



MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

CERTIFICADO DE EXAMEN CE DE DISEÑO de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE in accordance with Annex IV, Section 4, Directive 98/79/EC PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 12/09/2007 Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado n°/Certificate no 2007 09 0532 ED Desde/From 19/11/2018 Hasta/To 18/11/2023 ON n°/NB no 0318

A favor de/In favour of: Fabricante/Manufacturer: Nombre/Name: DIA. Pro Diagnostic Bioprobes S.r.l. Dirección/Address: Via G. Carducci, 27-20099- Sesto San Giovanni - Milano (Italy). Representante autorizado ante la UE/Authorized EU representative: Nombre/Name: Idem Dirección/Address: Idem

Para el producto/For the product: Categoría/Category: Productos Sanitarios para Diagnóstico "In Vitro" / In Vitro Diagnostic Medical Devices Grupo genérico/Generic group: Diagnóstico de enfermedades infecciosas / Diagnostic of infectious diseases Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Elaborado en/In the facilities: DIA. Pro Diagnostic Bioprobes S.r.l. Via G. Carducci, 27-20099- Sesto San Giovanni - Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total N° 2003 12 0388 CT/ This certificate must be accompanied by the EC Full Quality Assurance System Certificate N° 2003 12 0388 CT.

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente N° 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ This certificate is issued on the assessment of the design documentation contained in dossier N° 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.

Madrid, 19 de noviembre de 2018 DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



Fdo. M^o Jesús Lamas Díaz

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CERTIFICADO DE EXAMEN CE DE DISEÑO de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE in accordance with Annex IV, Section 4, Directive 98/79/EC PRÓRROGA/EXTENSION — Fecha inicial/ Initial date: 12/09/2007 Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado n°/Certificate no 2007 09 0532 ED Desde/From 19/11/2018 Hasta/To 18/11/2023 ON n°/NB no 0318

A favor de/In favour of: Fabricante/Manufacturer: Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l. Dirección/Address: Via G. Carducci, 27-20099- Sesto San Giovanni - Milano (Italy). Representante autorizado ante la UE/Authorized EU representative: Nombre/Name: Idem Dirección/Address: Idem

Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.

Clasificación/Classification: Lista A, Anexo II / List A, Annex II Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis C, mediante técnicas de Inmunoabsorción enzimática (ELISA) / Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis C infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]

HCV IgM ELISA cualitativo-cuantitativo / ELISA qualitative-quantitative

- CVM/CE (96 tests)

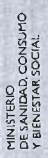
Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 19 de noviembre de 2018 DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



Fdo. M^o Jesús Lamas Díaz

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CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC
PRÓRROGA/EXTENSION — Fecha inicial/Initial date: 11/12/2003
Fecha de última prórroga/Last extension date: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
2003 12 0395 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:
Nombre/Name: DIA. Pro Diagnostic Bioprobes S.r.l.
Dirección/Address: Via G. Carducci, 27-20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/Authorized EU representative:
Nombre/Name: Idem **Dirección/Address:** Idem

Para el producto/For the product:
Categoría/Category: Productos Sanitarios para Diagnóstico "In Vitro" / In Vitro Diagnostic Medical Devices
Grupo genérico/Generic group: Diagnóstico de enfermedades infecciosas / Diagnostic of infectious diseases
Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Elaborado en/In the facilities:
Dia. Pro Diagnostic Bioprobes S.r.l.
Via G. Carducci, 27-20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total N° 2003 12 0388 CT/ This certificate must be accompanied by the EC Full Quality Assurance System Certificate N° 2003 12 0388 CT.

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente N° 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva. This certificate is issued on the assessment of the design documentation contained in dossier N° 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



Fdo. M^a Jesús Lamas Díaz

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 Fecha de la firma: 19/11/2018
 Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS
CORREO ELECTRÓNICO: 0n0318@aemps.es
 Página 1 de 2
 Localizador: PVAN79R411
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 28022 MADRID
 Tel.: (+34) 902 101 322 (+34) 91 822 59 97
 Fax: (+34) 91 822 52 89
ORGANISMO NOTIFICADO 0318

CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE
in accordance with Annex IV, Section 4, Directive 98/79/EC
PRÓRROGA/EXTENSION — Fecha inicial/Initial date: 11/12/2003
Fecha de última prórroga/Last extension date: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
2003 12 0395 ED	Desde/From 19/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:
Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.
Dirección/Address: Via G. Carducci, 27-20099- Sesto San Giovanni – Milano (Italy).
Representante autorizado ante la UE/Authorized EU representative:
Nombre/Name: Idem **Dirección/Address:** Idem

Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.
Clasificación/Classification: Lista A, Anexo II / List A, Annex II

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis D, mediante técnicas de Inmunoabsorción enzimática (ELISA) Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis D infection, by Enzyme-linked immunosorbent assay (ELISA)
[NANDO: IVD 0203]

HIV IgM ELISA cualitativo / ELISA qualitative
 - DIM.CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in its declaration of conformity.

Madrid, 19 de noviembre de 2018
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



Fdo. M^a Jesús Lamas Díaz

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 Fecha de la firma: 19/11/2018
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EC DESIGN-EXAMINATION CERTIFICATE

in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓROGA/EXTENSION — Fecha inicial/Initial date: 15/03/2004

Fecha de última prórroga/Last extension date: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
2004 03 0425 ED	Desde/From 26/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:

Nombre/Name: DIA. Pro Diagnostic Bioprobes S.r.l.

Dirección/Address: Via G. Carducci, 27-20099- Sesto San Giovanni – Milano (Italy).

Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem **Dirección/Address:** Idem

Para el producto/For the product:

Categoría/Category: Productos Sanitarios para Diagnóstico "In Vitro" / *In Vitro Diagnostic Medical Devices*

Grupo genérico/Generic group: Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

Tipo/Type: Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

Elaborado en/In the facilities:

Dia. Pro Diagnostic Bioprobes S.r.l.

Via G. Carducci, 27-20099- Sesto San Giovanni – Milano (Italy).

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total N° 2003 12 0388 CT/ This certificate must be accompanied by the EC Full Quality Assurance System Certificate N° 2003 12 0388 CT.

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente N° 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ This certificate is issued on the assessment of the design documentation contained in dossier N° 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



agencia española de medicamentos y productos sanitarios

Fdo. M^a Jesús Lamas Diaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 23/11/2018

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CORREO ELECTRÓNICO

0m0316@aemps.es

Página 1 de 2

ORGANISMO NOTIFICADO 0318

Localizador: 396955XAC

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28022 MADRID

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CERTIFICADO DE EXAMEN CE DE DISEÑO
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

EC DESIGN-EXAMINATION CERTIFICATE

in accordance with Annex IV, Section 4, Directive 98/79/EC

PRÓROGA/EXTENSION — Fecha inicial/Initial date: 15/03/2004

Fecha de última prórroga/Last extension date: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
2004 03 0425 ED	Desde/From 26/11/2018 Hasta/To 18/11/2023	0318

A favor de/In favour of:

Fabricante/Manufacturer:

Nombre/Name: Dia. Pro Diagnostic Bioprobes S.r.l.

Dirección/Address: Via G. Carducci, 27-20099- Sesto San Giovanni – Milano (Italy).

Representante autorizado ante la UE/Authorized EU representative:

Nombre/Name: Idem **Dirección/Address:** Idem

Tipo de producto / Device type: Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

Clasificación/Classification: Lista A, Anexo II / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación, cuantificación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) / *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA)*
[NANDO: IVD 0203]

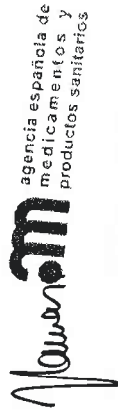
HBe Ag & Ab ELISA cualitativo / ELISA qualitative

- HBe-CE (96 tests)

Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



agencia española de medicamentos y productos sanitarios

Fdo. M^a Jesús Lamas Diaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 23/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

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Página 2 de 2

ORGANISMO NOTIFICADO 0318

Localizador: 396955XAC

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28022 MADRID

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Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	CMV IgG CODE: CMVG.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018




Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	CMV IgM CODE: CMVM.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none">• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018




Dia.Pro
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Bio*Probes*

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HSV1&2 IgG CODE: HSVG.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)
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PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018




Dia.Pro
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Bio*Probes*

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HSV1&2 IgM CODE: HSVM.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)
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PLACE & DATE OF FIRST ISSUE	MILANO – OCTOBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018



Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	TOXO IgG CODE: TOXOG.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
 PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
 DIRECTIVE 98/79/EC
 FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none"> FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 05/2018



Dia.Pro
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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	TOXO IgM CODE: TOXOM.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL
DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none">FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 05/2018



Dia.Pro
Diagnostic
Bio*Probes*

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HP IgG CODE: HPG.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001-Nr 50 100 5931/A UNI CEI EN ISO 13485-Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013



Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HP IgM CODE: HPM.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS
THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC
FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001-Nr 50 100 5931/A UNI CEI EN ISO 13485-Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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PLACE & DATE OF FIRST ISSUE	MILANO – APRIL 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 12/2013




Dia.Pro
Diagnostic
Bio*Probes*

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	VCA IgM CODE: VCAM.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS
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FOR IN VITRO DIAGNOSTIC DEVICES.

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.
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PLACE & DATE OF FIRST ISSUE	MILANO – SEPTEMBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 12/2013

GBG-MDL SRL
Global Biomarketing Group
Moldova
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Republic of Moldova

NovaTec Immundiagnostica GmbH
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November 18th, 2019

To whomever it may concern:

By hereby, we, **NovaTec Immundiagnostica GmbH**, Waldstraße 23 A6, 63128 Dietzenbach, Germany, declare that **GBG-MDL SRL** Global Biomarketing Group Moldova, 65 Tighina Str., office 607, MD-2001 Chisinau, Republic of Moldova is our authorized distributor designated by us to promote, to register, to distribute and to represent our products in the territory of the Republic of Moldova.

This declaration is valid until December 31th, 2020 unless terminated by either party before the date of expiration.

With best regards

NovaTec Immundiagnostica GmbH


NOVATEC
Britta-Maria Duchmann Berlie
General Manager
IMMUNDIAGNOSTICA GmbH
Waldstraße 23 A6
63128 Dietzenbach, Germany

Product List – CE Marked

Certified by

ISO 13485:2016

EC – Directive 98 / 79 EC
For In-Vitro-Diagnostics

2019-10

NovaLisa®

Virology

Prod. No.	Name
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
GHIM0590	Chikungunya Virus IgM µ-capture
CMVG0110	Cytomegalovirus (CMV) IgG
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM µ-capture
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSVMO250	Herpes simplex Virus 1+2 (HSV) IgM
HSV1G0500	Herpes simplex Virus 1 (HSV-1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV-2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV-2) IgM
INFA0290	Influenza Virus A IgA
INFG0290	Influenza Virus A IgG
INFMD290	Influenza Virus A IgM
INFA0300	Influenza Virus B IgA
INFG0300	Influenza Virus B IgG
INFMD300	Influenza Virus B IgM
MEAG0330	Measles Virus IgG
AMEA7330	Avidity Measles Virus IgG
MEAM0330	Measles Virus IgM
MUMG0340	Mumps Virus IgG
MUMM0340	Mumps Virus IgM
PAIA0360	Parainfluenza Virus 1,2,3 IgA
PAIG0360	Parainfluenza Virus 1,2,3 IgG
PARG0370	Parvovirus B 19 IgG
PARM0370	Parvovirus B 19 IgM
RSVA0380	Respiratory syncytial Virus IgA
RSVG0380	Respiratory syncytial Virus IgG
RSVM0380	Respiratory syncytial Virus IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG

RUBM0400	Rubella Virus IgM µ-capture	MYCG0350	Mycoplasma pneumoniae IgG
TICG0440	TBE / FSME IgG	MYCM0350	Mycoplasma pneumoniae IgM
TICM0440	TBE / FSME IgM	TETG0430	Clostridium tetani toxin IgG
PTICG044	TBE / FSME IgG plus	TETG5043	Clostridium tetani toxin 5S IgG
		PTETG043	Clostridium tetani toxin 5S IgG plus

VZV0490	Varicella-Zoster Virus (VZV) IgA		
VZV0490	Varicella-Zoster Virus (VZV) IgG		
VZVM0490	Varicella-Zoster Virus (VZV) IgM		
ZVG0790	Zika Virus IgG capture		
ZVM0790	Zika Virus IgM µ-capture		

NovaLisa® Bacteriology

Prod. No.	Name
BAR0900	Bartonella
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BRUG0050	Bruceella IgG
BRUM0050	Bruceella IgM
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM
MYCA0350	Mycoplasma pneumoniae IgA

NovaLisa® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TOXM0460	Toxoplasma gondii IgM µ-capture

NovaLisa® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
FIL0760	Filariasis
SCHG0410	Schistosoma mansoni IgG
SCHM0410	Schistosoma mansoni IgM
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa® Fungi

Prod. No.	Name
ASPG0680	Aspergillus fumigatus IgG
ASPM0680	Aspergillus fumigatus IgM
CANA0060	Candida albicans IgA
CANG0060	Candida albicans IgG
CANM0060	Candida albicans IgM

NovaLis[®] Hormones

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
FT41050	Free T4
TSH1030	TSH

PROTEIN HORMONES
(ELISAs for the determination of proteins in plasma and serum)

Prod. No.	Name
DNOV030	LH
DNOV031	FSH
DNOV032	Prolactin
DNOV033	AFP
DNOV034	beta HCG

Hormones

STEROID HORMONES
(ELISAs for the determination of steroid hormones in plasma and serum)

Prod. No.	Name
DNOV001	Cortisol
DNOV002	Testosterone
DNOV003	17 beta-Estradiol
DNOV004	17-OH Progesterone
DNOV005	DHEA-S
DNOV006	Progesterone
DNOV007	Free Estrinol
DNOV008	Androstenedione
DNOV009	Free Testosterone
DNOV011	Total Estrinol
DNOV012	Aldosterone

STEROID HORMONES IN URINE
(ELISAs for the determination of steroid hormones in urine)

Prod. No.	Name
DNOV010	Urinary Cortisol

STEROID-HORMONES-IN-SALIVA
(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
DSNOV20	Cortisol Saliva
DSNOV21	Testosterone Saliva
DSNOV22	17 beta-Estradiol Saliva
DSNOV24	DHEA-S Saliva
DSNOV25	Progesterone Saliva
DSNOV26	Estrinol Saliva
DSNOV27	Androstenedione Saliva

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
DNOV051	Free T3
DNOV053	Total T3
DNOV054	Total T4
DNOV057	Thyroglobulin

DIABETES MONITORING
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV111	Insulin
DNOV112	C-Peptide

CIRCULATING IMMUNO COMPLEXES
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV093	CIC-C1q
DNOV094	CIC-C3d
DNOV096	CH-50

TUMOR MARKERS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV060	CEA
DNOV061	CA 125
DNOV062	CA 15-3
DNOV063	CA 19-9

MISCELLANEOUS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

NovoLisa® Autoimmune

Autoimmune
(ELISAs for the determination of specific autoimmune antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO

Rheumatology
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
RFM3010	Rheumatoid Factor IgM

NovoLisa® Recombinant Antigens

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
CHAG00680	Chagas (Trypanosoma cruzi) IgG
TRYP00570	Chagas
HANG00670	Hantavirus IgG
HANN00670	Hantavirus IgM
HELA00220	Helicobacter pylori IgA
PHELA0022	Helicobacter pylori IgA plus
HEVG00780	Hepatitis E Virus (HEV) IgG
HEVM00780	Hepatitis E Virus (HEV) IgM
HSV1G00500	Herpes simplex Virus 1 (HSV-1) IgG
HSV1M00500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G00540	Herpes simplex Virus 2 (HSV-2) IgG
HSV2M00540	Herpes simplex Virus 2 (HSV-2) IgM
MAL00620	Malaria
STRO00690	Strongyloides
ZVG00790	Zika Virus IgG capture
ZVM00790	Zika Virus IgM μ-capture

NovoLisa® Quantitative Assays (WHO standardized)

Prod. No.	Name
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG00090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovoLisa® Quantitative Assays

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
FT41050	Free T4
HELA00220	Helicobacter pylori IgA
HELG00220	Helicobacter pylori IgG
PHELA0022	Helicobacter pylori IgA plus
PHELG0022	Helicobacter pylori IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani 5S toxin IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	TBE / FSME IgG
PTICG044	TBE / FSME IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovaLisa® IgM µ-capture Assays

Prod. No.	Name
CHIM0590	Chikungunya Virus IgM µ-capture
DVM0640	Dengue Virus IgM µ-capture
RUBM0400	Rubella Virus IgM µ-capture
TOXM0460	Toxoplasma gondii IgM µ-capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa® Antibody Assays

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0370	Leishmania infantum IgG
IMAL0620	Malaria
STRO0690	Strongyloides
TAE0420	Taenia solium IgG
TCCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa® Avidity Assays

Prod. No.	Name
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
AMEA7330	Avidity Measles Virus IgG
ARUB7400	Avidity Rubella Virus IgG
ATOX7460	Avidity Toxoplasma gondii IgG

NovaLisa® Liquor Diagnostic

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM

ВЕКТОР



ОГРН 1025404347550
ИНН 5433104584/ КПП 543301001
р/с 40702810244020101090
в Сибирском банке ПАО Сбербанк,
БИК 045004641
корр. сч. 30101810500000000641
ОКВЭД 21.20.2, 72.11 / ОКПО 23548172

от 18.11.2019 № КС-151

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«GBG-MLD» SRL
Республики Молдова, г. Кишинев,
ул. Тигина, 65, оф. 607
Чайковскому Т.К.

