test come controllo esterno. Gli utenti devono seguire le linee guida federali, statali e locali appropriate relative ai controlli di qualità esterni.

VALUTAZIONE DELLA PRESTAZIONE

Valore di taglio: 50 ng hHb/ml

Sensibilità : 99 % Specificità : 99,9 %
+ Valore predittivo : 99,9 % - Valore predittivo : 96,7 %

		Riferimenti	
		+ Risultato	- Risultato
Test	+Risultato	99	0
	- Risultato	1	30

Non c'è effetto gancio (resistenza di misurazione fino a 100.000 ng/ml).

Reattività Incrociata: Non ci sono interazioni di reazione incrociata con l'emoglobina come segue:
1000 mg/L Bovini Hb
1000 mg/L Pecora Hb
1000 mg/L Cavallo Hb
1000 mg/L Maiale Hb
1000 mg/L Capra Hb
1000 mg/L Coniglio Hb
1000 mg/L Cane Hb

Controllo di Qualità Interno: Per il controllo di qualità interno sono state utilizzate le seguenti sostanze: h Emoglobina, h Albumina, h Aptoglobina, h Mioglobina, h Transferrina.

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1. Cohen AM et al. Cancer of Colon: Cancer. Principles and Practice of Oncology, Vincent T De Vita Jr. et al. 5th Edition 1997 p. 1144-1197.
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Consultazione del manuale d'uso


Attenzione, consultare il manuale d'uso

IVD
Dispositivo medico diagnostico utilizzato all'esterno del corpo


Solo monouso


Numero di test nella confezione


Temperatura di immagazzinamento

REF
Numero di catalogo

LOT
Numero del lotto


Data di Scadenza

TEST IT for healthy generations

INSTRUCCIONES DE USO
Prueba de Sangre Oculta en Heces (FOB)
Para Detección de hHB
(hemoglobina humana) en Heces

prueba diagnóstica *in vitro*

Solo para uso profesional de diagnóstico *in vitro*

Código de Producto: TIHHB02

INFORMACIÓN BÁSICA
La presencia de sangre oculta en las heces se relaciona con enfermedades gastrointestinales como la diverticulitis, los pólipos y la enfermedad de Crohn, que pueden provocar cáncer colorrectal si no se tratan. Se ha demostrado que el diagnóstico precoz mediante el cribado de sangre oculta en heces y el tratamiento de estos problemas reducen significativamente la mortalidad por cáncer colorrectal. Muchas organizaciones, como la OMS (Organización Mundial de la Salud), recomiendan la detección de sangre oculta en heces para el diagnóstico del cáncer de intestino grueso.
Los métodos de prueba inmunocromatográfica ofrecen una especificidad clínica superior a la de las pruebas químicas (por ejemplo, el guayaco) y no requieren restricciones dietéticas.

USO PREVISTO
La Prueba de Sangre Oculta (Hidden) en Heces es una prueba inmunocromatográfica cualitativa para la detección de hemoglobina humana (hHb) en heces humanas para uso profesional.

REACTIVOS
Anticuerpo monoclonal antihemoglobina-A de ratón, anticuerpo policlonal antiratón (IgG) de cabra y anticuerpo monoclonal antihemoglobina B conjugados con partículas coloidales coloreadas.

MÉTODO
La Prueba de Sangre Oculta en Heces utiliza tecnología inmunocromatográfica en fase sólida para la detección cualitativa de hHb en heces humanas. La prueba es un ensayo inmunométrico de dos puntos en el que se utiliza una combinación de anticuerpos monoclonales y policlonales para detectar de forma selectiva la hHb en muestras con un alto grado de sensibilidad. El anticuerpo monoclonal antihemoglobina de ratón A se inmovilizó en la zona de prueba "T" y los anticuerpos policlonales anti-ratón cabra (IgG) se inmovilizaron en la zona de control "C" de la membrana de nitrocelulosa. El anticuerpo monoclonal antihemoglobina B conjugado con partículas coloreadas se secó en una almohadilla conjugada.
La muestra se introduce desde la almohadilla de muestra. Si la muestra contiene hHb a un nivel detectable, la hHb se une al anticuerpo monoclonal antihemoglobina B móvil conjugado con partículas coloreadas. Las moléculas de hHb se unen al anticuerpo monoclonal antihemoglobina de ratón inmovilizado y, como resultado, las moléculas de hHb que ya se han unido al anticuerpo monoclonal antihemoglobina móvil A (conjugado con partículas coloreadas) se inmovilizan en el área de prueba "T", creando así una señal coloreada visible en el área de prueba "T" (una línea de prueba coloreada), lo que indica un resultado positivo de la prueba. Si la muestra no contiene hHb a un nivel detectable, la muestra se desplaza a la zona de prueba "T" junto con el anticuerpo monoclonal antihemoglobina B no unido (libre) conjugado con partículas coloreadas. El anticuerpo monoclonal anti-hemoglobina A de ratón inmovilizado no puede unirse al anticuerpo monoclonal anti-hemoglobina B movilizado conjugado con partículas coloreadas, por lo que no puede obtenerse ninguna señal coloreada visible en el área de prueba "T" (ninguna línea coloreada de prueba), lo que indica un resultado negativo de la prueba. El anticuerpo monoclonal antihemoglobina B conjugado con partículas coloidales móviles se une a los anticuerpos policlonales inmovilizados de cabra anti-ratón (IgG), independientemente del contenido de hHb de la muestra líquida, mientras la muestra líquida pasa por el área de control "C". Por consiguiente, la acumulación de partículas coloidales coloreadas produce una señal coloreada visible en el área de control "C" (una línea de control coloreada), lo que indica un resultado válido de la prueba. La línea coloreada debe ser visible en el área de control "C" en todos los casos; si no hay línea coloreada visible en el área de control "C", el resultado de la prueba debe indicarse como no válido.

