ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Digitally signed by Ceaicovschi Tudor
Date: 2022.03.07 09:47:41 EET
Reason: MoldSign Signature
Location: Moldova

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

РАЗРЕШЕНИЕ
на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311 **ОГРН: 1037739078970**

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключающей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: _____ (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа по сертификации: _____ (подпись) **В. И. Погодин**

Председатель экспертной комиссии: Курбатова (подпись) **Е. Д. Курбатова**

М.П.

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

ООО «МЕДЛАКОР С.-П.»
194100,г.С-Петербург, ул. А.Матросова, д.4, корп. 2, Лит.П
Тел./факс (812) 295-87-55, 646-72-23

АНАЛИТИЧЕСКИЙ ПАСПОРТ

Набор контрольных растворов белков мочи + глюкозы и pH
«БМ-контроль-ССК + глюкоза и pH с калибратором»

Код ОКП 93 9816
Регистрационное удостоверение № ФСР 2010/08997
ТУ 9398-269-52208224-2010
Кат № 04.01.05
Номер серии К 14 -21
Срок годности до: 07.12.2022 г.

НАЗНАЧЕНИЕ

Набор «БМ-контроль-ССК + глюкоза и pH с калибратором» предназначен для контроля правильности и воспроизводимости результатов определения в моче

белков - по их реакции с сульфосалициловой кислотой
- с помощью диагностических полосок

глюкозы – ферментативным методом (глюкозооксидазным)
- качественным по реакции Бенедикта
- с помощью диагностических полосок

pH - с помощью диагностических полосок

СОСТАВ НАБОРА

Набор «БМ-контроль-ССК + глюкоза и pH с калибратором» содержит 8 флаконов контрольных растворов:

- 1 флакон калибратора с концентрацией белка 0,1 г/л - 10 мл
- 1 флакон калибратора с концентрацией белка 0,2 г/л - 10 мл
- 1 флакон калибратора с концентрацией белка 0,4 г/л - 10 мл
- 1 флакон калибратора с концентрацией белка 0,8 г/л - 10 мл
- 2 флакона уровень №1 по 10 мл
- 2 флакона уровень №2 по 10 мл

В паспорте набора указывается среднее значение концентрации белка мочи и глюкозы с контрольными пределами (X±2S).

Технические характеристики набора:

- коэффициент вариации результатов измерения концентрации белков, %, не более	10	Соответствует
- коэффициент вариации результатов измерения концентрации глюкозы, %, не более	5	Соответствует
- межфлаконная вариация, %, не более	5	Соответствует
- допустимый разброс результатов определения концентрации белков в разных наборах одной серии, %, не более	10	Соответствует
глюкозы в разных наборах одной серии, %, не более	5	Соответствует
- срок хранения набора, мес	12	
- температура хранения, ^{0}C	2 - 8^{0}C	
- после вскрытия флакона раствор можно хранить, дней, не более	14	

Начальник отдела
Технического контроля — Краснопольская Е.В.

«_07 » __декабря___ 2021г

VACUTEST kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi / disposable labware***

indirizzo / *address*: ***Via dell'Industria, 12 35020 Arzergrande (PD) - Italia***

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*:

Sistema di prelievo di sangue e altri liquidi biologici mediante provette con vuoto predeterminato in plastica "VACUTEST KIMA".

"VACUTEST KIMA" vacuum blood and biological liquids collection tubes in plastic.

nome commerciale / *brand name*: **"VACUTEST KIMA"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. *"Dispositivi Medico–Diagnostici In Vitro"*.
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 01/01/2015**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com
IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n.
CERTIFICATE No.

4265/5/A

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

MEUS S.r.l.

Unità Operative / *Operative Units*
Via Leonardo Da Vinci, 24B-26-28 - Zona Industriale Tognana - 35028 Piove di Sacco (PD) - Italia
Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia.
Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.
Via dell'Industria 2-16 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi.

Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Design and production of moulds for plastic labware.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0860CM_03_IT

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com
IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n.
CERTIFICATE No.

4265/5/B

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ROLL S.r.l.

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Leonardo Da Vinci, 24A - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Injection moulding of thermoplastic materials for medical devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0860CM_03_IT

CISQ is a member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com
IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n.
CERTIFICATE No. **4265/5/D**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

VACUTEST KIMA S.r.l.

Sede / *Head office*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Uffici direzionali e amministrativi
Unità Operative / *Operative Units*
Via dell'Industria, 12 - 35020 Arzergrande (PD) – Italia
Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.
Via Leonardo Da Vinci, 22 – 35028 Piove di Sacco (PD)
Uffici commerciali e magazzino.