Авторизация от производителя

Акционерное общество «Вектор-Бест» (Российская Федерация, 630559, Новосибирская область, рабочий поселок, Кольцово, Научно-производственная зона, корпус 36, к. 211) официально удостоверяет, что «GBG-MLD» SRL (Республика Молдова, г. Кишинев, ул. Тигина, 65, оф. 607) имеет право участвовать от имени АО «Вектор-Бест» в тендерах, проводимых медицинскими учреждениями Республики Молдова и осуществлять рекламно-информационное сопровождение.

Срок действия авторизации по 31 декабря 2020 года включительно.

Коммерческий директор АО «Вектор-Бест»

 Гусев Ю.М.



Сертификат

mdc medical device certification GmbH

устанавливает, что на предприятии

ВЕКТОР



АО «Вектор-Бест»
630559, Новосибирская область, р.л. Кольцово,
Научно-производственная зона, корпус 36, к. 211,
Российская Федерация

с производственными площадками согласно приложению к Сертификату применительно к областям

проектирование и разработка, производство и реализация
медицинских изделий in-vitro диагностики
(ПЦР, ИФА, биохимия)

была введена и применяется

СИСТЕМА УПРАВЛЕНИЯ КАЧЕСТВОМ

Проведенная проверка системы управления качеством показала,
что данная система соответствует требованиям стандарта:

EN ISO 13485

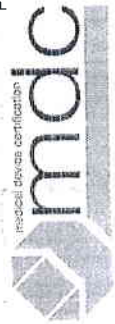
Изделия медицинские – Системы менеджмента качества –
Регулирующие системные требования

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Дата выдачи 2018-07-13
Срок действия до 2020-07-03
Регистрационный № D1213100017
Отчет № P18-00489-117996
Штутгарт, Германия 2018-07-13

J. All

Руководитель сертификационного органа



mdc medical device certification GmbH
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Приложение к Сертификату

от 2018-07-13

Стр. 1 из 1

№ D1213100017

Месторасположение	Область действия
АО «Вектор-Бест», ул. Арбузова, 1/1, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство и реализация медицинских изделий in vitro диагностики
АО «Вектор-Бест», 630559, Новосибирская область, р.л. Кольцово, Научно-производственная зона, корпус 36, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики
АО «Вектор-Бест», ул. Пасечная, 3, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики

EC DECLARATION OF CONFORMITY

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2-4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products: Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure: Annex III (not including section 6).

Manufacturer:

ZAO "Vector-Best"
 Address: AHC, Koltsovo,
 Novosibirsk Region, 630559, Russia,
 Tel. +7 (383) 363 20 60,
 Fax: +7 (383) 363 35 55

European authorized representative:

Bioron GmbH,
 Rheinhorststr. 18, D-67071
 Ludwigshafen, Germany.
 tel.: +49 (0) 621 5720 915,
 fax: +49 (0) 621 5720 916

Date: 2013/04/12



Murat Khusainov
 General Director ZAO «Vector-Best»

No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep TTV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1056
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1058
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombiBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombiBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectoHSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectoHSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectoHHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectoHHV-6 - IgG	ELISA kit for determination of IgG to human herpes virus type 6	D-2166
17.	Ureaplasma urealyticum - IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum - IgA-EIA-BEST	ELISA kit for determination of IgA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis - IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus	D-3356

24.	Ascaris-IgG-EIA-BEST	antigens ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lambliia-antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lambliia antibodies	D-3552
26.	Lambliia-IgM-EIA-BEST	ELISA kit for determination of IgM to Lambliia antibodies	D-3554
27.	Lambliia-antigen-EIA-BEST	ELISA kit for determination of Lambliia antigen	D-3556
28.	Helicobacter pylori-CagA-antigen-EIA-BEST	ELISA kit for determination of total antibodies to CagA Helicobacter pylori	D-3752
29.	TSH-EIA-BEST	ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST	ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST	ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST	ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST	ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST	ELISA kit for determination of IgA to Mycoplasma hominis	D-4358
36.	Mycoplasma pneumoniae-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST	ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vectocrimean - CHF - IgG	ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39.	Vectocrimean - CHF - IgM	ELISA kit for determination of IgM to Crimean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST	ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST	ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST	ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST	ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST	ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST	ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST	ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST	ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST	ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST	ELISA kit for determination of concentration of gamma-Interferon	A-8752
52.	Interleukine-4-EIA-BEST	ELISA kit for determination of concentration of Interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST	ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST	ELISA kit for determination of concentration of alpha-Interferon	A-8758
55.	Interleukine-6-EIA-BEST	ELISA kit for determination of concentration of Interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST	ELISA kit for determination of concentration of Interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST	ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST	ELISA kit for determination of concentration of N-terminal prohormone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST	ELISA kit for determination of concentration of troponin I	A-9106



Doc. 2/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: SX 60129534 0001
Report No.: 21264033 005

Organization:
EUROIMMUN
Medizinische Labor diagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:
Sites included:

EUROIMMUN Medizinische Labor diagnostika AG
Am Schenkenberg 9, 21627 Groß Gerau, Germany
Activities: Design and development, production
EUROIMMUN Medizinische Labor diagnostika AG
Am Born 24, 23627 Groß Gerau, Germany
Activities: Design and development, distribution,
installation, service
EUROIMMUN Medizinische Labor diagnostika AG
Im Koppel 1, 02747 Herrnhut, Germany
Activity: Production

Certification Body



Date: 2018-06-08

Dipl.-Ing. Sven Hoffmann



Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: SX 60129534 0001
Report No.: 21264033 005

Organization:
EUROIMMUN
Medizinische Labor diagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:
Sites included:

EUROIMMUN Medizinische Labor diagnostika AG
Am Fliesenplatz 1, 02746 Bernsdorf, Germany
Activity: Production
EUROIMMUN Medizinische Labor diagnostika AG
Schloßstraße 11, 91251 Pegnitz, Germany
Activities: Production, installation, service
EUROIMMUN Medizinische Labor diagnostika AG
Am der Traue 1, 21923 Selmedorf, Germany
Activities: Design and development, production, service

Certification Body



Date: 2018-06-08

Dipl.-Ing. Sven Hoffmann





Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

Hereby certifies that the organization

EUROIIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

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

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

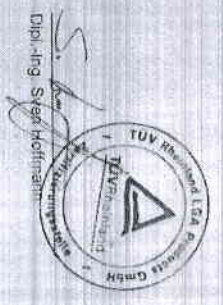
Effective Date: 2018-06-08
Certificate Registration No.: SX 60129534 0001
An audit was performed. Report No.: 21264033 005
This Certificate is valid until: 2020-05-18

Certification Body

Date: 2018-06-08



Deutsche
Akkreditierungsstelle
D-22111 Lübeck



Dipl.-Ing. Siegf. Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel: +49 201 805 1371 Fax: +49 201 805 5353 www.tuev.com www.lga.com www.tuev.de



TÜV Rheinland

LGA Products GmbH

Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev. 0

Attachment to
Certificate
Registration No.: SX 60129534 0001
Report No.: 21264033 005

Organization:
EUROIIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:

Design and development, production, installation, service
and distribution of immunobiochemical test systems, immuno-
fluorescence test systems, molecular diagnostic/diagnostic
test systems, test systems for the determination of
infectious agents and instruments/software for
in vitro diagnosis

Sites included:
EUROIIMMUN Medizinische Labordiagnostika AG
Markstraße 2-22, 23561 Duesow, Germany
Activities: Design and development, production, distribution

Certification Body



Deutsche
Akkreditierungsstelle
D-22111 Lübeck

Date: 2018-06-08



Dipl.-Ing. Siegf. Hoffmann

Roseto degli Abruzzi, 11 January 2020

Authorization Letter

To whom it may concern

We, **LIOFILCHEM S.R.L.**, manufacturer of diagnostics for microbiology, certified ISO 9001 and ISO 13485, located in Via Scozia, Zona Industriale, 64026 Roseto degli Abruzzi (TE) Italy

do hereby authorize the company

GBG-MLD SRL
65 Tighina Str. Office 607
MD-2001, Chisinau
Moldova

to distribute our following products in **Moldova** (below defined as "the Territory"):

The medical devices manufactured by Liofilchem comply with the European Union directive 98/79/EC for in vitro diagnostic devices (IVD).

A Quality Agreement is attached to this letter as Annex 1.

This authorization is valid to 31.12.2022 and is not automatically renewed.

The cooperation between **GBG-MLD SRL** and **Liofilchem** can be terminated by either Party, before 31.12.2022 through a 30 day written notice.

In faith,

Fabio Brocco
COO
Liofilchem

Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l. con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 31.0 del 08.01.2016

dichiara sotto la propria responsabilità

- che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
- che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
- che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
- che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
- di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio del prodotto;
- che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE.

EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the *in vitro* medical-diagnostic device listed in the attached table, Revision 31.0 of 08.01.2016

hereby certifies under its own responsibility

- that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
- the above mentioned is not included in Annex II, List A and B of Directive 98/79/EC;
- that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
- that the manufacturing process follows suitable principles of quality assurance;
- that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
- that the device in question, was introduced into the market provided with CE mark

Direttore Tecnico/ Technical Director
Dott. Silvio Brocco



PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

Rev. 31.0 del 08.01.2016

10002	DNA AGAR + BLU DI TOLUIDINA	10046	SERUM TELLURITE AGAR
10004	CLED ANDRADE AGAR	10047	BISMUTH SULFITE AGAR
10004*	CLED ANDRADE AGAR	10047*	BISMUTH SULFITE AGAR
10005	MAC CONKEY SOBIBITOL AGAR	10048	E.M.B. LEVINE AGAR
10005*	MAC CONKEY SOBIBITOL AGAR	10048*	E.M.B. LEVINE AGAR
10006	TRYPTIC SOY AGAR + 0,8% YEAST EXTRACT	10050	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10007	BACILLUS CEREUS AGAR (PENG)A	10050*	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10007*	BACILLUS CEREUS AGAR (PENG)A	10051	Legionella BCYE Agar
10007*	BACILLUS CEREUS AGAR (PENG)A	10051*	Legionella BCYE Agar
10011	YEAST GLUCOSE CHLORAMPHENICOL AGAR	10052	YERSINIA SELECTIVE AGAR
10011*	YEAST GLUCOSE CHLORAMPHENICOL AGAR	10052*	YERSINIA SELECTIVE AGAR
10011*	YEAST GLUCOSE CHLORAMPHENICOL AGAR	10052*	YERSINIA SELECTIVE AGAR
10013	DNAse TEST AGAR	10053	WILKINS CHALGREEN AGAR
10013*	DNAse TEST AGAR	10053*	WILKINS CHALGREEN AGAR
10014	Purple Lactose Agar	10054	WURTZ LACTOSE AGAR
10014*	Purple Lactose Agar	10054*	WURTZ LACTOSE AGAR
10014*	Purple Lactose Agar	10054*	WURTZ LACTOSE AGAR
10017	CZAPPEK DOX AGAR	10056	X.L.D. AGAR
10018	DRIGALSKY LACTOSE AGAR	10056*	X.L.D. AGAR
10021	BIGGY (NICKERSON) AGAR	10057	BILE AESCULIN AGAR
10021*	BIGGY (NICKERSON) AGAR	10057*	BILE AESCULIN AGAR
10022	BRIILLIANT GREEN AGAR	10058	TRYPTIC SOY AGAR Irradiated -30 ml-
10022*	BRIILLIANT GREEN AGAR	10060	BRYAN HEART INFUSION AGAR
10023	Chocobias Agar	10060*	BRYAN HEART INFUSION AGAR
10023*	Chocobias Agar	10064	CHRISTENSEN URSEA AGAR
10024	TRYPTOSE AGAR	10065	SCHAEDELER KKV AGAR(Sheep Blood 5%)
10024*	TRYPTOSE AGAR	10065*	SCHAEDELER KKV AGAR(Sheep Blood 5%)
10025	COLUMBIA AGAR (Horse Blood 5%)	10067	SCHAEDELER KVN AGAR (Sheep Blood 5%)
10025*	COLUMBIA AGAR (Horse Blood 5%)	10069	X.L.T. 4 AGAR
10028	CLED AGAR	10069*	X.L.T. 4 AGAR
10028*	CLED AGAR	10074S	TRYPTIC SOY AGAR+NEUTRALIZING Irradiated
10027	BACILLUS CEREUS AGAR (Mucosa)	10076	MUELLER HINTON II MOD. AGAR
10027*	BACILLUS CEREUS AGAR (Mucosa)	10076*	MUELLER HINTON II MOD. AGAR
10028	ISOSENSITEST AGAR	10078*	MUELLER HINTON II MOD. AGAR
10028*	ISOSENSITEST AGAR	10079	CASSTONE AGAR
10029	MAC CONKEY AGAR	10079*	CASSTONE AGAR
10029*	MAC CONKEY AGAR	10080	HAEKOPHYLUS TEST AGAR
10030	MANNITOL SALT AGAR	10080*	HAEKOPHYLUS TEST AGAR
10030*	MANNITOL SALT AGAR	10082	HELDOLBACTER PYLDRI AGAR
10031	MUELLER HINTON II AGAR	10082*	HELDOLBACTER PYLDRI AGAR
10031*	MUELLER HINTON II AGAR	10090	M.R.S. Agar
10031*	MUELLER HINTON II AGAR	10090*	M.R.S. Agar
10033*	PSEUDOMONAS (CETRIMIDE) AGAR	10095	BRYAN HEART AGAR FOR HAEMOPHILUS
10035	SABOURAUD AGAR	10129	MAC CONKEY AGAR MNG
10035*	SABOURAUD AGAR	10129*	MAC CONKEY AGAR MNG
10035*	SABOURAUD AGAR Irradiated	10131	Mueller Hinton II Agar (Sheep Blood 5%)
10036	S.S. AGAR	10131*	Mueller Hinton II Agar (Sheep Blood 5%)
10036*	S.S. AGAR	10132	MUELLER HINTON FASTidious AGAR 90 mm
10037	TRYPTIC SOY AGAR	10134	Legionella BCPA Agar
10037*	TRYPTIC SOY AGAR	10141	SALMONELLA TEST AGAR
10037*	TRYPTIC SOY AGAR Irradiated	10141*	SALMONELLA TEST AGAR
10039	ROGOSA AGAR	10142	BLOOD AGAR (Sheep Blood 7%,ISO 10580)
10040	NEW YORK CITY AGAR	10142*	BLOOD AGAR (Sheep Blood 7%,ISO 10580)
10040*	NEW YORK CITY AGAR	10143	Mueller Hinton Agar + 5 % Horse Blood Lyophil
10041	LISTERIA PALCAM AGAR	10145	CAMPYLOBACTER KARMALI AGAR
10041*	LISTERIA PALCAM AGAR	10146	CAMPYLOBACTER PRESTON AGAR
10042	CRYSTAL VIOLET AGAR (Sheep Blood 5%)	10146	CAMPYLOBACTER AGAR (Sheep Blood 10%)
10042*	CRYSTAL VIOLET AGAR (Sheep 5%)	10225	LISTERIA PALCAM AGAR 140 mm
10043	HEKTOEN ENTERIC AGAR	10231	MUELLER HINTON II AGAR 140 mm
10043*	HEKTOEN ENTERIC AGAR	10233	R.F.M.L. AGAR
10044	NUTRIENT AGAR	10235	SABOURAUD CAF AGAR + GENTAMICIN
10044*	NUTRIENT AGAR	10235*	SABOURAUD CAF AGAR + GENTAMICIN
10044*	NUTRIENT AGAR	10236	CLED AGAR 140 mm