PRECAUCIONES Y LIMITACIONES
1.Sólo para uso profesional y de diagnóstico *in vitro*.
2.Antes de utilizar la prueba, lea detenida y completamente este prospecto. La prueba se debe realizar respetando estrictamente estas instrucciones para obtener resultados precisos.
3.No utilizar los kits de prueba después de la fecha de caducidad. El dispositivo de ensayo es de un solo uso. No reutilizar.
4.El dispositivo de prueba debe permanecer en su bolsa sellada original hasta su uso. No usar la prueba si el cierre está roto o la bolsa está dañada.
5. Llevar guantes desechables mientras se realiza la prueba.
6. Este kit de prueba debe ser manipulado sólo por personal debidamente cualificado, formado en procedimientos de laboratorio y familiarizado con sus peligros potenciales Llevar ropa de protección adecuada, guantes y protección ocular/facial y manipular según las Buenas Prácticas de Laboratorio requeridas.
7.Si la escasa cantidad de sangre no está repartida uniformemente en las heces, no es posible detectar la sangre. Por ello, es recomendable que el muestreo de heces se realice de diferentes zonas de las heces. De esta forma se incrementa la posibilidad de muestreo de sangre en las heces.
8.Es recomendable repetir la prueba cada seis meses, ya que no hay sangrado continuo en caso de cáncer de intestino grueso. Por consiguiente, se incrementa la posibilidad de detectar un tumor que sangra periódicamente.

9.Las siguientes son enfermedades que provocan hemorragias, en las que la prueba da un resultado positivo aunque el paciente no padezca un cáncer de intestino grueso.
-Rupturas en el aparato digestivo
-Varices esofágicas
-Medicamentos que causan irritación gástrica, por ejemplo, la aspirina
-Tumor gástrico o tumor maligno
-Divertículo de Meckel
-Colitis ulcerosa
-Pólipos del intestino grueso
-Hemorroides
10. Todas las muestras de pacientes deben manipularse considerando que pueden transmitir la enfermedad. Observar las precauciones establecidas contra peligros microbiológicos a lo largo de todos los procedimientos y seguir los procedimientos estándar para desechar las muestras de forma adecuada.
11. Esta prueba indicará sólo la hemoglobina humana (hHb) selectiva total en la muestra, y no debe utilizarse como única base para el diagnóstico.
Al igual que en todos las pruebas de diagnóstico, debe tenerse en cuenta que una identificación de diagnóstico no puede basarse en el resultado de una sola prueba. El diagnóstico puede ser realizado únicamente por un experto tras la evaluación de todos los hallazgos clínicos y de laboratorio.

ALMACENAMIENTO

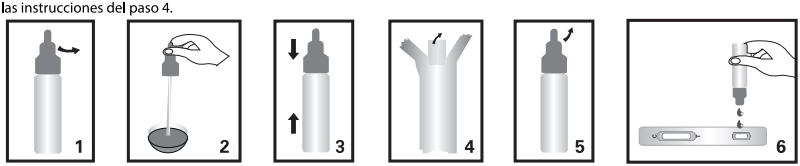
Este dispositivo de prueba debe mantenerse alejado de la luz solar directa, la humedad, el calor y las fuentes de radiación. Almacenar a 4 - 30°C (39 - 86°F). No congelar.
La prueba en su envase original y en óptimas condiciones de almacenamiento se mantiene estable hasta la fecha de caducidad. El dispositivo de prueba debe usarse como máximo en la siguiente hora después de abrir la bolsa.
Componentes del kit : Casetes de prueba, tubos de recogida de muestras con buffer solución, instrucciones de uso.
Materiales adicionales necesarios que no se proporcionan : Copa de recogida y temporizador.
Materiales adicionales recomendados que no se proporcionan : Materiales de control negativo y positivo.