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
18/01/2007	18/01/2022	17/01/2025

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 004 A

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

0860CM_03_IT

Spankeren, 17 April 2013

ELITechGroup VITAL SCIENTIFIC

P.O. Box 100
6950 AC Dieren
Van Rensselaerweg 4
6956 AV Spankeren/Dieren
The Netherlands
Tel: +31 313 430500
Fax: +31 313 427807
Email: info@vital.nl
Website: www.vitalscientific.
Vat no.: NL801339650B01

CONFIRMATION LETTER

To whom it may concern,

Vital Scientific B.V., manufacturers of clinical chemistry analyzers having headquarters and factory at:

Van Rensselaerwerg 4,
6956 AV Spankeren/Dieren
The Netherlands

and being a company of ELITech Group, hereby confirms that clinical chemistry analyzer **Selectra ProM** is a closed system. We can guarantee the performance of the analyzer only when ELITech clinical chemistry reagents are used.

Vital Scientific B.V.

i/a

Vital Scientific BV
P.O. Box 100 - Van Rensselaerweg 4
6956 AV Spankeren/Dieren
The Netherlands

A. Altink
Managing Director

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:
9362-8

Initial Certification Date:
March 28, 2012

Date of Certification Decision:
March 24, 2021

Issuing Date:
March 27, 2021

Valid Until:
March 27, 2024

ISO 13485:2016 CERTIFICATION ™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN ™

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

_____

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

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Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

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Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

4426

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
Life and Health Sciences, UL LLC

Check Certificate Status: here

File Number	A12241	Cycle Start	May 23, 2020
Certificate Number	1458.200523	Effective Date	May 23, 2020
Initial Issue Date	June 26, 2018	Expiry Date	May 22, 2023

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1034230-1

Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test kits and reagents for the detection or determination of cardiac markers, tumor markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing as well as associated in vitro diagnostic devices for sampling and analysis systems for rapid tests.

Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs and lancets.

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

Report No.: 1089325-40
Effective date: 2021-12-02
Expiry date: 2024-12-01
Issue date: 2021-11-29

TÜV Rheinland LGA Products GmbH · TÜVRheinland® · Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1034230-1

Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Manufacture and distribution
/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development and distribution
/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development and manufacture
/04	c/o nal von minden GmbH Raseweg 4 37124 Rosdorf Germany	Administration and distribution

Report No.: 1089325-40
Effective date: 2021-12-02
Expiry date: 2024-12-01
Issue date: 2021-11-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

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

Registration No.: HL 60131398 0001

Report No.: 21200072 015

Manufacturer:
nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products:
- IVDs for the detection of infectious disease markers
- IVDs for the detection of the tumor marker PSA
- Urine tests for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60114562 0001

Expiry Date: 2023-11-27

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

Effective Date: 2018-11-28

Date: 2018-11-27

Notified Body

Dipl.-Ing. Sven Hoffmann

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60131398 0001
Report No.: 21200072 015

Manufacturer: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

Products included:

In vitro diagnostica for self-testing:
- HCG pregnancy tests
- LH ovulation tests
- Single- and multi-constituent test strips for urinalysis

In vitro diagnostica rapid tests:
- Chlamydia trachomatis Rapid Tests
- PSA Rapid Tests

Site included:

nal von minden GmbH
Friedenstr. 32
93053 Regensburg
Germany

Activities: Design and development

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

Date: 2018-11-27

Dipl.-Ing. Sven Hoffmann

Certificate

Standard	**ISO 9001:2015**
Certificate Registr. No.	**01 100 1810016**

Certificate Holder:

nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

including the locations according to annex

Scope:

Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.
Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

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

Validity:

The certificate is valid from 2021-09-10 until 2024-09-09.
First certification 2018

2021-09-10

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

No.	Location	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development, distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

2021-09-10

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

EC Certificate

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

Registration No.: HL 60119814 0001

Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products:
Products for self-testing

(see attachment for products and sites included)

Replaces Certificate, Registration No.: HL 60076687 0001

Expiry Date: 2022-05-28

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

Effective Date: 2017-05-29

Date: 2017-05-29

Notified Body

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60119814 0001
Report No.: 21265422 001

Manufacturer:
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Products for self-testing:
- Single and multi-parameter disposable test strips for urine analysis
- indicator test strips and papers for measurement of pH in urine

Additional site for warehousing and logistics:

Bahnstr. 120
52355 Düren, Germany

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2017-05-29

Dipl.-Ing. Sven Hoffmann

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization:
MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

Scope:
Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

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

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Germany

No.	Facility	Scope
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**
Neumann-Neander-Str. 6-8
52355 Düren
Germany

including the locations according to annex

Scope: Design and development, production and distribution of products for filtration, rapid tests, water analysis, chromatography and bioanalysis

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

Validity: The certificate is valid from 2020-05-29 until 2023-05-28.