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

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10240	SCHAEDLER K AGAR (Sheep Blood 5%) 140mm
10241	SCHAEDLER KKV AGAR(Sheep blood 5%) 140mm
10242	SABOURAUD CAF AGAR 140 mm
10243	SABOURAUD CAF AGAR + GENTAMICIN 140mm
10244	DERMATOPHYTE (D.T.M.) AGAR 140 mm
10245	BRUCELLA BLOOD AGAR w HEMIN AND VITAMIN K1
10246	Chromatic™ MH
10247	Brucella Blood Agar with Hemin and Vitamin K1
10249	Purple Lactose Agar 140 mm
10334	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10334*	NEOMYCIN BLOOD AGAR (Sheep Blood 5%)
10335	MUELLER HINTON CHOCOLATE AGAR
10353	BORDET GENGOU AGAR (Sheep Blood 15%)
10353*	BORDET GENGOU AGAR (Sheep Blood 15%)
10405	SCHAEDLER CNA AGAR (Sheep Blood 5%)
10407	VANCOMYCIN SCREEN AGAR
10408	WILKINS CHALGREN AGAR +5% SHEEP BLOOD
10409	CAMPYLOBACTER CCDA AGAR
10410	MUELLER HINTON AGAR w VITALEX
10411	BILE ESCULIN AZIDE AGAR w VANCOMYCIN
10412	Legionella BCYE Agar w/o Cysteine
10413	XLD Agar EP, USP, JP Formulation
10416	MIDDLEBROOK 7H11 AGAR
10424	Legionella BCYE Agar w Vancomycin + Colistin
10425	SCEDOSPORIUM SELECTIVE AGAR
10438	MacConkey Agar No.2
10438*	MacConkey Agar No.2
10439	Group A Selective Strep Agar w/ 5% Sheep Blood
10599	CHROMATIC™ MRSA
10600	OXACILLIN RESISTANCE STAPHYLOCOCCUS AGAR
10601	CHOCOLATE AGAR w/o VITOX
10602	CAMPYLOBACTER SKIRROW AGAR
10605	HELICOBACTER PYLORI EGG YOLK EMULSION AGAR
10620	O.A.LISTERIA
11023	CHOCOLATE BACITRACIN AGAR
11023*	CHOCOLATE BACITRACIN AGAR
11024	COLUMBIA CNA AGAR (Sheep Blood 5%)
11024*	COLUMBIA CNA AGAR (Sheep Blood 5%)
11025	COLUMBIA AGAR (Sheep Blood 5%)
11025*	COLUMBIA AGAR (Sheep Blood 5%)
11027	DESOXYCHOLATE AGAR
11027*	DESOXYCHOLATE AGAR
11030	ANAEROBIC AGAR
11033	PSEUDOMONAS ISOLATION AGAR
11033*	PSEUDOMONAS ISOLATION AGAR
11035	SABOURAUD CAF AGAR
11035*	SABOURAUD CAF AGAR
11035S	SABOURAUD CAF AGAR Irradiated
11037	TRYPTIC SOY AGAR (Sheep Blood 5%)
11037*	TRYPTIC SOY AGAR (Sheep Blood 5%)
11038	TRYPTIC SOY AGAR (Horse Blood 5%)
11038*	TRYPTIC SOY AGAR (Horse Blood 5%)
11040	THAYER MARTIN AGAR
11040*	THAYER MARTIN AGAR
11041	AZIDE AGAR (Sheep Blood 5%)
11041*	AZIDE AGAR (Sheep Blood 5%)
11052	DERMATOPHYTE (D.T.M.) AGAR
11052*	DERMATOPHYTE (D.T.M.) AGAR
11054	GARDNERELLA AGAR (Sheep Blood 5%)
11054*	GARDNERELLA AGAR (Sheep Blood 5%)

11057	ENTEROCOCCO AGAR
11057*	ENTEROCOCCO AGAR
11058	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11058*	SLANETZ BARTLEY AGAR(m-ENTEROCOCCUS)
11060	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11060*	CLOSTRIDIUM AGAR (Sheep Blood 5%)
11065	SCHAEDLER K AGAR (Sheep Blood 5%)
11065*	SCHAEDLER K AGAR (Sheep Blood 5%)
11070	MYCOSEL AGAR
11070*	MYCOSEL AGAR
11132	MUELLER HINTON FASTIDIOUS AGAR (140mm)
11124	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11124*	COLUMBIA CNA MOD. AGAR (Sheep blood 5%)
11135	SABOURAUD AGAR MODIFIED
11135*	SABOURAUD AGAR MODIFIED
11143	HERELLEA AGAR
11143*	HERELLEA AGAR
11185	VOGEL JOHNSON AGAR
11185*	VOGEL JOHNSON AGAR
11195	T.C.B.S. AGAR
11195*	T.C.B.S. AGAR
11196	SPS AGAR
11196*	SPS AGAR
11200	PAR TEST AGAR
11200*	PAR TEST AGAR
11205	MYCOPLASMA AGAR
11206	Mueller Hinton II Agar + 2% NaCl
11231	Mueller Hinton II Agar (Sheep Blood 5%) 140mm
11235	SABOURAUD CAF AGAR + TTC
11235*	SABOURAUD CAF AGAR + TTC
11236	Sabouraud CAF Agar + Actidione
11250	TINSDALE AGAR
11250*	TINSDALE AGAR
11335	SABOURAUD AGAR + GENTAMICIN
11335*	SABOURAUD AGAR + GENTAMICIN
11501	ENTEROCOCCUS AGAR + VANCOMYCIN
11506	BURKHOLDERIA CEPACIA SELECTIVE AGAR
11509	R.P.M.I. AGAR
11510	M.HINTON+GLUCOSE+METHYLEN BLUE
11511	NEISSERIA-MORAXELLA MEDIUM
11512	NUTRIENT AGAR acc.to ISO 21528
11513	NUTRIENT AGAR acc.to ISO 6579
11517	COLUMBIA AGAR(Sheep Blood 5%)+VANCOMYCIN
11518	Mueller Hinton Agar + Cloxacillin
11610	Chromatic™ E.coli O157
11611	CHROMATIC™ DETECTION
11612	CHROMATIC™ CANDIDA
11614	CHROMATIC™ SALMONELLA
11616	CHROMATIC™ STAPH AUREUS
11617	CHROMATIC™ STREPTO B
11618	CHROMATIC™ MH
11619	CHROMATIC™ CRE
11621	CHROMATIC™ VRE
11622	CHROMATIC™ ESBL
11627	Chromatic™ Enterococcus
11629	CHROMATIC™ ESBL + AmpC
11629*	CHROMATIC™ ESBL + AmpC
11631	Chromatic™ OXA-48
11632	Chromatic™ Clostridium difficile
11634	Chromatic™ Detection opaque

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS
Rev. 31.0 del 08.01.2016

470290	CARY BLAIR TRANSPORT MEDIUM 6x500 ml	810013	COLUMBIA AGAR BASE
470300	Fluid Thioglycollate Medium 5 x 500 ml	8100135	COLUMBIA AGAR BASE
470320	PEPTONE WATER 8X500 ml	810014	DESOXYCHOLATE AGAR
470370	TRYPTIC SOY BROTH 5 x 500 ml	8100145	DESOXYCHOLATE AGAR
471070	SABOURAUD BROTH 4x500 ml	810015	DESOXYCHOLATE CITRATE AGAR
471120	PHYSIOLOGICAL SOLUTION 8X240 ml	810016	DIPYCNOL LACTOSE AGAR
472000	PHYSIOLOGICAL SOLUTION 8X500 ml	810019	E.M.B. LEVINE AGAR
481110	CHROMATIC** CANDIDA CY100 ml	810021	HEKTOX ENTERIC AGAR
481130	CHROMATIC** DETECTION 6X100 ml	810025	HEKTOX ENTERIC AGAR
481140	CHROMATIC** SALMONELLA 6X100 ml	810022	S.G. MEDIUM
481150	CHROMATIC** STAPH AUREUS 6X100 ml	810023	MULLER IRON AGAR
481160	CHROMATIC** STREP B 6X100 ml	810024	M.M.S. AGAR (ISO 6788)
482100	Chromatic** 2. coli O157 & 2 H7	810025	M.H.S. BROTH (ISO FOR 15214)
490010	HEMO AEROBIC Culture 5X50 ml	810026	LOWENSTEIN JENSEN MEDIUM
490020	HEMO AEROBIC Culture 10X100 ml	440022	LYSINE IRON AGAR
490040	HEMO AEROBIC Culture Pediatric 6X100 ml	810028	MAC CONKEY AGAR
490050	HEMO AEROBIC Culture NEONATAL 6X8 ml	810035	MAC CONKEY AGAR
490060	HEMO AEROBIC Culture NEONATAL 6X8 ml	810029	MANNITOL SALT AGAR
493000	Fluid Thioglycollate Medium 5 x 100 ml	810026	MANNITOL SALT AGAR
495010	TRYPTIC SOY BROTH 6x100 ml	810030	M.U.V.P. BROTH
495020	Fluid Thioglycollate Medium 5 x 100 ml	810033	MULLER HINTON AGAR
50042	URITEST PENTA	810035	MULLER HINTON AGAR
50045	URITEST M	810034	MULLER HINTON BROTH
50046	URITEST F	810035	MULLER KAUFFMANN BROTH
50047	URITEST OF	810036	NUTRIENT BROTH
50048	URITEST N	810037	NUTRIENT BROTH
50049	URITEST Z	810038	PEPTONE WATER
50050	URITEST M+D	810039	PHENYLALANINE AGAR
50047	URITEST EC	810041	PSEUDOMONAS CETIMIDE AGAR (ISO 8380-1)
50048	URITEST PENTA	8100415	PSEUDOMONAS CETIMIDE AGAR
50049	URITEST M	810042	SS AGAR (MODIFIED)
50050	URITEST F	8100425	SS AGAR (MODIFIED)
50051	URITEST N	810043	SCHMELZER AGAR BASE
50052	URITEST Z	810044	PURPLE LACTOSE AGAR
50053	URITEST M	810046	SAMON'S CITRATE AGAR
50054	URITEST F	810047	SCHMELZER AGAR
50055	URITEST Z	810048	AEROMONAS AGAR BASE
50056	URITEST M+D	810049	LEONNELLA BOYE AGAR BASE (ISO 11731)
50057	URITEST EC	810050	Fluid Thioglycollate Medium
50058	URITEST FF	8100505	Fluid Thioglycollate Medium
50059	URITEST M	810051	TOOD HEWITT BROTH
50060	URITEST F	8100515	TOOD HEWITT BROTH
50061	URITEST M	810052	TRYPTIC SOY AGAR
50062	URITEST F	8100525	TRYPTIC SOY BROTH (HAIN EPI 5 KG)
50063	URITEST Z	810053	TRYPTIC SOY BROTH
50064	URITEST M+D	8100535	TRYPTIC SOY BROTH
50065	URITEST EC	810055	T.S.J. AGAR USP
50066	URITEST FF	810056	CLOSTRIDIUM BROTH
50067	URITEST M	810058	CLOSTRIDIUM BROTH
50068	URITEST F	810057	MAC CONKEY AGAR No.2
50069	URITEST Z	8100575	MAC CONKEY AGAR No.2 5 KG
50070	URITEST M+D	810060	X.L.D. AGAR (ISO 6570)
50071	URITEST EC	810063	X.L.D. AGAR
50072	URITEST FF	810061	TRICHOMONAS BROTH
50073	URITEST M	810065	(ISO AGAR BASE (ISLAM)
50074	URITEST F	810070	YEAST GLUCOSE CHLORAMPHENICOL AGAR
50075	URITEST Z	8100705	YEAST GLUCOSE CHLORAMPHENICOL AGAR 5 KG
50076	URITEST M+D	810071	PSEUDOMONAS AGAR BASE

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS
Rev. 31.0 del 08.01.2016

810072	CZAPEK DOX BROTH	810076	MAC CONKEY MMS AGAR
810074	TRYPTON SULFITE NEOMYCIN AGAR	810079	MALONATE BROTH
810075	PHENYLALANINE MALONATE BROTH	810079	MALONATE BROTH
810076	BRUCELLA AGAR BASE	810079	PHENOL RED BROTH BASE
810077	WORT BROTH W/O NCI	810079	RAPPAPORT VASSILIADIS BROTH (ISO 6785-5370)
810082	XLT 4 AGAR	810079	ROGOSA AGAR
810085	CZAPEK DOX AGAR	810079	ROGOSA BROTH
810086	HEIN OCELOT GLOSTRIDIAL AGAR	810079	SABOURAUD CAF AGAR + ACTINOMY
810087	STAPHYLOCOCCUS BROTH	810080	S.F. BROTH
810088	AL KALINE PEPTONE WATER	810081	S.I.M. MEDIUM
810089	MALT AGAR	810082	STUART TRANSPORT MEDIUM
810090	SABOURAUD AGAR	810083	TETRAATHONATE BROTH BASE
810095	SABOURAUD ALUM	810085	TETRAATHONATE BROTH
810096	SABOURAUD BROTH	810085	VOGEL JOHNSON AGAR
810097	UREA AGAR BASE (ISO 6785)	810088	BLOOD AGAR BASE N. 2
810098	MAC CONKEY SORBITOL AGAR	810089	AMES TRANSPORT MEDIUM (w/ CHARCOAL)
810099	P.P.L.O. BROTH	8100915	AMES TRANSPORT MEDIUM (w/ CHARCOAL)
810100	MULLER HINTON AGAR MODIFIED	810093	TRYPTONE AGAR
810101	YERSINIA SELECTIVE AGAR BASE	810095	MAC CONKEY AGAR w/ CRYSTAL VIOLET
810102	GLD ANDRAGE AGAR	810100	TRYPTIC BLE AGAR
810103	COLUMBIA CHA AGAR BASE	810100	TRYPTOPAN BROTH
810104	BACILLUS CEREUS AGAR BASE (MODEL) ISO 7202	810100	CAMPYLOBACTER KURUMAI AGAR BASE
810105	CLOSTRIDIUM DIFFICILE AGAR BASE	810103	SABOURAUD CAF AGAR
810107	TRYPTONE YEAST AGAR	8101035	SABOURAUD CAF AGAR 5 KG
810108	ANDRAGE LACTOSE PEPTONE WATER	810105	DINAKA TEST AGAR
810109	ODON HEAL AGAR	810106	TRYPTONE WATER (ISO 3111)
810110	LEIODINELLA CYE AGAR BASE	810107	GLOSTRIDIUM PERFRIGENS AGAR BASE
810112	MAC CONKEY AGAR w/ BLE SALT	810107	BLE ASCULIN AGAR
810120	CAMPYLOBACTER BLOOD FREE MEDIUM BASE	810111	MULLER IRON AGAR MOD.
810121	CAMPYLOBACTER ENRICHMENT BROTH BASE	810114	MIDDLEBROOK 7H9 BROTH BASE
810132	MOTILITY TEST AGAR	810117	NUTRIENT BROTH N.2
810134	BLANETZ BARTLEY AGAR BASE ISO 7202-2	810118	Muller Hinton Broth
810135	BIGGY (ICKERSON) AGAR	810121	ANTIBIOTIC TEST MEDIUM
810136	BACILLUS CEREUS AGAR BASE (PREMIA)	810122	CLOSTRIDIUM BROTH w/ AGAR
810137	SCHMELZER BROTH	8101225	CLOSTRIDIUM BROTH (w/ AGAR)
810140	E.M.B. AGAR w/ LACTOSE + SUCROSE	810123	PHENOL RED AGAR BASE
810141	LIVER BROTH	810127	PHENOL RED AGAR BASE
810144	MRS BROTH w/ GLUCOSE	810129	ANTIBIOTIC MEDIUM
810145	SELENITE BROTH	810130	Oxidation/fermentation MEDIUM
8101455	SELENITE BROTH	810133	TRYPTONE BROTH
810146	SABOURAUD MALT AGAR	810135	MANNITOL MOTILITY TEST MEDIUM
810147	BLANETZ AND BARTLEY AGAR + TTC	810136	MOTILITY AND BARTLEY AGAR + TTC
8101475	BLANETZ AND BARTLEY AGAR + TTC	810137	TRYPTONE SOYA YEAST EXTRACT BROTH
810148	SPS AGAR	810145	LB AGAR
810151	BLE ASCULIN BROTH	810151	BISMUTH SULPHITE AGAR
810152	AMES TRANSPORT MEDIUM + CHARC	810152	Lysine Desaminoase Broth
810153	AMES TRANSPORT MEDIUM + CHARC	810154	CF BASAL MEDIUM
810154	AZIDE BLOOD AGAR BASE	810155	ORFANTINE CARBAMIDYL ASF BROTH
810155	AZIDE VIOLET BLOOD AGAR BASE	810156	ANDRAGE (RICHARDSON) AGAR
810157	BIOTONE AGAR	810159	PSEUDOMONAS AGAR F
810158	BIOTONE BROTH	810160	PSEUDOMONAS AGAR F
810159	CPM SELECTIVE WITH CAF	810161	UREA BROTH
810160	DERMATOPHYTES (T.M.) AGAR	8101615	ANTIBIOTIC AGAR N.11
810161	DETRIOSE BROTH	810169	SWINER SELECTIVE ENTEROCOCCUS AGAR
810163	G.H. HAINA BROTH	810170	NETRO-BROTH
810164	HERELLEA AGAR	810171	(DIANOMATIC SENSITIVITY TEST AGAR) (S.T.)
810165	HERELLEA AGAR	810173	T.S.J. AGAR w/ EP
8101655	KOGER CITRATE MEDIUM	810174	EMCOH BROTH
810168	LISTERIA PALCAM AGAR	810175	MANNITOL SALT BROTH
810169	L.U.T.M. MEDIUM		