RECOLECCIÓN Y PREPARACIÓN DE LA MUESTRA

- La prueba puede realizarse utilizando muestras de heces. Las muestras de heces si no se analizan en un plazo de 6 horas después de su recogida, se pueden almacenar a 2 - 8 °C hasta que se analicen en un plazo de 3 días. La muestra preparada en el tubo de recogida de muestras puede almacenarse durante 6 meses a - 20°C si no se analiza en la hora siguiente a su preparación.
- La muestra no se debe recoger durante el periodo de menstruación o en los tres días siguientes, o si el paciente padece hemorroides sangrantes o sangre en la orina, ya que se pueden obtener resultados falsos positivos.
- No se precisan restricciones dietéticas. La prueba es un método de análisis cómodo que emplea anticuerpos antihemoglobina humana que hace reconocer sólo la hemoglobina humana con alta sensibilidad.

PROCEDIMIENTO DE PRUEBA

1. Abra el tubo de prueba de la muestra girando la tapa (Figura 1).
2. Introduzca y gire la varilla en la muestra de heces en al menos 3 partes diferentes de la muestra (Figura 2).
3. Introduzca la varilla con la muestra recogida en el tubo de ensayo y ciérrelo firmemente. Agite bien el tubo de prueba de la muestra hacia arriba y hacia abajo durante 2 minutos (Figura 3).
* Asegúrese de que buffer solución y la muestra fecal en el tubo es homogéneo y tiene baja densidad de sólidos .
4. Extraiga el kit de prueba de su bolsa protectora de aluminio y coloque la prueba sobre una superficie plana (Figura 4).
5. Abra el tapón que hay en la punta del tubo de prueba de la muestra (Figura 5).
6. Extraiga 2 gotas de muestra en el pocillo de muestras del casete de prueba (Figura 6).
7. Los resultados deben leerse en 10 minutos, como se muestra a continuación. No interprete los resultados después de 20 minutos, los resultados que se formen después de 20 minutos deben considerarse inválidos.
NOTA: En caso de que la muestra extraída no migre en la prueba debido a las partículas, centrifugue la muestra extraída en el tubo de recogida de muestras. A continuación, recoja 80 µl de sobrenadante y viértalo en el pocillo de muestra de un nuevo dispositivo de prueba y siga las instrucciones del paso 4.



INTERPRETACIÓN DE RESULTADOS

Negativo : Sólo hay sola línea de color visible en la zona " C".
Positivo : Se observan dos líneas de color visibles en las áreas de "T" y "C".
Baja concentración de hHb puede causar una tenue línea en la zona " T". Incluso una línea tan débil en la zona " T" debe ser considerado como "positivo".
Inválido : No se ve ninguna línea coloreada o sólo se ve una línea coloreada en la zona "T"; la prueba debe repetirse con un nuevo dispositivo de prueba.

CONTROL DE CALIDAD

Las pruebas tienen funciones integradas de control de calidad del procedimiento. Al finalizar la prueba, el usuario verá una línea coloreada en la zona "C" de la prueba en las muestras negativas y una línea coloreada en las zonas "T" y "C" en las muestras positivas. La aparición de la línea de control "C" se considera un control interno del procedimiento. Esta línea indica que se ha añadido un volumen de muestra suficiente, así como que el resultado de la prueba es válido. Se recomienda utilizar como control externo un control negativo y un control positivo para verificar el funcionamiento correcto de la prueba. Los usuarios deben seguir la normativa local y estatal adecuada relativa a los controles de calidad externos.

EVALUACIÓN DEL RENDIMIENTO

Valor de corte : 50 ng hHb/ml

Sensibilidad : 99 % Especificidad : 99,9 %
+ Valor Predictivo : 99,9 % - Valor Predictivo : 96,7 %

		Referencias	
		+ Resultado	- Resultado
Prueba	+ Resultado	99	0
	- Resultado	1	30

No hay efecto gancho (Rango de medición hasta 100.000 ng/ml).

Reactividad Cruzada : No existe ninguna interacción de reacción cruzada con la hemoglobina, como se indica a continuación:

1000 mg/L Hb Bovino
1000 mg/L Hb Oveja
1000 mg/L Hb Caballo
1000 mg/L Hb Cerdo
1000 mg/L Hb Cabra
1000 mg/L Hb Conejo
1000 mg/L Hb Perro

Control de Calidad Interno: Para el control de calidad interno se utilizaron las siguientes sustancias: h Hemoglobina, h Albúmina, h Haptoglobina, h Mioglobina, h Transferrina.