2020-05-25

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

No.	Location	Scope
/01	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for chromatography and bioanalysis
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, water analysis. Service and administration
/03	MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2020-05-25

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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

1. 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;
2. che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. 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;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. 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

1. 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;
2. the above mentioned is not included in Annex II , List A and B of Directive 98/79/EC;
3. 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;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the device in question, was introduced into the market provided with CE mark.

Roseto, 08.01.2016

Direttore Tecnico/ Technical Director
Dott. Silvio Brocco

10002	DNA AGAR + BLU DI TOLUIDINA
10004	CLED ANDRADE AGAR
10004*	CLED ANDRADE AGAR
10005	MAC CONKEY SORBITOL AGAR
10005*	MAC CONKEY SORBITOL AGAR
10006	TRYPTIC SOY AGAR + 0,6% YEAST EXTRACT
10007	BACILLUS CEREUS AGAR (PEMBA)
10007*	BACILLUS CEREUS AGAR (PEMBA)
10011	YEAST GLUCOSE CHLORAMPHENICOL AGAR
10011*	YEAST GLUCOSE CHLORAMPHENICOL AGAR
10013	DNase TEST AGAR
10013*	DNase TEST AGAR
10014	Purple Lactose Agar
10014*	Purple Lactose Agar
10017	CZAPEK DOX AGAR
10018	DRIGALSKY LACTOSE AGAR
10021	BIGGY (NICKERSON) AGAR
10021*	BIGGY (NICKERSON) AGAR
10022	BRILLIANT GREEN AGAR
10022*	BRILLIANT GREEN AGAR
10023	Chocolate Agar
10023*	Chocolate Agar
10024	TRYPTOSE AGAR
10024*	TRYPTOSE AGAR
10025	COLUMBIA AGAR (Horse Blood 5%)
10025*	COLUMBIA AGAR (Horse Blood 5%)
10026	CLED AGAR
10026*	CLED AGAR
10027	BACILLUS CEREUS AGAR (Mossel)
10027*	BACILLUS CEREUS AGAR (Mossel)
10028	ISOSENSITEST AGAR
10028*	ISOSENSITEST AGAR
10029	MAC CONKEY AGAR
10029*	MAC CONKEY AGAR
10030	MANNITOL SALT AGAR
10030*	MANNITOL SALT AGAR
10031	MUELLER HINTON II AGAR
10031*	MUELLER HINTON II AGAR
10033	PSEUDOMONAS (CETRIMIDE) AGAR
10033*	PSEUDOMONAS (CETRIMIDE) AGAR
10035	SABOURAUD AGAR
10035*	SABOURAUD AGAR
10035S	SABOURAUD AGAR Irradiated
10036	S.S. AGAR
10036*	S.S. AGAR
10037	TRYPTIC SOY AGAR
10037*	TRYPTIC SOY AGAR
10037S	TRYPTIC SOY AGAR Irradiated
10039	ROGOSA AGAR
10039*	ROGOSA AGAR
10040	NEW YORK CITY AGAR
10040*	NEW YORK CITY AGAR
10041	LISTERIA PALCAM AGAR
10041*	LISTERIA PALCAM AGAR
10042	CRYSTAL VIOLET AGAR (Sheep Blood 5%)
10042*	CRYSTAL VIOLET AGAR (Sheed 5%)
10043	HEKTOEN ENTERIC AGAR
10043*	HEKTOEN ENTERIC AGAR
10044	NUTRIENT AGAR
10044*	NUTRIENT AGAR