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS
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810073	Yeast Extract Broth/Lactose medium	811701	PEPTONE BACTERIOLOGICAL
810074	Trypsine Phenylalanine Broth	8117015	PEPTONE BACTERIOLOGICAL
810075	Trypsine Phenylalanine Broth	811801	SU2000
810076	Coffin's Meat Medium	8118015	SU2000
810077	POLYPEPTONE	811901	BLE SALT N.3
810078	BRAIN HEART INFUSION	8119015	BLE SALT N.3
810079	BRAIN HEART INFUSION	812001	LIVER EXTRACT
810080	ACID HYDROLYSATE OF CASEIN	8120015	LIVER EXTRACT
810081	BEEF EXTRACT	812101	LYSINE EXTRACT
810082	BEEF EXTRACT	8121015	PEPTONE MYCOLOGICAL
810083	LACTOSE	812201	PROTEOSE PEPTONE
810084	LACTOSE	8122015	PROTEOSE PEPTONE
810085	CYSTRINE HEART AGAR	812202	3-INDOLYLACETYL SELECTIVE AGAR
810086	CHROMATIC** SALMONELLA	812203	3-INDOLYLACETYL SELECTIVE AGAR
810087	CHROMATIC** DETECTION	812301	ROY PEPTONE
810088	CHROMATIC** CANDIDA	8123015	ROY PEPTONE
810089	Chromatic** E.coli O157	812401	BLE ASCULIN AZIDE AGAR
810090	CHROMATIC** MMSA	812402	DEXTROSE AGAR
810091	CHROMATIC** STAPH AUREUS	812405	BLOOD AGAR BASE
810092	CHROMATIC** STREP B	812406	BORDET GENGOU AGAR BASE
810093	SABOURAUD CAF (ISO 6788) AGAR	812407	BRAIN HEART INFUSION AGAR
810094	MULLER HINTON F AGAR	812408	BRAIN HEART INFUSION BROTH
810095	CHROMATIC** SPS	812409	BRIGHT GREEN AGAR
810096	SODIUM CHLORIDE	812413	COLUMBIA AGAR BASE
810097	AGAR	810014	DESOXYCHOLATE AGAR
810098	AGAR	810015	DESOXYCHOLATE CITRATE AGAR
810099	GELATIN BACTERIOLOGICAL	810016	PRIGL SKY LACTOSE AGAR
810100	GELATIN BACTERIOLOGICAL	810019	E.M.B. LEVINE AGAR
810101	SODIUM SELENITE	810021	HEKTOX ENTERIC AGAR
810102	TRYPTONE	810022	S.G. MEDIUM
810103	TRYPTONE	810023	JAeger IRON AGAR
810104	TRYPTONE	810024	M.M.S. AGAR (ISO 6785 15214)
810105	YEAST EXTRACT	810025	M.H.S. BROTH (ISO 6785 15214)
810106	YEAST EXTRACT	810026	LOWENSTEIN JENSEN MEDIUM
810107	MALT EXTRACT	810027	LYSINE IRON AGAR
810108	MALT EXTRACT	810028	MAC CONKEY AGAR
810109	CAMPYLOBACTER AGAR BASE	810029	MANNITOL SALT AGAR
810110	TRYPTONE	810032	M.R. BROTH (ISO 6785)
810111	GLUCOSE	810033	MULLER HINTON AGAR
810112	T.C.B.S. AGAR	810034	MULLER HINTON BROTH
810113	SERRA LIPOLYTIC AGAR	810035	MULLER KAUFFMANN BROTH
810114	YEAST EXTRACT AGAR (ISO 6788)	810036	NUTRIENT BROTH
810115	HEART INFUSION BROTH	810038	PEPTONE WATER
810116	HEART INFUSION BROTH	810039	PHENYLALANINE AGAR
810117	MIDDLEBROOK 7H9 AGAR BASE	810041	PSEUDOMONAS CETIMIDE AGAR (ISO 8380-1)
810118	SABOURAUD CAF (ISO 6788) AGAR	810042	SS AGAR (MODIFIED)
810119	WURTZ LACTOSE AGAR	810043	SCHMELZER AGAR BASE
810120	BORDETTEST AGAR	810044	PURPLE LACTOSE AGAR
810121	STAPHYLOCOCCUS 110 AGAR	810047	MONSIEUR AGAR
810122	BLE BACTERIOLOGICAL	810048	AEROMONAS AGAR BASE
810123	IRON SULPHITE AGAR	810049	LEONNELLA BOYE AGAR BASE (ISO 11731)
810124	CARY BLAIR TRANSPORT MEDIUM	810050	Fluid Thioglycollate Medium
810125	CASERIN PEPTONE	810051	TOOD HEWITT BROTH
810126	GLUCOSE	8100515	TOOD HEWITT BROTH
810127	GLUCOSE	810052	TRYPTIC SOY AGAR
810128	CHROMATIC** M1	8100525	TRYPTIC SOY BROTH
810129	CHROMATIC** CRE AGAR BASE	810053	TRYPTIC SOY BROTH

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820007	MAC CONKEY AGAR No.2	820070	MAC CONKEY MMS AGAR
820010	X.L.D. AGAR (ISO 6570)	820072	MALONATE BROTH
820011	TRYPTONE	820074	PHENOL RED BROTH BASE
820012	TRICHOMONAS BROTH	820075	RAPPAPORT VASSILIADIS BROTH
820013	OSR AGAR BASE (ISLAM)	820076	ROGOSA AGAR
820014	YEAST GLUCOSE CHLORAMPHENICOL AGAR	820077	ROGOSA BROTH
820015	PSEUDOMONAS AGAR BASE	820078	SABOURAUD CAF AGAR + ACTINOMY
820016	CZAPEK DOX AGAR	820079	SABOURAUD CAF AGAR + ACTINOMY
820017	TRYPTON SULFITE NEOMYCIN AGAR	820080	S.F. BROTH
820018	PHENYLALANINE MALONATE BROTH	820081	S.I.M. MEDIUM
820019	BRUCELLA AGAR BASE	820082	STUART TRANSPORT MEDIUM
820020	AL KALINE PEPTONE WATER	820083	TETRAATHONATE BROTH BASE
820021	MALT AGAR	820084	TETRAATHONATE BROTH
820022	SABOURAUD AGAR	820085	VOGEL JOHNSON AGAR
820023	UREA AGAR BASE (ISO 6785)	820088	BLOOD AGAR BASE N. 2
820024	MAC CONKEY SORBITOL AGAR	820089	AMES TRANSPORT MEDIUM (w/ CHARCOAL)
820025	P.P.L.O. BROTH	820091	AMES TRANSPORT MEDIUM (w/ CHARCOAL)
820026	MULLER HINTON AGAR MODIFIED	820093	TRYPTONE AGAR
820027	YERSINIA SELECTIVE AGAR BASE	820095	MAC CONKEY AGAR w/ CRYSTAL VIOLET
820028	GLD ANDRAGE AGAR	820096	TRYPTIC BLE AGAR
820029	COLUMBIA CHA AGAR BASE	820097	TRYPTOPAN BROTH
820030	BACILLUS CEREUS AGAR BASE (MODEL) ISO 7202	820098	CAMPYLOBACTER KURUMAI AGAR BASE
820031	CLOSTRIDIUM DIFFICILE AGAR BASE	820100	DINAKA TEST AGAR
820032	TRYPTONE YEAST AGAR	820101	TRYPTONE WATER (ISO 3111)
820033	ANDRAGE LACTOSE PEPTONE WATER	820102	GLOSTRIDIUM PERFRIGENS AGAR BASE
820034	MIDDLEBROOK 7H9 AGAR BASE	820103	BLE ASCULIN AGAR
820035	ODON HEAL AGAR	820107	MULLER IRON AGAR MOD.
820036	LEIODINELLA CYE AGAR BASE	820114	MIDDLEBROOK 7H9 BROTH BASE
820037	MAC CONKEY AGAR w/ BLE SALT	820117	NUTRIENT BROTH N.2
820038	CAMPYLOBACTER BLOOD FREE MEDIUM BASE	820118	Muller Hinton Broth
820039	CAMPYLOBACTER ENRICHMENT BROTH BASE	820121	ANTIBIOTIC TEST MEDIUM
820040	MOTILITY TEST AGAR	820122	CLOSTRIDIUM BROTH w/ AGAR
820041	BLANETZ BARTLEY AGAR BASE ISO 7202-2	8201225	CLOSTRIDIUM BROTH (w/ AGAR)
820042	BIGGY (ICKERSON) AGAR	820123	PHENOL RED AGAR BASE
820043	BACILLUS CEREUS AGAR BASE (PREMIA)	820127	PHENOL RED AGAR BASE
820044	E.M.B. AGAR w/ LACTOSE + SUCROSE	820129	ANTIBIOTIC MEDIUM
820045	LIVER BROTH	820133	TRYPTONE BROTH
820046	MRS BROTH w/ GLUCOSE	820135	MANNITOL MOTILITY TEST MEDIUM
820047	SELENITE BROTH	820136	MOTILITY AND BARTLEY AGAR + TTC
820048	SABOURAUD MALT AGAR	820137	TRYPTONE SOYA YEAST EXTRACT BROTH
820049	BLANETZ AND BARTLEY AGAR + TTC	820145	LB AGAR
820050	BLANETZ AND BARTLEY AGAR + TTC	820151	BISMUTH SULPHITE AGAR
820051	BLE ASCULIN BROTH	820152	Lysine Desaminoase Broth



Hektoen Enteric Agar

Selective and differential medium for detection of pathogenic intestinal bacteria from food and clinical specimens, according to ISO 21567.

Instructions For Use

ENGLISH

DESCRIPTION

Hektoen Enteric Agar is a moderately selective medium used for the isolation and cultivation of Gram-negative enteric microorganisms, especially *Shigella* spp, from faeces, foodstuffs and other materials of sanitary importance. This medium meets the requirements of the APHA and ISO 21567 for the isolation and differentiation of *Salmonella* and *Shigella* spp.

TYPICAL FORMULA

	(g/l)
Enzymatic Digest of Meat	12.0
Yeast Extract	3.0
Lactose	12.0
Saccharose	12.0
Salicin	2.0
Bile Salts No. 3	9.0
Sodium Chloride	5.0
Sodium Thiosulfate	5.0
Ammonium Ferric Citrate	1.5
Acid Fuchsin	0.1
Bromothymol Blue	0.065
Agar	15.0
Final pH 7.5 ± 0.2 at 25°C	

METHOD PRINCIPLE

Enzymatic digest of meat provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Lactose, saccharose and salicin are fermentable carbohydrates. Bile salts and acid fuchsin inhibit Gram-positive organisms. Sodium chloride maintains the osmotic balance of the medium. Ammonium ferric citrate and sodium thiosulfate enable the detection of hydrogen sulfide production. Bromothymol blue together with acid fuchsin act as the pH indicator system. Agar is the solidifying agent.

PREPARATION

Dehydrated medium: Suspend 76 g of the powder, in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. DO NOT AUTOCLAVE.

Medium in bottles: Melt the content of the bottle in a water bath at 100°C (loosening the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Inoculate the plates by directly streaking the specimen on the agar surface or spread the sample from an enrichment culture. Incubate aerobically at 35 ± 2°C for 18-24 h.

INTERPRETING RESULTS

Shigella and *Providencia* spp, form green, moist colonies.

Salmonella and *Proteus* spp, grow as blue-green colonies, with or without black center due to H₂S production.

Coliforms, which are mostly rapid lactose-saccharose-salicin fermenters, develop red-salmon colonies surrounded by a zone of bile precipitate.

Enterococci, Staphylococci and other Gram-positive bacteria are partially or completely inhibited.

Notice that further testing should be conducted to confirm the presumptive identification of organisms isolated on this medium.

APPEARANCE OF THE MEDIUM

Dehydrated medium: free-flowing, homogeneous, light beige.

Prepared medium: slightly opalescent, green.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles: 2 years.
Ready-to-use plates: 6 months.

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table. Incubation for productivity: 50-100 CFU. Incubation for selectivity: 10⁴-10⁶ CFU. Incubation conditions: aerobically at 35 ± 2°C for 18-24 hours.

QC Table.

Microorganism	ATCC®	Result	Specification
<i>Salmonella Typhimurium</i>	ATCC® 14028	Good	Blue-green colonies with black centre
<i>Shigella flexneri</i>	ATCC® 12022	Good	Green colonies
<i>Proteus mirabilis</i>	ATCC® 12453	Good	Blue-green colonies with black centre
<i>Klebsiella pneumoniae</i>	ATCC® 13883	Good	Red-salmon colonies with zone of bile precipitate
<i>Escherichia coli</i>	ATCC® 8739	Partially to completely inhibited	Red-salmon colonies with or without zone of bile precipitate
<i>Enterococcus faecalis</i>	ATCC® 29212	Inhibited	---

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for *in vitro* diagnostic use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

- ISO 21567:2004. Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Shigella* spp.
- Perez JM, P. Cavalli, C. Roure, R. Renic, Y. Collie, and A. M. Freydisse (2003) Comparison of Four Chromogenic Media and Hektoen Agar for Detection and Presumptive Identification of *Salmonella* Strains in Human Stools. J Clin Microbiol; 41(3):1130-1134.
- American Public Health Association (1992) Compendium of Methods for the Microbiological Examination of Foods 3rd Edition. APHA Inc. Washington DC.
- Biscicelli N.B. Jr. and Schade J.(1974) Evaluation of Hektoen Enteric Agar for the detection of *Salmonella* in foods and feeds. - Journ of AOAC; 57: 992-996.

PRESENTATION

	Contents	Ref.
Hektoen Enteric Agar	90 mm ready-to-use plates	10043
Hektoen Enteric Agar	90 mm ready-to-use plates	10043*
Hektoen Enteric Agar	Bottles	402230
Hektoen Enteric Agar	Bottles	412220
Hektoen Enteric Agar	Dehydrated medium	500 g of powder
Hektoen Enteric Agar	Dehydrated medium	100 g of powder
Hektoen Enteric Agar	Dehydrated medium	5 kg of powder
Hektoen Enteric Agar	Dehydrated medium	620021
Hektoen Enteric Agar	Dehydrated medium	610021
Hektoen Enteric Agar	Dehydrated medium	610021.5

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Medical Diagnostic Device	Manufacturer	Contains sufficient for	Use by	Caution, consult instruction for Use	Fragile, handle with care	Do not reuse
REF	Cartidge number								

LIOFILCHEM® s.r.l.



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E.M.B. LEVINE AGAR

Terrano selettivo per l'isolamento di enterobatteri gram-negativi (ammonizzato Farmacopea SU)

FORMULA TIPICA

	(g/l)
Pepone	10,0
Lattosio	10,0
Fosfato dipotassico	2,0
Eosina Y	0,4
Blu di Metilene	0,005
Agar	15,0
pH finale 7,2 ± 0,2 a 25°C	

DESCRIZIONE

E.M.B. LEVINE AGAR è un terreno selettivo per l'isolamento di enterobatteri gram-negativi conforme con le specifiche della Farmacopea degli Stati Uniti (USP). E.M.B. LEVINE AGAR è utilizzato per l'analisi sia di campioni clinici che alimentari come i prodotti caseari principalmente per l'individuazione e la conferma dei coliformi.

PRINCIPIO

Il peptone è la fonte di azoto, il lattosio è il carboidrato fermentabile ed il fosfato dipotassico è il tampone. Eosina Y e blu di metilene sono gli indicatori. Questi coloranti permettono anche di differenziare i microorganismi che fermentano il lattosio da i non fermentanti sulla base del loro assottimento all'interno delle colonne batteriche. Il blu di metilene agisce anche come agente selettivo in grado di inibire parzialmente i batteri gram-positivi.

PREPARAZIONE

Sospendere 37,2 g di polvere in 1 litro di acqua distillata. Scaldare fino a completo scioglimento. Autoclavare a 121°C per 15 minuti. Raffreddare a 49-50°C. Mescolare accuratamente. Distribuire in pastiglie prali.

TECNICA

Utilizzare le procedure appropriate per ottenere colture isolate dai campioni in esame. Si dovrebbe seminare anche un terreno non selettivo per aumentare la probabilità di recupero quando la popolazione di batteri gram-negativi è bassa e per avere inoltre una indicazione degli altri organismi presenti nel campione. Incubare le pastiglie, al riparo dalla luce, a 35±2 per 18-24 ore. Se dopo 24 ore non si verifica nessuna crescita, rincubare per altre 24 ore.

INTERPRETAZIONE DEI RISULTATI

I microorganismi che fermentano il lattosio, come i coliformi, mostrano colonie blu-verdi, mentre le colonie dei lattosio-non fermentanti come *Stenotrophomonas* spp. e *Shigella* spp. appaiono ricche trasparenti color arancio. Alcuni batteri gram-positivi, come gli streptococchi fecali, stafilococchi e lieviti, crescono su questo terreno formando di solito colonie puniformi. Diversi batteri gram-negativi non patogeni e che non fermentano il lattosio sono in grado di crescere su questo terreno ma possono essere distinti dai ceppi patogeni tramite analisi biochimiche.

CONSERVAZIONE

Il polvere è molto igroscopica, conservare a 10-30°C in ambiente asciutto nel suo contenitore originale chiuso ermeticamente. Utilizzare prima della data di scadenza apposta sull'etichetta o finché non sono evidenti segni di deterioramento o contaminazione. Conservare le pastiglie prali a 2-8°C al riparo dalla luce.

AVVERTENZE E PRECAUZIONI

Il prodotto non contiene sostanze nocive in concentrazioni superiori ai limiti stabiliti dalla legislazione corrente e perciò non è classificato come pericoloso. Comunicare per un uso corretto del prodotto al raccomandanda di consultare la scheda di sicurezza. Il prodotto è progettato esclusivamente per uso diagnostico in vitro e deve essere utilizzato da parte di personale qualificato.

SMALTIMENTO DEI RIFIUTI

Smaltimento dei rifiuti deve essere effettuato secondo le normative nazionali e locali vigenti.

BIBLIOGRAFIA

- Holt-Harris and Tongue (1916) J. Infect. Dis. 18:596.
- Levine (1918) J. Infect. Dis. 23:43.
- Marshall ed. (1963) Standard methods for the examination of dairy products, 16th ed. American Public Health Association, Washington, D.C.
- Downes and Ho ed. (2001) Compendium of methods for the examination of dairy products, 16th ed. American Public Health Association, Washington, D.C.
- United States Pharmacopoeial Convention, Inc. (2001) The United States Pharmacopoeia 25th/The National formulary 20 - 2002. The United States Pharmacopoeial Convention, Rockville, Md.