REFERENCIAS

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5. Burtis CA et al. Tietz: Fundamentals of Clinical Chemistry 4th Edition 1996
6. Ahlquist DA. Fecal Occult Blood Testing for Colorectal Cancer Gastroenterology Clinics of North America. Vol. 26 Number 1 March 1997. p 41 55
7. Hidenori Nakama et al. Accurancy of Immunological Fecal Occult Blood Testing for Colorectal Cancer Screening. Preventive Medicine 23, 309-313. 1993
8. Young GP, St John DJB. Faecal occult blood tests: choice, usage and clinical applications. Clin Biochem Rev 1992;13:161-167.

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CE
Fabricante
Consulte las instrucciones de uso
IVD En producto para diagnóstico médico *in vitro*
Atención, mire las instrucciones de uso
Para un solo uso
REF Número del catálogo
Número de pruebas
LOT Número de lote
Temperatura de almacenamiento
Fecha de caducidad

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DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

Medical Devices Directive 93/42/EEC has been taken as reference for these processes

Company Name:	**Biobase Biodustry (Shandong) Co., Ltd.** No. 51 South Gongye Road, Jinan, Shandong Province, China
Examination Intent:	Examination the completeness of the Technical Documentation according to the requirements of Annex II excluding section 4 (Module H) of 93/42/EEC
Product(s):	**Alcohol Pad**
Type(s)/Model(s):	/
Classification:	**IIa** (according to the classification rules of Annex IX 93/42/EEC)
Harmonized Standards:	**EN ISO 13485:2016; EN ISO 15223-1:2016; EN ISO 14937:2009; EN 15986:2011**
Examination Period:	October 9, 2018
Date of Expiry:	October 8, 2023
Review Result:	We, Jinan Biobase Biotech Co., Ltd, declare that during the self-testing and performance evaluation, no Non-compliance according to the requirements of Annex II excluding section 4 (Module H) of 93/42/EEC has been detected.

Year of DOC marking: **2018**

Signed for and on behalf of Company: **Biobase Biodustry (Shandong) Co., Ltd.**

General Manager: Robert Wang

Document No: BKMD-1810093

CE

Declaration of Conformity V 1.0

Declaration of Conformity CE

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

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

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

Standards Applied:

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

Start of CE-Marking: 2015-3-31

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

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Declaration of Conformity CE

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

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

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

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Start of CE-Marking: 2015-3-31

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

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-20s、BC-30s

Including reagents as following:

M-30D DILUENT

M-30CFL LYSE

PROBE CLEANSER

Applied Standards:

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

Declaration of Conformity V 1.0

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

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

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Certificate Holder:

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

Certification Mark:

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

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

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

Report No.: **SH2005501**

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

Date of Issue: 2020-08-20

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

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Overall Scope Statement

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

Date of Issue: 2020-08-20

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

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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Facility Scopes:

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

Date of Issue: 2020-08-20

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

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

America

CERTIFICATE

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Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

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

Date of Issue: 2020-08-20

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

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

Product Service

Certificate

No. Q5 044751 0164 Rev. 02

Holder of Certificate:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
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518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate:

**Design and development,
production and distribution of
Active medical devices (intended) for monitoring,
diagnosis, anesthesia, breathing and intensive care;
In-vitro diagnostic instruments;
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)**

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

Report No.: SH2005501

Valid from: 2020-09-01

Date, 2020-07-24

Christoph Dicks
Head of Certification/Notified Body

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

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

Product Service

Certificate

No. Q5 044751 0164 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
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Certificate

No. Q5 044751 0164 Rev. 02

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor,
Center Monitoring System, Telemetry Monitoring System,
Pulse Oximeter, Temperature Probe, Flow Sensor,
Ambulatory Blood pressure Monitor,
Defibrillator/Monitor and Accessories, Electrocardiograph,
Anesthesia Machine and accessories, Ventilator,
Air compressor, Endoscope Camera System,
Ultrasonic Diagnostic Equipment and Accessories,
Digital Radiography System, Radiography System,
Hematology Analyzer, Clinical Chemistry Analyzer,
Urine Analyzer, Microplate Reader,
Microplate Washer for invitro diagnostic use,
Chemiluminescence Immunoassay Analyzer,
Flow Cytometer, (Auto) Sample Processing System,
Auto Slide Maker&Stainer, Glycohemoglobin Analyzer,
Specific Protein Analyzer, Reagents for Hematology Analyzer,
Reagents for Clinical Chemistry Analyzer,
Chemiluminescence Immunoassay Reagents,
Chemiluminescence Immunoassay Calibrators and Controls,
Reagents for Flow Cytometer,
Reagents for Glycohemoglobin Analyzer,
Calibrators and Controls for Glycohemoglobin Analyzer,
Disposable Anesthesia Mask, Reusable Anesthesia Mask,
Respiratory Mask, Disposable Breathing Circuit,
Reusable Breathing Circuit, Heat and Moisture Exchanger,
Filter, Breathing Bag.

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