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SPECIFICHE DI PRODOTTO

DENOMINAZIONE

E.M.B. LEVINE AGAR

PRESENTAZIONE

Terrano disidratato in polvere

CONSERVAZIONE

10-30°C

CONFEZIONAMENTO

Ref.	Contenuto	Confezionamento
610019	500 g	500 g di polvere in contenitore di plastica
620019	100 g	100 g di polvere in contenitore di plastica

pH DEL TERRENO

7,2 ± 0,2

IMPIEGO

E.M.B. LEVINE AGAR è un terreno selettivo per l'isolamento di enterobatteri gram-negativi conforme con le specifiche della Farmacopea degli Stati Uniti (USP)

TECNICA

Fer riferimento alla scheda tecnica del prodotto

ASPETTO DEL TERRENO

Terrano disidratato
Aspetto omogeneo
Colore: rosso chiaro-porpora
Temperatura: 35°C
Aspetto: opaco
Colore: rosso scuro blu-porpora

VALIDITÀ DALLA DATA DI PRODUZIONE

4 anni

CONTROLLO DI QUALITÀ

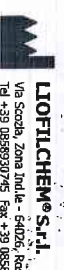
- Controllo caratteristiche generali, etichettatura e stampa
- Controllo microbiologico
Inoculo per produttività: 10-100 UFC/ml
Inoculo per selettività: 104-105 UFC/ml
Inoculo per specificità: 5104 UFC/ml
Condizioni di incubazione: 18-24 ore a 36 ± 1°C

Microorganismo

Microorganismo	ATCC	Crescita	Caratteristiche
<i>Escherichia coli</i>	25922	Buona	Colonie verdi con riflessi metallici
<i>Klebsiella pneumoniae</i>	13883	Buona	Colonie rosa
<i>Proteus mirabilis</i>	25933	Buona	Colonie incolore
<i>Pseudomonas aeruginosa</i>	27853	Buona	Colonie incolore
<i>Salmonella typhimurium</i>	14028	Buona	Colonie incolore
<i>Streptococcus faecalis</i>	19433	Inibizione	—

TABELLA DEI SIMBOLI

LOT	Per uso IVD	Per uso diagnostico in vitro	Fabbricante	Data di scadenza	Tenere lontano da fonti di calore
Numero di lotto	IVD		Fabbricante	Data di scadenza	Tenere lontano da fonti di calore
Numero di catalogo		Limiti di temperatura	Contenuto sufficiente per strip test	Attenzione, consultare le istruzioni per l'uso	



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ENDO AGAR

Medium for coliforms confirmatory test.

TYPICAL FORMULA (g/l)

Peptone	10.0
Lactose	10.0
Dipotassium Phosphate	3.5
Agar	15.0
Sodium Sulphite	2.5
Basic Fuchsin	0.5
Final pH = 7.5 ± 0.2 at 25 °C.	

DIRECTIONS

Suspend 41.5 g of powder in 1 liter of distilled or deionized water. Heat to boiling with frequent and careful overturnings until complete dissolution. Autoclave at 121 °C for 15 minutes. Evenly disperse the precipitate when dispensing. Use immediately.

DESCRIPTION

ENDO AGAR is used for confirming the presence of coliforms organisms.

TECHNIQUE

For the confirmation of presumptive tests with liquid media, subculture tubes showing gas, or acid and gas formation, onto an Endo Agar plate. Incubate at 36 ± 1 °C for 24 hours. Lactose fermenting coliforms (e.g. *E. coli*) give rise to deep red colonies which color the surrounding medium and possess a golden metallic sheen. Non-lactose fermenters form colorless translucent colonies, against the pink to colorless medium.

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: medium purple.

Prepared medium

Appearance: opalescent with precipitates.

Color: pink.

Incubation conditions: 36 ± 1 °C for 24 ± 2 hours.

Microorganism	ATCC	Growth	Characteristics
<i>Staphylococcus aureus</i>	25923	markedly to completely inhibited	red colonies w / green metallic sheen colorless to pink colonies
<i>Escherichia coli</i> □□	25922	good	
<i>Salmonella typhimurium</i>	14028	good	

PERFORMANCE AND LIMITATIONS

If the medium is to be used the same day it is rehydrated, it does not need to be autoclaved. Boil to dissolve completely before dispensing into plates.

STORAGE

The powder is very hygroscopic: store the powder at 10-30 °C, in a dry environment, in its original container tightly closed and use it before the expiry date on the label or until signs of deterioration or contamination are evident. The medium should be used the day it is prepared; if it is necessary store in the dark at 2-8 °C for no more than 3 days.

REFERENCES

- Endo, S. (1904). Uber ein Verfahren zum Nachweis der Typhusbacillen. Centr. Bakt., Abt 1, Orig. 35:109-110.
- American Public Health Association. (1975). Standard methods for the examination of water and wastewater, 14th ed.

PRESENTATION

Product	REF		
ENDO AGAR (12.0 l)	610020	500 g	
ENDO AGAR (2.4 l)	620020	100 g	

TABLE OF SYMBOLS

LOT	Batch code	Caution, consult accompanying documents	Manufacturer	Contains sufficient for <n> tests	Keep away from heat source
REF	Catalogue number	Fragile, handle with care	Use by	Temperature limitation	



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KLIGLER IRON AGAR

Differential medium for enterobacteria identification.

TYPICAL FORMULA	(g/l)
Protease Peptone	20,0
Sodium Chloride	5,0
Yeast Extract	3,0
Meat Extract	3,0
Ferrous Sulfate	0,2
Sodium Thiosulphate	0,3
Lactose	10,0
Glucose	1-0
Phenol Red	0,024
Agar	11,0

Final pH = 7.4 ± 0.2 at 25 °C.

DIRECTIONS
Suspend 53.5 g of powder in 1 liter of distilled or deionized water. Heat to boiling until completely dissolved. Dispense into final tubes. Sterilize in autoclave at 121°C for 15 minutes. Cool in a slanting position.

DESCRIPTION
KLIGLER IRON AGAR is a solid medium used to distinguish between *Enterobacteriaceae* on the basis of their ability to ferment lactose and / or glucose and to produce hydrogen sulphide.

PREPARATION
Inoculate by stabbing the butt and abundantly streaking the slope. Incubate at 36 ± 1°C for 18-24 hours and check the color of the medium both in the butt and at the slope. Also check for the presence of gas in the butt and the presence of the black precipitate (H₂S).

QUALITY CONTROL

Dehydrated medium
Appearance: free-flowing, homogeneous.
Color: pinkish beige.

Prepared medium
Appearance: slightly opalescent, slight precipitate.
Color: slightly orange-red.

Incubation conditions: 36 ± 1°C for 18-24 hours.

Microorganism	ATCC	Growth	Slant/butt	Gas	H ₂ S
<i>Citrobacter freundii</i>	8090	good	acid/acid	+	+
<i>Escherichia coli</i>	25922	good	acid/acid	+	-
<i>Proteus vulgaris</i>	6380	good	alkaline/acid	-	+

PERFORMANCE AND LIMITATIONS

A pure culture is essential when inoculating Kligler Iron Agar. If inoculated with a mixed culture, irregular observations may occur.

STORAGE

The powder is very hygroscopic: store the powder at 10-30 °C, in a dry environment, in its original container tightly closed and use it before the expiry date on the label or until signs of deterioration or contamination are evident.

Store prepared tubes at 2-8°C.

REFERENCES

1. MacFaddin, J.F. (1976). *Biochemical tests for identification of medical bacteria*.
2. Kligler, L.J. (1918). *J. Exp. Med.* 28: 319-322.



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PRESENTATION		REF	Net weight
Product	KLIGLER IRON AGAR (9.31)	610023	500 g
	KLIGLER IRON AGAR (1.81)	620023	100 g

TABLE OF SYMBOLS

LOT	Batch code	D	Caution, consult accompanying documents	M	Manufacturer	Σ	Contents sufficient for <td> tests	IVD	In Vitro Diagnostic Medical Device
REF	Catalogue number	I	Fragile, handle with care	Σ	Use by	⚠	Temperature limitation	🔥	Keep away from heat source



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S.S. AGAR (MODIFIED)

Terrano selettivo per l'isolamento di *Salmonella* spp. e *Shigella* spp.

SPECIFICHE DI PRODOTTO

FORMULA TIPICA

	(g/l)
Peptone	5,5
Estratto di Carne	5,0
Lattosio	10,0
Sodiotrosolfato	8,5
Estratto di Lievito	5,0
Sodio Citrato	1,0
Sali di Bile N.3	1,5
Ammonio Ferroso Citrato	0,33 mg
Verde Brillante	0,025
Rosso Neutro	14,0
Agar	
pH Finale	7,0 ± 0,2

DESCRIZIONE

S.S. AGAR (MODIFIED) è un terrano altamente selettivo per l'isolamento di *Salmonella* spp ed alcune specie di *Shigella* da materiale clinico, alimenti ed altri campioni.

PRINCIPIO

I microrganismi Gram-positivi ed i coliformi sono inibiti dai componenti selettivi: verde brillante, sali di bile, fosfoliato e citrato. La differenziazione dei microrganismi è ottenuta attraverso l'introduzione del lattosio nel terrano; gli organismi che fermentano il lattosio producono acidificazione, che, in presenza del rosso neutro, determina la formazione di colonie rosse. I lattosio non-fermentatori producono colonie incolori. Il fosfoliato, in combinazione con il ferro, agisce come un indicatore per la produzione di solfuro che è indicata da un annerimento del centro delle colonie.

PREPARAZIONE

Sospensione 52,0 g di polvere in 1 litro di acqua distillata o deionizzata sterile. Mescolare bene. Riscaldare agitando di frequente a bollore fino a completa dissoluzione. NON AUTOCCLAVARE. Raffreddare il terrano a 45-50°C. In condizioni di asepsi dispensare in piastre Petri e fascioli solidificare il terrano mantenendolo i copricchi parzialmente rimossi.

TECNICA

Inoculare, sterzando il campione da analizzare sulla superficie del terrano al fine di isolare colonie pure da campioni contenenti una flora mista. Incubare a 38±1°C per 18-24 ore.

INTERPRETAZIONE DEI RISULTATI

Salmonella spp ed altri microrganismi non fermentanti il lattosio possono produrre colonie orobee, tralucanti o trasparenti, con o senza differenziano per le colonie rosastre di aspetto mucide.

CONSERVAZIONE

Il prodotto può essere conservato a 10-30°C al riparo dalla luce, fino alla data di scadenza indicata in etichetta. Eliminare se vi sono segni evidenti di deterioramento o contaminazione.

AVVERTENZE E PRECAUZIONI

Il prodotto non contiene sostanze nocive in concentrazioni superiori ai limiti fissati dalla normativa vigente, perciò non è classificato come pericoloso; per il suo impiego si consiglia comunque di consultare la scheda di sicurezza. Il prodotto è destinato esclusivamente per l'uso diagnostico in vitro e deve essere utilizzato da parte di personale qualificato.

SMALTIMENTO DEI RIFIUTI

Lo smaltimento del prodotto deve essere effettuato secondo le vigenti regolamentazioni nazionali e locali.

- Geop L.D. (1985). Escherichia, Salmonella, Shigella and Yersinia, p. 450-456. In Manual of clinical microbiology, 6th ed. American Society of microbiology.
- Leifson E. (1983). J. Fainol, Bacteriol. 40: 581.
- Rose, H.H., and W.H. Kobayashi (1942). J. Lab. Clin. Med. 27: 1081-1083.

DENOMINAZIONE

S.S. AGAR (MODIFIED)

PRESENTAZIONE

Terrano deidratato

CONSERVAZIONE

10-30°C

CONFEZIONAMENTO

Ref.	Contenuto	Modalità di confezionamento
610042	500 g	500 g di polvere in fiascino in plastica
620042	100 g	100 g di polvere in fiascino in plastica
6100425	5 kg	5 kg di polvere in contenitore in plastica

pH DEL TERRANO

7,0 ± 0,2

IMPIEGO

S.S. AGAR è un terrano altamente selettivo per l'isolamento di *Salmonella* spp ed alcune specie di *Shigella* da materiale clinico, alimenti ed altri campioni.

TECNICA

Fare riferimento alla scheda tecnica del prodotto

ASPETTO DEL TERRANO

Terrano deidratato

Aspetto: omogeneo

Colore: rosa chiaro

Terrano preparato

Aspetto: opaco

Colore: viola

VALIDITÀ DALLA DATA DI PRODUZIONE

4 anni

CONTROLLO DI QUALITÀ

1. Controllo caratteristiche generali, etichettatura e stampa

2. Controllo microbiologico

Dimensione dell'inoculo per produttività: 10⁷-10⁸ UFC/ml

Dimensione dell'inoculo per sensibilità: 10⁵-10⁶ UFC/ml

Dimensione dell'inoculo per specificità: 5*10⁶ UFC/ml

Condizioni di incubazione: 18-24 h a 35 ± 2°C in aerobiosi

Microrganismo	ATCC®	Crescita	Caratteristiche
<i>Shigella flexneri</i>	ATCC® 12022	Buona	Colonie incolori
<i>Salmonella typhimurium</i>	ATCC® 14028	Buona	Colonie incolori con o senza centro nero
<i>Enterococcus faecalis</i>	ATCC® 29212	Inibita	—
<i>Staphylococcus aureus</i>	ATCC® 25923	Inibita	—
<i>Escherichia coli</i>	ATCC® 25922	Parzialmente inibita	Colonie rosa o rosse

TABELLA DEI SIMBOLI

LOT	Numero di lotto	IVD	Per uso diagnostico in vitro	Fabbricante	Data di scadenza
REF	Numero di catalogo		Limiti di temperatura		Contenuto sufficiente per ≤ 10 test
			Attenzione, consultare le istruzioni per l'uso		

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S.S. AGAR (MODIFIED)

Selective medium for the isolation of *Salmonella* spp. and *Shigella* spp.

TYPICAL FORMULA	(g/l)
Peptone	5,5
Meat Extract	5,0
Lactose	10,0
Sodium Thiosulfate	8,5
Yeast Extract	5,0
Sodium Citrate	1,0
Bile Salts N.3	1,5
Ferric Ammonium Citrate	1,5
Brightfast Green	0,33 mg
Neutral Red	0,025
Agar	14,0
Final pH 7.0 ± 0.2	

DESCRIPTION
S.S. AGAR (MODIFIED) is a highly selective medium for the isolation of *Salmonella* spp. and some species of *Shigella* from clinical specimens and food.

PRINCIPLE
Gram-positive microorganisms and coliforms are inhibited by selective components: brilliant green, bile salts n.3, sodium thiosulfate and citrate. The differentiations of microorganisms is obtained through the introduction of lactose in the medium. Lactose fermented bacteria cause acidification, thus formation of red colonies for the presence of neutral red. Non-fermented microorganisms form inverted colourless colonies. Sodium thiosulfate in combination with iron acts as indicator for sulphur production causing the blackening of the colony center.

PREPARATION
Suspend 52.0 g of the powder in 1 litre of distilled or deionized water. Mix well. Heat to boil shaking frequently until dissolved completely. **DO NOT AUTOCLAVE.** Cool to 45-50°C. In aseptic conditions dispense in Petri dishes and let solidify the medium with the lids of the plates partially removed.

TECHNIQUE
Inoculate the plate streaking the sample onto the agar surface to isolate pure colonies from samples containing a mixed flora. Incubate at 36±1°C for 18-24 hours.

INTERPRETATION OF RESULTS
Salmonella spp. and other lactose non-fermented microorganisms can produce opaque, translucent or transparent colonies, with or without black center. *Shigella* colonies are colourless. The few lactose fermented microorganisms, that are able to grow on the medium, show reddish mucoid colonies.

STORAGE
10-30°C away from light, until the expiry date on the label. Eliminate if signs of deterioration or contamination are evident.

WARNING AND PRECAUTIONS
The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is designed for *in vitro* diagnostic use only and must be used by properly trained operators.

DISPOSAL OF WASTE
Disposal of waste must be carried out according to the national and local regulations in force.

- REFERENCES**
- Gray L.D. (1995). Escherichia, Salmonella, Shigella and Yersinia, p. 450-456. In Manual of clinical microbiology, 8th ed. American Society of Microbiology.
 - Lefson E. (1995). J. Pathol. Bacteriol. 40: 581.
 - Rose, H.M., and M.H. Kitchin (1942). J. Lab. Clin. Med. 27: 1081-1083.



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PRODUCT SPECIFICATIONS

NAME	S.S. AGAR (MODIFIED)		
PRESENTATION	Dehydrated medium		
STORAGE	10-30°C		
PACKAGING	Content	Packaging	
	610042	500 g	500 g of powder in plastic bottle
	620042	100 g	100 g of powder in plastic bottle
610042S	5 kg	5 kg of powder in plastic container	

pH OF THE MEDIUM
7.0 ± 0.2

USE
S.S. AGAR (MODIFIED) is a highly selective medium for the isolation of *Salmonella* spp. and some species of *Shigella* from clinical specimens and foods

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Dehydrated medium
Appearance: free-flowing, homogeneous
Colour: light-pink
Reconstituted medium
Appearance: opalescent
Colour: purple

SHELF LIFE
4 years

- QUALITY CONTROL**
- Control of general characteristics, label and print
 - Microbiological control
Inoculum for productivity: 10⁷-10⁸ UFC/ml
Inoculum for selectivity: 10⁷-10⁸ UFC/ml
Inoculum for specificity: ≤10⁴ UFC/ml
Incubation Conditions: 18-24 h at 35 ± 2°C. In aerobiosis

Microorganism	ATCC®	ATCC®	Growth	Features
<i>Shigella flexneri</i>	ATCC® 12022	ATCC® 14028	Good	Colourless colonies
<i>Salmonella typhimurium</i>	ATCC® 14028	ATCC® 29212	Good	Colourless colonies with or without black center
<i>Enterococcus faecalis</i>	ATCC® 29212	ATCC® 25923	Inhibited	—
<i>Staphylococcus aureus</i>	ATCC® 25923	ATCC® 25922	Partially inhibited	Pink or red colonies
<i>Escherichia coli</i>	ATCC® 25922			

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Diagnostic Medical Device	Manufacturer	Contains sufficient for 4x4 tests	Use by
REF	Catalogue number	TEMP	Temperature limitation	MANU	CAUTION	Caution, consult instructions for use



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RAPPAPORT VASSILIADIS SOY (RSV) BROTH

Enrichment medium for *Salmonella* spp. isolation from meat and dairy products, feces and sewage polluted water, according to ISO 6579 and ISO 6785.

TYPICAL FORMULA

	(g/l)
Soyone	4,5
Sodium Chloride	7,2
Potassium Ethyhydrogen Phosphate	1,26
Di-Potassium Hydrogen Phosphate	0,18
Magnesium Chloride Anhydrous	13,58
Malachite Green	0,036
Final pH = 5.2 ± 0.2 at 25 °C.	

DIRECTIONS

Suspend 27 g of powder in 1 liter of distilled or deionized water. Heat gently until completely dissolved. Dispense into final containers. Sterilize in autoclave at 115°C for 15 minutes.

DESCRIPTION

RAPPAPORT VASSILIADIS SOY (RSV) BROTH is used for selectively enriching *Salmonella* from meat and dairy products, feces and sewage polluted water, according to ISO 6579:2002 and ISO 6785:2001.

TECHNIQUE

The procedure recommended by ISO 6579:2002 is the following:

- Add a 25 g sample to 225 ml of Buffered Peptone Water.
- Incubate at 37 ± 0.5 °C for 16-20 hours.
- Transfer 0.1 ml of the pre enriched culture to a tube containing 10 ml of Rappaport Vassiliadis Soy (RSV) Broth and 1 ml to a flask containing 10 ml of Mueller Kauffmann Novobioch Broth (MKTB).
- Incubate the inoculated RVB Broth at 41.5 ± 0.5 °C for 24 ± 3 hours.
- Incubate the inoculated MKTB at 37 ± 1 °C for 24 ± 3 hours.
- Using a culture obtained from the RSV Broth inoculate by means of a 3 mm loop, a large size Petri dish containing X.L.D. Agar (ref. 10056), proceed in the same way from the enrichment tube by inoculating a second plating medium (e.g. Colorex *Salmonella* Agar (ref. 10514), or another suitable selective *Salmonella* Plating-out medium chosen by the laboratory).
- Using the cultures obtained in MKTB after 24 hours of incubation, repeat the procedure with the same two selective plating-out media.
- Invert the dishes and incubate at 37 ± 1 °C for 24 ± 3 hours.
- Examine for the presence of typical colonies. Any typical or suspected colony should be subjected to a biochemical and serological confirmation using a pure subculture on a Nutrient Agar plate.

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.
Color: pale green to green.

Prepared medium

Appearance: clear.
Color: blue.

Incubation conditions: 41.5 ± 0.5 °C for 16-48 hours.

Microorganism	ATCC	Growth
<i>Escherichia coli</i>	25922	markedly inhibited
<i>Klebsiella pneumoniae</i>	13883	markedly inhibited
<i>Salmonella typhimurium</i>	14028	good
<i>Salmonella enteritidis</i>	13076	good

PERFORMANCE AND LIMITATIONS

The combined inhibitory factors of this medium (i.e. magnesium chloride, low pH) may inhibit certain *Salmonella*, such as *S. typhi* and *S. choleraesuis*. Isolation techniques should include a variety of enrichment broths and isolation media.



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STORAGE
The powder is very hygroscopic: store the powder at 10-30 °C, in a dry environment, in its original container tightly closed and use it before the expiry date on the label or until signs of deterioration or contamination are evident.
Store prepared tubes at 2-8 °C.

REFERENCES

1. ISO 6785:2001, IDP 93:2001, Milk and milk products — Detection of *Salmonella* spp.
2. Vassiliadis, P. (1983), J. Appl. Bact. 54, 69.
3. Morriño, M.A., J.J. Borrego, P. Romero (1986), J. App. Bact. 61: 169-176.

PRESENTATION

Product	REF	Net weight
RAPPAPORT VASSILIADIS BROTH (18,7 l)	610175	500 g
RAPPAPORT VASSILIADIS BROTH (3,7 l)	620175	100 g

TABLE OF SYMBOLS

REF	In Vitro Diagnostic Medical Device	Temperature limitation	Manufacturer	Use by	Contains sufficient for <=> tests	LOT	Batch code
		Keep away from heat source			Caution, consult accompanying documents		



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Chromatic™ Candida

Chromogenic selective medium for the isolation and differentiation of *Candida* spp. directly from clinical and nonclinical specimens.



DESCRIPTION

Chromatic™ Candida is a chromogenic selective medium used for the isolation and differentiation of *Candida* species directly from clinical and nonclinical specimens permitting to distinguish among *C. albicans*, *C. tropicalis*, *C. krusei*, *C. dubliniensis* and *C. parapsilosis*.

Although *Candida albicans* remains the most common cause of human Candidiasis, the frequency of infection attributed to other members of the genus is also increasing. Effective treatment requires both early diagnosis and prompt initiation of therapy against fungal infection.

TYPICAL FORMULA

	(g/l)
Peptone	10.0
Chloramphenicol	0.5
Chromogenic Mix	25.2
Agar	15.0
Final pH 6.1 ± 0.2 at 25°C	

METHOD PRINCIPLE

Peptone provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Chloramphenicol is the selective agent inhibiting most of the bacteria. Chromogenic mix allows to identify the *Candida* genus on the basis of the color and morphology of the colonies. Agar is the solidifying agent.

PREPARATION

Dehydrated medium: Suspend 50.7 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. DO NOT AUTOCLAVE.

Medium in bottles: Melt the content of the bottle in a water bath at 100°C (loosening the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Ferni dishes.

TEST PROCEDURE

Inoculate the medium by direct streaking, spread plating or membrane filtration method. Incubate aerobically at 30-37°C for 24-48 hours.

INTERPRETING RESULTS

After incubation observe the color and the morphology of the colonies and interpret the results as indicated in the ID table.

ID Table:

Microorganism	Typical colony color
<i>Candida albicans</i>	Green
<i>Candida dubliniensis</i>	Yellow-green
<i>Candida glabrata</i>	Beige
<i>Candida krusei</i>	Pink, pale edges
<i>Candida parapsilosis</i>	Pale pink-white
<i>Candida tropicalis</i>	Blue

See pictures in Appendix I.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.
Prepared medium: slightly opalescent, very light beige.

ENGLISH

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles: 1 year.
Ready-to-use plates: 6 months.

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU.
Inoculum for selectivity: 10⁷-10⁸ CFU.
Incubation conditions: aerobically at 35 ± 2°C for 24-48 hours.

QC Table:

Microorganism	ATCC®	Growth	Specification
<i>Candida albicans</i>	ATCC® 10231	Good	Green colonies
<i>Candida krusei</i>	ATCC® 14243	Good	Pink colonies
<i>Candida parapsilosis</i>	ATCC® 22019	Good	Pale pink-white colonies
<i>Candida tropicalis</i>	ATCC® 750	Good	Blue colonies
<i>Escherichia coli</i>	ATCC® 25922	Inhibited	---
<i>Staphylococcus aureus</i>	ATCC® 25923	Inhibited	---

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for *in vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. Odds, F.C. And Bernaerts, 1994. CHROMagar Candida, a new differential medium for presumptive identification of clinically important *Candida* species. J. Clin. Microbiol. 32: 1923-1929.
2. Wingard, J.R. Importance of *Candida* species other than *C. albicans* as pathogens in oncology patients. Clin Infect Dis. 1995; 20: 115-25.
3. Pfaller, Huston and Coffman, 1996. J. Clin. Microbiol. 32: 1923-1929.
4. Maertens JA. History of the development of azole derivatives. J Clin Microbiol Infect. 2004; 10: 1-10.

PRESENTATION

Chromatic™ Candida	Contents	Ref.
Chromatic™ Candida	90 mm ready-to-use plates	11612
Chromatic™ Candida	60 mm ready-to-use plates	163692
Chromatic™ Candida	Bottles	481110
Chromatic™ Candida	Dehydrated medium	500 g of powder 610613
Chromatic™ Candida	Dehydrated medium	100 g of powder 620613

TABLE OF SYMBOLS

LOT	REF	IVD	Temperature Limitation	Manufacturer	Use by	Caution, consult instruction for Use	Fragile, handle with care
Batch code	Catalogue number	In vitro Diagnostic Medical Devices	Temperature Limitation	Manufacturer	Use by	Caution, consult instruction for Use	Fragile, handle with care
							Do not reuse

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Terreno cromogenico selettivo per l'isolamento e la differenziazione di *Candida* spp. direttamente da campioni clinici e non clinici.

Chromatic™ Candida

DESCRIZIONE

Chromatic™ Candida è un terreno cromogenico selettivo utilizzato per l'isolamento e la differenziazione di *Candida* specie direttamente da campioni clinici a non clinici, permettendo di distinguere tra *C. albicans*, *C. tropicalis*, *C. krusei*, *C. glabrata*, *C. dubliniensis* and *C. parapsilosis*.

Sebbene *Candida albicans* sia ancora la causa più comune di Candidosi negli umani, la frequenza di infezioni attribuite ad altri membri del genere sta aumentando. Un trattamento efficace necessita sia di una diagnosi precoce che di un inizio tempestivo della terapia contro l'infezione funginea.

FORMULA TIPICA

	(g/l)
Peptone	10,0
Cloranticolesolo	0,5
Miscela Cromogenica	25,2
Agar	15,0
pH Finale	6,1 ± 0,2 a 25°C

PRINCIPIO DEL METODO

Il peptone fornisce aminoacidi, azoto, carbonio, vitamine e minerali per la crescita degli organismi. Il cloranticolesolo è l'agente selettivo inibendo la maggior parte dei batteri. La miscela cromogenica permette di identificare il genere di *Candida* sulla base del colore e della morfologia delle colonie. L'agar è l'agente solidificante.

PREPARAZIONE

Terreno disidratato
Sospendere 50,7 g di polvere in 1 litro di acqua distillata o deionizzata sterile. Mescolare bene. Riscaldare agitando di frequente e bollire fino a completa dissoluzione.
NON AUTOCCLAVARE.

Terreno in fiasconi
Scegliere il contenitore di una fiascone in bagno maria a 100°C (con i tappi leggermente svitati) fino a completa dissoluzione del terreno. Verificare, una volta fatto, la buona omogeneità del terreno capovolgendo la fiascone dopo averne avvitato il tappo. Raffreddare a 45-50°C, mescolare bene senza formazione di bolle. Versare in piastre Petri in condizioni di asepsi.

PROCEDURA DEI TESTI

Inoculare il terreno per striscio, spalmamento o con il metodo delle membrane filtranti. Incubare a 30-37°C per 24-48 ore in atmosfera aerobica.

INTERPRETAZIONE DEI RISULTATI

Dopo l'incubazione osservare il colore delle colonie ed interpretare i risultati come indicato nella tabella ID.

Tabella ID.

Microorganismo	Colore delle colonie tipiche
<i>Candida albicans</i>	Verde
<i>Candida dubliniensis</i>	Giallo-verde
<i>Candida glabrata</i>	Beige
<i>Candida krusei</i>	Rosa, bordi chiari
<i>Candida parapsilosis</i>	Rosa chiaro-bianco
<i>Candida tropicalis</i>	Blu

Consultare le figure nell'Appendice I.

ASPETTO

Terreno disidratato: omogeneo, fine granulometria; beige chiaro
Terreno preparato: beige molto chiaro, leggermente opalescente.

CONSERVAZIONE

La polvere è fortemente igroscopica, conservare a 10-30°C in ambiente asciutto, nel suo contenitore originale chiuso ermeticamente. Conservare i fiasconi e le piastre pronte a 2-8°C al riparo dalla luce. Non usare il prodotto dopo la sua data di scadenza indicata sull'etichetta o se il prodotto mostra segni di contaminazione o deterioramento.

DURATA

Terreno disidratato: 4 anni.
Terreno in fiasconi: 1 anno.
Piastre pronte all'uso: 6 mesi.

CONTROLLO DI QUALITÀ

Le piastre vengono inoculate con i ceppi microbici indicati nella tabella CQ.
Inoculo per produttività: 50-100 UFC.
Inoculo per selettività: 10⁴-10⁶ CFU.
Condizioni di incubazione: ambiente aerobico a 35 ± 2°C per 18-24 ore.

Tabella CQ.

Microorganismo	Crescita	Specificità
<i>Candida albicans</i>	ATCC® 10231 Buona	Colonie verdi
<i>Candida krusei</i>	ATCC® 14243 Buona	Colonie rosa
<i>Candida parapsilosis</i>	ATCC® 22019 Buona	Colonie rosa chiaro-bianche
<i>Candida tropicalis</i>	ATCC® 750 Buona	Colonie blu
<i>Escherichia coli</i>	ATCC® 25922 Inibita	---
<i>Staphylococcus aureus</i>	ATCC® 25923 Inibita	---

AVVERTENZE E PRECAUZIONI
Il prodotto non contiene sostanze nocive in concentrazioni superiori ai limiti fissati dall'attuale legislazione e perciò non è classificato come pericoloso. Conoscitore si raccomanda di consultare la scheda di sicurezza per il suo corretto uso. Il prodotto è da intendersi per uso diagnostico in vitro e deve essere utilizzato esclusivamente da operatori adeguatamente addestrati.

SMALTIMENTO DEI RIFIUTI

Lo smaltimento dei rifiuti deve essere effettuato in conformità alle normative nazionali e locali in vigore.

BIBLIOGRAFIA

1. Odds, F.C. and Bernaerts, 1994. CHROMagar Candida, a new differential medium for presumptive identification of clinically important *Candida* species. J. Clin. Microbiol. 32: 1923-1929.
2. Wingard, JR. Importance of *Candida* species other than *C. albicans* as pathogens in oncology patients. Clin Infect Dis. 1995; 20: 115-25.
3. Pfaller, Huson and Coffman. 1996. J. Clin. Microbiol. 32: 1923-1929.
4. Maertens JA. History of the development of azole derivatives. J Clin Microbiol Infect. 2004; 10: 1-10.

PRESENTAZIONE

	Contenuto	Ref.
Chromatic™ Candida	Piastre da 90 mm pronte all'uso	11612
Chromatic™ Candida	Piastre da 60 mm pronte all'uso	163692
Chromatic™ Candida	Fiasconi	481110
Chromatic™ Candida	Terreno disidratato	500 g di polvere
Chromatic™ Candida	Terreno disidratato	100 g di polvere
Chromatic™ Candida	Terreno disidratato	620613

TABELLA DEI SIMBOLI

LOT	IVD	Fabbricatore	Utilizzare entro	Attenzione: Consultare le istruzioni per l'uso	Fragile, maneggiare con cura
Code del lotto	Diagnostico in vitro				
Numero di catalogo	Limiti di temperatura				
REF	Contenuto sufficiente per saggi				

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Chromatic™ Candida

Medio de cultivo cromogénico selectivo para el aislamiento y diferenciación de *Candida* spp. directamente desde muestras clínicas y no clínicas.

Instrucciones de Uso

ESPAÑOL

DESCRIPCIÓN

Chromatic™ Candida es un medio de cultivo cromogénico selectivo para el aislamiento y diferenciación de *Candida* spp. directamente desde muestras clínicas y no clínicas permitiendo diferenciar entre *C. albicans*, *C. tropicalis*, *C. krusei*, *C. glabrata*, *C. dubliniensis* y *C. parapsilosis*.

Aunque la *Candida albicans* es la causa más frecuente de Candidiasis en humanos, la incidencia atribuida a otros tipos dentro de este género está aumentando. Un tratamiento eficaz requiere un diagnóstico precoz y un rápido inicio de la terapia antifúngica.

FÓRMULA

Peptona	10.0	(g/l)
Cloranfénicol	0.5	
Mezcla Cromogénica	25.2	
Agar	15.0	
pH Final	6,1 ± 0,2	at 25°C

PRINCIPIO DEL MÉTODO

La Peptona proporciona aminoácidos, nitrógeno, carbono, vitaminas y minerales necesarios para el crecimiento de los hongos. El Cloranfenicol es un inhibidor de antibióticos de amplio espectro para un gran número de bacterias Gram-negativas y Gram-positivas. La Mezcla Cromogénica permite la identificación de los diferentes tipos de *Candida* según el color y la morfología de las colonias. El Agar es el agente solidificante.

PREPARACIÓN

Medio deshidratado Suspender 50.7 g del polvo deshidratado en 1 litro de agua destilada o desionizada. Mezclar bien. Calentar hasta la ebullición removiendo frecuentemente hasta la completa disolución. **NO AUTOCLAVAR.**

Medio en botellas Disolver el contenido de la botella en un baño con agua a 100°C (con el tapón ligeramente desmontado) hasta su completa disolución. Comprobar la homogeneidad del medio disuelto, girar la botella si es necesario para ayudar a la homogeneización. Enfriar a 45-50°C, mezclar bien evitando la formación de burbujas y distribuir en placas Petri de forma aseptica.

PROCEDIMIENTO DEL TEST

Inocular el medio en profundidad, por estración o con el método de filtración de membrana. Incubar en condiciones aeróbicas a 30-37°C durante 24-48 horas.

INTERPRETACIÓN DE LOS RESULTADOS

Después de incubar, observar el color y la morfología de las colonias e interpretar los resultados siguiendo la tabla de identificación.

Tabla de Identificación.

Microrganismo	Aspecto de las colonias
<i>Candida albicans</i>	Verde
<i>Candida dubliniensis</i>	Amarillo - verde
<i>Candida glabrata</i>	Beige
<i>Candida krusei</i>	Rosa, bordes claros
<i>Candida parapsilosis</i>	Bianco - rosa claro
<i>Candida tropicalis</i>	Azul

Ver fotos en el Apéndice 1.

ASPECTO

Medio deshidratado: suelto, homogéneo, beige claro.
Medio preparado: ligeramente opalescente, beige muy claro.

ALMACENAMIENTO
El polvo deshidratado es muy higroscópico, almacenar a 10-30°C, en un entorno seco, en su frasco original correctamente cerrado. Almacenar las botellas y las placas preparadas a 10-25°C fuera del contacto de la luz. No utilizar el producto fuera de la fecha de caducidad descrita en la etiqueta o si el producto presenta alguna muestra de deterioro o contaminación.

SHELF LIFE

Medio deshidratado: 4 años.
Medio en botellas: 1 año.
Placas preparadas: 6 meses.

CONTROL DE CALIDAD

Las placas se inoculan con las cepas indicadas en la siguiente tabla.
Inóculo para productividad: 50-100 CFU.
Inóculo para selectividad: 10⁴-10⁶ CFU.
Condiciones de incubación: aeróbicas a 35 ± 2°C durante 24-48 horas.

Tabla CC	Microrganismo	Crecimiento	Aspecto
	<i>Candida albicans</i>	ATCC® 10231	Bueno Colonias verdes
	<i>Candida krusei</i>	ATCC® 14243	Bueno Colonias rosas
	<i>Candida parapsilosis</i>	ATCC® 22019	Bueno Colonias blancas - rosa claro
	<i>Candida tropicalis</i>	ATCC® 750	Bueno Colonias azules
	<i>Escherichia coli</i>	ATCC® 25922	Inhibición
	<i>Staphylococcus aureus</i>	ATCC® 25923	Inhibición

ADVERTENCIAS Y PRECAUCIONES

Este producto no contiene sustancias peligrosas en concentraciones que excedan los límites fijados por la legislación actual y no está clasificado como peligroso. Se recomienda de todas formas la lectura de la hoja de seguridad para el uso apropiado. El producto está pensado para un uso exclusivo de diagnóstico *in vitro* y debe ser utilizado solo por operadores debidamente adiestrados.

DESECHO DE RESIDUOS

El desecho de los residuos debe realizarse según la regulación nacional y local vigente.

BIBLIOGRAFÍA

1. Odds, F.C. And Benaerts, 1994. CHROMagar Candida, a new differential medium for presumptive identification of clinically important *Candida* species. J. Clin. Microbiol. 32: 1923-1929.
2. Wingard, J.R. Importance of *Candida* species other than *C. albicans* as pathogens in oncology patients. Clin Infect Dis. 1995; 20: 115-25.
3. Pfaller, Huston and Coffman. 1996. J. Clin. Microbiol. 32: 1923-1929.
4. Maertens JA. History of the development of azole derivatives. J Clin Microbiol Infect. 2004; 10: 1-10.

PRESENTACIÓN

	Contenido	Ref.
Chromatic™ Candida	Placas lisas para uso de 90 mm	20 placas 11612
Chromatic™ Candida	Placas lisas para uso de 60 mm	20 placas 163692
Chromatic™ Candida	Botellas	6 x 100 ml botellas 4811110
Chromatic™ Candida	Medio deshidratado	500 g de polvo deshidratado 610613
Chromatic™ Candida	Medio deshidratado	100 g de polvo deshidratado 620613

TABLA DE SÍMBOLOS

LOT	Código de lote	✓	Sistema medio para el diagnóstico <i>in vitro</i>	✓	Estéril	✓	Utilizar antes de	✓	Fragil, manipular con cuidado
REF	Número de catálogo	✓	Límite de temperatura	✓	Contenido suficiente para el análisis	✓	Atención, consultar el documento adjunto	✓	No reutilizar

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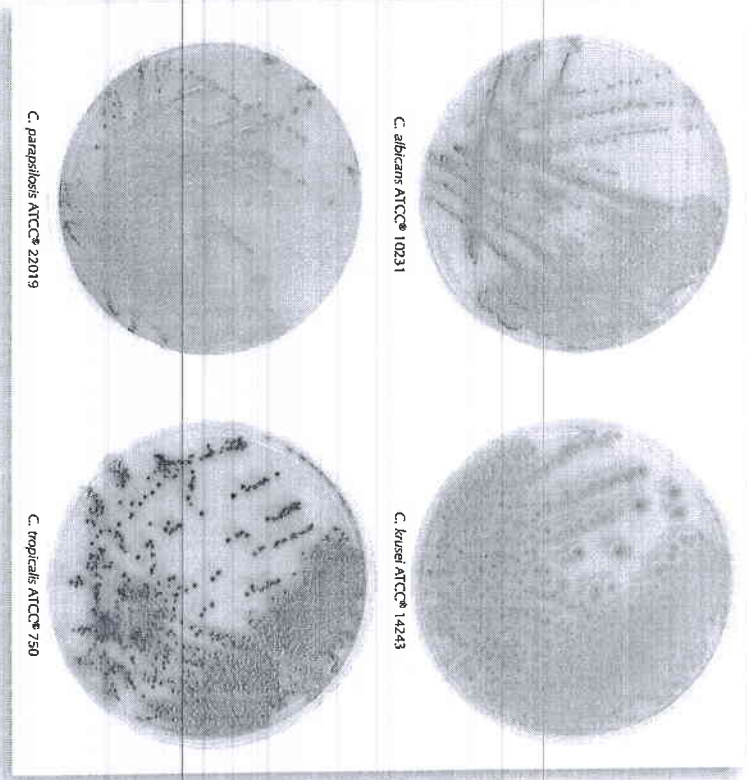


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Chromatic™ Candida

Chromogenic selective medium for the isolation and differentiation of *Candida* spp directly from clinical and nonclinical specimens.

Instructions For Use
Appendix 1



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Fluid Thioglycollate Medium

Liquid medium for sterility test and cultivation of fastidious anaerobic and aerobic microorganisms, according to Harmonized USP/EP/J and ISO 7937.

Instructions For Use
ENGLISH

DESCRIPTION

Fluid Thioglycollate Medium is a general purpose liquid enrichment medium used for sterility control of pharmaceutical products and for cultivation and isolation of fastidious anaerobic and aerobic microorganisms. The composition is in accordance with the requirements of the Harmonized US, European and Japanese Pharmacopoeia as well as with ISO 7937 for isolation of *Clostridium perfringens*.

TYPICAL FORMULA

	(g/0)
Enzymatic Digest of Casein	15,0
Yeast Extract	5,0
Glucose	5,5
Sodium Chloride	2,5
Sodium Thioglycollate	0,5
L-Cysteine	0,5
Resazurin	0,001
Agar	0,75
Final pH 7.1 ± 0.2 at 25°C	

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Glucose is a source of energy. Sodium chloride maintains the osmotic balance of the medium. Sodium thioglycollate and L-cysteine are included to reduce the redox potential of the medium and create an anaerobic atmosphere. These reducing agents also neutralize the bacteriostatic effects of mercury and other heavy metal compounds in the preparation to be tested for sterility. Resazurin is an oxidator-reduction indicator being pink when oxidized and colorless when reduced. The small amount of agar assists in the maintenance of a low redox potential by stabilizing the medium against convection currents, thereby maintaining anaerobiosis in the lower depths of the medium.

PREPARATION

Dehydrated medium Suspend 29,8 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into appropriate containers. Sterilize in autoclave at 121 °C for 15 minutes. **Medium in tubes/bottles** If the medium exhibits more than 20% pink color (due to oxidation), the medium may be reheated once for 5 minutes with cap slightly loosened in steam or boiling water in order to expel the oxygen.

TEST PROCEDURE

The medium can be directly inoculated with the test sample (the amount of the inoculated sample material should not be exceed 10% volume of the medium). Incubate at 30-35 °C for up to 14 days. Growth of strictly aerobic bacteria can be improved by slightly loosening the cap. According to ISO 7937 for confirmation of *Clostridium perfringens* inoculate each black colony from Sulfite Cycloserine Agar (ref. 402700) into Fluid Thioglycollate Medium. Incubate at 37 ± 1 °C for 18-24 hours. Subsequently, transfer 5 drops of the enrichment culture into Lactose Sulfite Medium (ref. 610358) and incubate at 46 ± 1 °C for 18-24 hours.

INTERPRETING RESULTS

Turbidity of the medium indicates microbial growth. Obligate anaerobic microorganisms such as *Clostridium sporogenes* are growing in the lower, yellowish part of the broth medium. The growth of facultative anaerobic microorganisms such as *Staphylococcus aureus* is distributed throughout all the medium. Aerobic microorganisms such as *Pseudomonas aeruginosa* are able to grow in the upper slightly pink layer (oxidized part) of the medium.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.
Prepared medium: slightly opalescent, light amber. (20% or less of upper layer may be pink).

STORAGE

The powder is very hygroscopic, store the powder at 10-30 °C, in a dry environment, in its original container tightly closed. Store bottles and tubes at 10-25 °C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles: 2 years.
Medium in tubes: 1 year.

QUALITY CONTROL

Fluid Thioglycollate Medium is inoculated with the microbial strains indicated in the QC table. Inoculum for productivity: ≤ 100 CFU. Incubation for productivity: 24 h at 30-35 °C for bacteria, 48 h at 20-25 °C for yeasts, 72 h at 20-25 °C for moulds. Incubation conditions: (Pharmacopoeia growth promotion); 18-24 h at 37 ± 1 °C for *Clostridium perfringens* (ISO 11133).

QC Table:

Microorganism	ATCC®	Specification
<i>Bacillus subtilis</i>	ATCC® 6633	Visible turbidity
<i>Clostridium sporogenes</i>	ATCC® 19404	Visible turbidity
<i>Escherichia coli</i>	ATCC® 8739	Visible turbidity
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Visible turbidity
<i>Staphylococcus aureus</i>	ATCC® 6538	Visible turbidity
<i>Candida albicans</i>	ATCC® 10231	Visible turbidity
<i>Aspergillus brasiliensis</i>	ATCC® 16404	Visible turbidity
<i>Clostridium perfringens</i>	WDCM 00007	Slight to good turbidity

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for *in vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

- ISO 11133:2014, Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
- ISO 7937:2004, Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of *Clostridium perfringens* – Colony count technique.
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- Bewer, H. (1940) Clear liquid medium for the aerobic "cultivation" of anaerobes. J. Am. Med. Assoc. 115:598-600.

PRESENTATION

Fluid Thioglycollate Medium	Tubes	Contents	Ref.
Fluid Thioglycollate Medium	Tubes	20 x 10 ml tubes	24124
Fluid Thioglycollate Medium	Tubes	100 x 10 ml tubes	26124
Fluid Thioglycollate Medium	Tubes	10 x 20 ml tubes	21241
Fluid Thioglycollate Medium	Tubes	20 x 20 ml tubes	24241
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (flip-off cap)	400020
Fluid Thioglycollate Medium	Bottles	6 x 300 ml bottles (flip-off cap)	400120
Fluid Thioglycollate Medium	Bottles	6 x 1000 ml bottles (flip-off cap)	400220
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (screw cap)	452060
Fluid Thioglycollate Medium	Bottles	25 x 100 ml bottles (screw cap)	453060
Fluid Thioglycollate Medium	Bottles	6 x 900 ml bottles (screw cap)	463100
Fluid Thioglycollate Medium	Bottles	6 x 1000 ml bottles (screw cap)	495020
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (perforable cap)	493000
Fluid Thioglycollate Medium	Bottles	6 x 500 ml bottles (wide neck)	470300
Fluid Thioglycollate Medium		500 g of powder	610050
Fluid Thioglycollate Medium		100 g of powder	620050
Fluid Thioglycollate Medium		5 kg of powder	6100505

TABLE OF SYMBOLS

LOT	Search code	In vitro Diagnostic Medical Device	Manufacture	Use by	Single handle with care	Keep away from sunlight
REF	Qualitative number	Temperature limitation	Contains sufficient for auto tests	Caution, consult instruction for use	Do not reuse	



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ROGOSA AGAR

Selective basal medium for lactobacilli isolation and enumeration.

TYPICAL FORMULA

	(g/l)
Tryptone	10,0
Yeast Extract	5,0
Glucose	10,0
Arabinose	5,0
Saccharose	5,0
Sodium Acetate	15,0
Ammonium Citrate	2,0
Monopotassium Phosphate	6,0
Magnesium Sulfate	0,57
Manganese Sulfate	0,12
Ferrous Sulfate	0,03
Agar	15,0
Final pH = 5,4 ± 0,2 at 25 °C.	

DIRECTIONS

Suspend 73,7 g of powder in 1 liter of distilled or deionized water, Add 1 ml of Tween 80 supplement (code 80031) and 1,32 ml of glacial acetic acid. Heat until completely dissolved. Boil for 2-3 minutes. Cool to 45-50°C. Dispense in petri dishes. Do not sterilize in autoclave and do not overheat.

DESCRIPTION

ROGOSA AGAR is a selective basal medium for isolating, cultivating and enumerating oral, vaginal, and fecal lactobacilli. The low pH and the high sodium acetate concentration effectively suppress other bacterial flora and allow the lactobacilli to flourish.

TECHNIQUE

Spread with a sterile spatulum the material to examine on the surface of the solidified medium. Inoculate at 36 ± 1 °C for 40-48 hours. It is preferable to incubate in an atmosphere containing 95% of hydrogen and 5% carbon dioxide: this prevents exaporation, provides micro-aerophilic conditions favoured by lactobacilli and carbon dioxide has a stimulating effect on their growth. If a suitable container is not available, overlay the inoculated plates with a second layer of Rogosa Agar before incubation. Thermophilic lactobacilli are to be incubated at 42 °C for 48 hours, psychrotrophic organisms are to be incubated at 30 °C for 2 days and at 22 °C for a further day. Leuconostocs from meat are incubated at 25 °C for 3 days.

QUALITY CONTROL

Dehydrated medium

Appearance: homogeneous with soft clumps.

Colour: beige.

Prepared medium

Appearance: slightly opalescent, may have slight precipitates.

Colour: light amber.

Incubation conditions: 36 ± 1 °C for 40-48 hours.

Microorganism	ATCC	Growth
<i>Lactobacillus casei</i>	9595	good
<i>Lactobacillus delbrueckii</i>	4797	good
<i>Staphylococcus aureus</i>	25923	markedly to completely inhibited

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PERFORMANCE AND LIMITATIONS

Since the nutritional requirements of organisms are different, some strains may be encountered that fail to grow or grow poorly on this medium. The medium is slightly acid and positive reactions may be slower than with phenol red carbohydrate medium. The salt in the formulation makes the media not suitable for isolation of dairy lactobacilli, e.g. *L. lactis*, *L. bulgaricus*, *L. Helveticus*.

STORAGE

The powder is very hygroscopic: store the powder at 10-30 °C, in a dry environment. In its original container tightly closed and use it before the expiry date on the label or until signs of deterioration or contamination are evident. Store prepared plates at 2-8 °C.

REFERENCES

1. Rogosa, M., J.A. Mitchell, and R.F. Wiseman, (1971) J. Bacteriol. 62:132.
2. Rogosa, M., J.A. Mitchell, and R.F. Wiseman, (1951), J. Dental Res. 30:682.
3. ISOTCS34/SC06WG15, (1984). Enumeration of Lactobacteriaceae in meat and meat products.
4. Sharpe M.E. (1960) Lab. Practice 9: 223-227.

PRESENTATION

Product	REF	Weight
ROGOSA AGAR (6.7 l)	610176	500 g
ROGOSA AGAR (1.3 l)	620176	100 g
TWEEN 80 supplement	80031	2 x 50 ml

TABLE OF SYMBOLS

LOT	Batch code	Caution: consult accompanying documents	Manufacturer	Use by	Contains sufficient for 10^{10} tests	Temperature indication	IVD	In Vitro Diagnostic Medical Devices
REF	Catalogue number	Fragile handle with care						Keep away from heat source

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Kovac's Reagent

Reagent for Indole test of Enterobacteriaceae.

ENGLISH

DESCRIPTION
Kovac's Reagent is used in determining the ability of bacteria, primarily Enterobacteriaceae, to produce indole by the deamination of tryptophan.

KIT CONTENTS

- 4 x 25 ml bottles of Kovac's Reagent.
- 1 instruction sheet.

METHOD PRINCIPLE

Indole is one of the degradation products of the bacterial metabolism of the amino acid tryptophan. The bacteria that own the enzyme tryptophanase are able to hydrolyze and deaminate the tryptophan with the production of indole, pyruvic acid and ammonia. Indole test is based on the formation of a red to purple colored complex, due to the indole reaction with aldehydic group of p-dimethylaminobenzaldehyde. The chief requirement for culturing an organism prior to performing the indole test is that the medium contains a sufficient quantity of tryptophan.

REAGENTS

5% (w/v) p-dimethylaminobenzaldehyde dissolved in a solution of 23% hydrochloric acid and 75% isobutyl alcohol.

TEST PROCEDURE

Inoculate a tube of Peptone Water (ref. 24098) with the organism to be tested and incubate at 35 ± 2°C for 24-48 hours. Add 2-3 drops of Kovac's Reagent directly to the tube.

INTERPRETATION OF RESULTS

The formation of a red to purple color ("cherry-red ring") in the reagent layer on top of the medium within 30 sec indicates a positive reaction for indole production. A negative reaction shows no color change.

QUALITY CONTROL FOR THE USER

Positive and negative controls should be run simultaneously with the organism to be tested.

Control strains

Control strains	Color	Indole test
<i>Escherichia coli</i>	ATCC® 25922	Red to purple
<i>Proteus mirabilis</i>	ATCC® 25933	No color change
		Negative

PRECAUTIONS

Kovac's Reagent is classifiable as hazardous under current legislation. It is recommended that the Safety Data Sheet be consulted on its use. The product is intended for *in vitro* diagnostic use only and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

STORAGE AND TRANSPORT CONDITIONS

2-8°C away from light, until the expiry date on the label. However, our stability studies have shown that the storage or transport at 18-25°C for 4 days, or at 35-39°C for 48 hours, do not alter in any way the performance of the product. Eliminate if signs of deterioration or contamination are evident.

ELIMINATING USED MATERIAL

After use, used Kovac's Reagent and the material that has come into contact with the sample must be decontaminated and disposed of in accordance with the laboratory procedures for the decontamination and disposal of potentially infected material.

BIBLIOGRAPHY

1. Murray, Baron, Pfaller, Tenover and Tenkum: Manual of Clinical Microbiology (1995).
2. Bailey and Scott's: Diagnostic Microbiology (1986).
3. Edwin H Lennette: Manual of Clinical Microbiology (1995).

PRESENTATION

Product	Ref.	Content
Kovac's Reagent	80271	100-200 tests

TABLE OF SYMBOLS					
LOT	Batch code	IVD	In vitro Diagnostic Medical Device		Manufacturer
REF	Catalogue number		Temperature limitation		Certificate sufficient for use
			Use by		Caution, consult accompanying documents
			Fragile, handle with care		Do not reuse



FORM5 Rev. 2 / 19.06.2014



Kovac's Reagent

Reagente per il test dell'Indolo sulle Enterobacteriaceae.

ITALIANO

DESCRIZIONE
Kovac's Reagent è utilizzato per determinare la capacità di batteri, soprattutto Enterobacteriaceae, di produrre indolo attraverso la deaminazione del triptofano.

CONTENUTO DEL KIT

- 4 flaconi da 25 ml di Kovac's Reagent.
- 1 foglio istruzioni.

PRINCIPIO DEL METODO

L'indolo è uno dei prodotti della degradazione metabolica dell'aminoacido triptofano. I batteri che possiedono l'enzima triptofanasi sono in grado di idrolizzare e deaminare il triptofano con produzione di indolo, acido piruvico e ammoniaca. Il test dell'indolo si basa sulla formazione di un complesso di colore rosso-porpora, dovuto alla reazione dell'indolo con il gruppo aldeidico della p-dimetilamminobenzaldeide. Il requisito principale per coltivare un microorganismo prima di effettuare il test dell'indolo è che il terreno contenga una quantità sufficiente di triptofano.

REAGENTI

p-Dimetilamminobenzaldeide al 5% (p/v) disciolta in una soluzione di acido cloridrico al 23% ed alcool isobutirico al 75%.

PROCEDURA DEL TEST

Inoculare una provetta di Peptone Water (ref. 24098) con il microorganismo da esaminare ed incubare a 35 ± 2°C per 24-48 ore. Depositare 2-3 gocce di Kovac's Reagent direttamente nella provetta.

INTERPRETAZIONE DEI RISULTATI

Lo sviluppo di un colore rosso-porpora ("anello rosso-ciliegia") pressoché immediato (entro 30 secondi) nello strato di reagente sopra il terreno indica una reazione positiva per la produzione di indolo. Nessun cambiamento di colore equivale ad una reazione negativa.

CONTROLLO QUALITÀ PER L'UTILIZZATORE

I controlli positivo e negativo dovrebbero essere analizzati insieme al microorganismo da esaminare.

Cepi di controllo

Cepi di controllo	Colore	Test indolo
<i>Escherichia coli</i>	ATCC® 25922	Rosso-porpora
<i>Proteus mirabilis</i>	ATCC® 25933	Nessun cambiamento di colore
		Negativo

PRECAUZIONI

Kovac's Reagent è classificato come pericoloso ai sensi della legislazione vigente per il suo impiego si consiglia di consultare la scheda di sicurezza. Il prodotto è destinato esclusivamente ad uso diagnostico *in vitro*, e deve essere utilizzato in laboratorio da operatori adeguatamente addestrati, con metodi approvati di asepsi e di sicurezza nei confronti degli agenti patogeni.

CONDIZIONI DI CONSERVAZIONE E TRASPORTO

Conservare a 2-8°C al riparo dalla luce nella sua confezione originale, fino alla data di scadenza indicata in etichetta. Tuttavia i nostri studi di stabilità hanno dimostrato che la conservazione o il trasporto a 18-25°C per 4 giorni, oppure a 35-39°C per 48 ore, non alterano in nessun modo l'efficacia del prodotto. Eliminare se vi sono segni evidenti di deterioramento o contaminazione.

ELIMINAZIONE DEL MATERIALE USATO

Dopo l'utilizzazione, Kovac's Reagent e tutto il materiale venuto a contatto con il campione in esame o con culture dello stesso, deve essere decontaminato e smaltito in accordo con le tecniche in uso in laboratorio.

BIBLIOGRAFIA

1. Murray, Baron, Pfaller, Tenover and Tenkum: Manual of Clinical Microbiology (1995).
2. Bailey and Scott's: Diagnostic Microbiology (1986).
3. Edwin H Lennette: Manual of Clinical Microbiology (1995).

PRESENTAZIONE

Prodotto	Ref.	Contenuto
Kovac's Reagent	80271	100-200 test

TABELLA DEI SIMBOLI					
LOT	Numero al lotto	IVD	Per uso diagnostico <i>In vitro</i>		Fabbricatore
REF	Numero di catalogo		Unità di temperatura		Contenuto sufficiente per
			Data di scadenza		Attenzione, consultare le istruzioni per l'uso
			Fragile, maneggiare con cura		Non riutilizzare



FORM5 Rev. 2 / 18.06.2014



Mannitol Salt Agar

Selective medium for isolation and enumeration of staphylococci from clinical samples and other materials, according to USP/EP/IP.

Instructions For Use
ENGLISH

DESCRIPTION

Mannitol Salt Agar is a selective medium used for isolating pathogenic staphylococci from clinical samples, food and other materials of sanitary importance.

This medium is prepared according to recommendations of the harmonized USP/EP/IP method for the detection of *S. aureus* in non sterile pharmaceutical products.

TYPICAL FORMULA (g/l)

Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Beef Extract	1.0
D-Mannitol	10.0
Sodium Chloride	75.0
Phenol Red	0.025
Agar	15.0
Final pH 7.4 ± 0.2 at 25°C	

METHOD PRINCIPLE

Pancreatic digest of casein, peptic digest of animal tissue and beef extract provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Mannitol is the fermentable carbohydrate. The high salt content of 7.5% inhibits most bacteria other than staphylococci. Phenol red is the pH indicator. Agar is the solidifying agent.

PREPARATION

Dehydrated medium Suspend 111 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to 121°C for 15 minutes.

Medium in bottles

Melt the content of the bottle in a water bath at 100°C (loosening the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Inoculate plates by the direct streaking of the material to be examined over the agar surface. Incubate aerobically at 35 ± 2°C for 24-48 hours.
Harmonized USP/EP/IP method for microbiological examination of non sterile products recommends to inoculate the sample in Tryptic Soy Broth (ref. 24444). Subculture on a plate of Mannitol Salt Agar and incubate at 30-35°C for 18-72 hours.

INTERPRETING RESULTS

S. aureus cultivates with yellow or white colonies surrounded by a yellow zone. Confirm by identification tests.*
Coagulase-negative Staphylococci form small colorless to red colonies with no color change to the medium
*Suspect colonies can be subcultured to a moderately selective medium such as Baird Parker RPF Agar (ref. 10521, 402210) for the determination of coagulase activity (ISO 6888-2).

APPEARANCE OF THE MEDIUM

Dehydrated medium: free-flowing, homogeneous, beige-pink.
Prepared medium: slightly opalescent, pinkish-red.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles: 2 years.
Ready-to-use plates: 6 months.

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: 10-100 CFU

Inoculum for selectivity: 10⁵-10⁶ CFU

Incubation conditions: aerobically at 35 ± 2°C for 24-48 hours.

*30-35°C for 18-72 h (USP/EP/IP Growth Promotion Testing).

QC Table.

Microorganism	Growth	Specification
<i>Staphylococcus aureus</i>	ATCC® 25923	Good
<i>Staphylococcus aureus</i> *	ATCC® 6538	Yellow colonies with yellow zone
<i>Staphylococcus epidermidis</i>	ATCC® 12228	Good
<i>Escherichia coli</i>	ATCC® 25922	Inhibited
<i>Escherichia coli</i> *	ATCC® 8739	Inhibited

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

- European Pharmacopoeia 6.3 (2009), 2.6.13 Microbiological examination of non-sterile products: Test for specified microorganisms.
- United States Pharmacopoeia 32 NF 27 (2009), <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
- Japanese Pharmacopoeia 4.05 (2008), Microbiological examination of non-sterile products: Test for specified microorganisms.
- ISO 6888-2:1999 + A1:2003, Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) – Part 2: technique using rabbit plasma fibrinogen agar medium.
- Kloos, W.E., and T.L. Bannerman (1995) Staphylococcus and Micrococci. In Manual of clinical microbiology, 6th ed.
- Chapman, G.H. (1945) The significance of sodium chloride in studies of staphylococci. J. Bacteriol. 50:201-203.

PRESENTATION

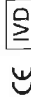
	Contents	Ref.
Mannitol Salt Agar	90 mm ready-to-use plates	10030
Mannitol Salt Agar	90 mm ready-to-use plates	10030*
Mannitol Salt Agar	Bottles	470080
Mannitol Salt Agar	Bottles	412290
Mannitol Salt Agar	Bottles	402290
Mannitol Salt Agar	Dehydrated medium	610029
Mannitol Salt Agar	Dehydrated medium	620029
Mannitol Salt Agar	Dehydrated medium	6100295

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Medical Diagnostic Device	Manufacturer	Use by	Fragile, handle with care
REF	Catalogue number	Temperature limitation	Contains sufficient for 400-200	Caution, consult instruction for Use	Do not reuse	

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Mannitol Salt Agar

Terreno selettivo per l'isolamento ed il conteggio di stafilococchi clinici, alimenti ed altri materiali di importanza sanitaria, in accordo a USP/EP/JP.

DESCRIZIONE

Mannitol Salt Agar è un terreno selettivo utilizzato per l'isolamento di stafilococchi patogeni da campioni clinici, alimenti ed altri materiali di importanza sanitaria.

Il terreno è preparato secondo il metodo armonizzato USP/EP/JP per la ricerca di *S. aureus* nei prodotti farmaceutici non sterili.

FORMULA TIPICA

	(g/l)
Digerito Pancreatico di Caseina	5.0
Digerito Peptico di Tessuto Animale	5.0
Estirato di Carne	1.0
D-Mannitolo	10.0
Sodio Cloruro	75.0
Rosso Fenolo	0.025
Agar	15.0

pH Finale 7.4 ± 0.2 a 25°C

PRINCIPIO DEL METODO

Il digerito pancreatico di caseina, il digerito peptico di tessuto animale e l'estratto di carne forniscono aminoacidi, azoto, carbonio, vitamine e minerali per la crescita dei microrganismi. Il mannitolo è il carboidrato fermentabile. La presenza di cloruro di sodio al 7.5% inibisce la maggior parte dei batteri ad eccezione degli stafilococchi. Il rosso fenolo è l'indicatore di pH. L'agar è l'agente solidificante.

PREPARAZIONE

Terreno disidratato
Sospendere 111 g di polvere in 1 litro di acqua distillata o deionizzata sterile. Mescolare bene. Riscaldare agitando di frequente e bollire per 1 minuto per ottenere la completa dissoluzione. Sterilizzare in autoclave a 121°C per 15 minuti.

Terreno in flaconi
Sciogliere il contenuto di un flacone in bagnomaria a 100°C (con il tappo leggermente svitato) fino a completa dissoluzione del terreno. Verificare, una volta fuso, la buona omogeneità del terreno capovolgendo il flacone dopo averne avvitato il tappo. Raffreddare a 45-50°C, mescolare bene senza formazione di bolle. Versare in piastre Petri in condizioni di asepsi.

PROCEDURA DEL TEST

Inoculare le piastre strisciando il campione da esaminare direttamente sulla superficie dell'agar. Incubare in atmosfera aerobica a 35 ± 2°C per 24-48 ore.
Per l'esame microbiologico dei prodotti non sterili, il metodo armonizzato USP/EP/JP raccomanda di inoculare il campione in Tryptic Soy Broth (ref. 24444). Subcoltivare su una piastra di Mannitol Salt Agar ed incubare a 30-35°C per 18-72 ore.

INTERPRETAZIONE DEI RISULTATI

S. aureus coltiva con colonie gialle o bianche circondate da un alone giallo. Confermare con test identificativi*. Gli stafilococchi coagulasi negativi formano piccole colonie da incolore a rosse con nessun cambiamento di colore del terreno.

*Le colonie sospette possono essere subcoltivate su un terreno moderatamente selettivo come Baird Parker RPF Agar (ref. 10521, 402210) per la determinazione dell'attività della coagulasi (ISO 6888-2).

ASPETTO

Terreno disidratato: omogeneo, fine granulometria, beige-rosa.
Terreno preparato: rosastro-rosso, leggermente opalescente.

CONSERVAZIONE

La polvere è fortemente igroscopica, conservare a 10-30°C, in ambiente asciutto, nel suo contenitore originale chiuso ermeticamente. Conservare i flaconi e le piastre pronte a 10-25°C al riparo dalla luce. Non usare il prodotto dopo la sua data di scadenza indicata sull'etichetta o se il prodotto mostra segni di contaminazione o deterioramento.

VALIDITÀ

Terreno disidratato: 4 anni.
Terreno in flaconi: 2 anni.
Piastre pronte all'uso: 6 mesi.

CONTROLLO DI QUALITÀ

Le piastre vengono inoculate con i ceppi microbici indicati nella tabella CQ.

Inoculo per produttività: 10-100 UFC.

Inoculo per selettività: 10⁴-10⁶ UFC.

Condizioni di incubazione: ambiente aerobico a 35 ± 2°C per 24-48 ore.

* 30-35°C per 18-72 ore (USP/EP/JP Growth Promotion Testing).

Tabella CQ

Microrganismi	Crescita	Specifiche
<i>Staphylococcus aureus</i>	ATCC® 25923	Buona
<i>Staphylococcus aureus</i> *	ATCC® 6538	Buona
<i>Staphylococcus epidermidis</i>	ATCC® 12228	Buona
<i>Escherichia coli</i>	ATCC® 25922	Inibita
<i>Escherichia coli</i> *	ATCC® 8739	Inibita

AVVERTENZE E PRECAUZIONI

Il prodotto non contiene sostanze nocive in concentrazioni superiori ai limiti fissati dall'attuale legislazione e perciò non è classificato come pericoloso. Ciononostante si raccomanda di consultare la scheda di sicurezza per il suo corretto uso. Il prodotto è da intendersi per uso diagnostico in vitro e deve essere utilizzato esclusivamente da operatori adeguatamente addestrati.

SMALTIMENTO DEI RIFIUTI

Lo smaltimento dei rifiuti deve essere effettuato in conformità alle normative nazionali e locali in vigore.

BIBLIOGRAFIA

- European Pharmacopoeia 6.5 (2009), 2.6.13 Microbiological examination of non-sterile products: Test for specified microorganisms.
- United States Pharmacopoeia 32 NF 27 (2009), <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
- Japanese Pharmacopoeia 4.05 (2008), Microbiological examination of non-sterile products: Test for specified microorganisms.
- ISO 6888-2:1999 + A1:2003, Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) – Part 2: Technique using rabbit plasma fibrinogen agar medium.
- Kloos, W.E., and T.L. Barmen (1995) Staphylococcus and Microcococcus. In Manual of clinical microbiology, 6th ed.
- Chapman, G.H. (1945) The significance of sodium chloride in studies of staphylococci. J. Bacteriol. 50:201-203.

PRESENTAZIONE

	Contenuto	Ref.
Mannitol Salt Agar	Plastre da 90 mm pronte all'uso	10030
Mannitol Salt Agar	Plastre da 90 mm pronte all'uso	10030*
Mannitol Salt Agar	Flaconi	Flaconi 6 x 500 ml 470080
Mannitol Salt Agar	Flaconi	Flaconi 6 x 200 ml 412290
Mannitol Salt Agar	Flaconi	Flaconi 6 x 100 ml 402290
Mannitol Salt Agar	Terreno disidratato	500 g di polvere 610029
Mannitol Salt Agar	Terreno disidratato	100 g di polvere 620029
Mannitol Salt Agar	Terreno disidratato	5 kg di polvere 6100295

TABELLA DEI SIMBOLI

LOT	Numero di lotto	in vitro Diagnostic Medical Device	Fabbricabile	Utilizzare entro	Fragile, maneggiare con cura
REF	Numero di catalogo	Limiti di temperatura	Contenuto sufficiente per (n° x n°)	Altezzazione. Consultare le istruzioni per l'uso	Num. registrazione

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