10046	SERUM TELLURITE AGAR
10047	BISMUTH SULFITE AGAR
10047*	BISMUTH SULFITE AGAR
10048	E.M.B. LEVINE AGAR
10048*	E.M.B. LEVINE AGAR
10050	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10050*	CAMPYLOBACTER AGAR (Sheep Blood 5%)
10051	Legionella BCYE Agar
10051*	Legionella BCYE Agar
10052	YERSINIA SELECTIVE AGAR
10052*	YERSINIA SELECTIVE AGAR
10053	WILKINS CHALGREEN AGAR
10053*	WILKINS CHALGREEN AGAR
10054	WURTZ LACTOSE AGAR
10054*	WURTZ LACTOSE AGAR
10056	X.L.D. AGAR
10056*	X.L.D. AGAR
10057	BILE AESCULIN AGAR
10057*	BILE AESCULIN AGAR
10058S	TRYPTIC SOY AGAR Irradiated -30 mL-
10060	BRAIN HEART INFUSION AGAR
10060*	BRAIN HEART INFUSION AGAR
10064	CHRISTENSEN UREA AGAR
10065	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10065*	SCHAEDLER KKV AGAR(Sheep Blood 5%)
10067	SCHAEDLER KVN AGAR (Sheep Blood 5%)
10069	X.L.T. 4 AGAR
10069*	X.L.T. 4 AGAR
10074S	TRYPTIC SOY AGAR+NEUTRALIZING Irradiated
10078	MUELLER HINTON II MOD. AGAR
10078*	MUELLER HINTON II MOD. AGAR
10079	CASITONE AGAR
10079*	CASITONE AGAR
10080	HAEMOPHYLUS TEST AGAR
10080*	HAEMOPHYLUS TEST AGAR
10082	HELICOBACTER PYLORI AGAR
10082*	HELICOBACTER PYLORI AGAR
10090	M.R.S. Agar
10090*	M.R.S. Agar
10095	BRAIN HEART AGAR FOR HAEMOPHILUS
10129	MAC CONKEY AGAR MMG
10129*	MAC CONKEY AGAR MMG
10131	Mueller Hinton II Agar (Sheep Blood 5%)
10131*	Mueller Hinton II Agar (Sheep Blood 5%)
10132	MUELLER HINTON FASTIDIOUS AGAR 90 mm
10134	Legionella BMPA Agar
10141	SALMONELLA TEST AGAR
10141*	SALMONELLA TEST AGAR
10142	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10142*	BLOOD AGAR (Sheep Blood 7%)(ISO 10560)
10143	Mueller Hinton Agar + 5 % Horse Blood Lysed
10145	CAMPYLOBACTER KARMALI AGAR
10146	CAMPYLOBACTER PRESTON AGAR
10148	CAMPYLOBACTER AGAR (Sheep Blood 10%)
10225	LISTERIA PALCAM AGAR 140 mm
10231	MUELLER HINTON II AGAR 140 mm
10233	R.P.M.I. AGAR
10235	SABOURAUD CAF AGAR + GENTAMICIN
10235*	SABOURAUD CAF AGAR + GENTAMICIN
10236	CLED AGAR 140 mm

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

12031	MUELLER HINTON II AGAR (120X120 mm)
12032	Mueller Hinton II Agar (Sheep Blood 5%) (120 mm x 120 mm)
12033	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L β-NAD) (120 mm x 120 mm)
13012	CLED/MACCONKEY/TSA BLOOD AGAR
13012*	CLED/MACCONKEY/TSA BLOOD AGAR
13013	BAIRD PARKER/BIGGY/MACCONKEY
13013*	BAIRD PARKER/BIGGY/MACCONKEY
13014	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13014*	COLUMBIA CNA/CIOCCOLATO/THAYER MARTIN
13017	CLED/MACCONKEY MMG/MALTO
13017*	CLED/MACCONKEY MMG/MALTO
13018	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13018*	BROM CRESOL PURPLE/COLUMBIA CNA/M.CONKEY
13019	CLED/MACCONKEY/CETRIMIDE
13019*	CLED/MACCONKEY/CETRIMIDE
13020	MAC CONKEY/B.PARKER/TSA BLOOD
13345	GARDNERELLA V./ROGOSA/THAYER MARTIN
13345*	GARDNERELLA V./ROGOSA/THAYER MARTIN
13356	Gard.V. / Chocolate / Thayer Martin
13371	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13371*	BAIRD PARKER/MACCONKEY/SABOURAUD CAF
13480	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13480*	MACCONKEY/VOGEL JOHNSON/SABOURAUD
13602	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13602*	SABOURAUD CAF/BAIRD PARKER/BILE ESCULINE
13607	CHOC. BAC./COLUMBIA/MAC CONKEY
13607*	CHOC. BAC./COLUMBIA/MAC CONKEY
13614	CLED/MACCONKEY/ENTEROCOCCO
13614*	CLED/MACCONKEY/ENTEROCOCCO
165312	MYCOPLASMA AGAR
18007	CHROMATIC™ STAPH AUREUS/ MRSA
18008	TSA BLOOD/CROMagar ORIENTATION
18008*	TSA BLOOD/CROMagar ORIENTATION
18009	Chromatic™ Salmonella/Hektoen Enteric
18011	CHROMATIC™ DETECTION/ESBL
18012	BRILLIANT GREEN / SS AGAR
18012*	BRILLIANT GREEN / SS AGAR
18015	BIGGY (NICKERSON) / MALT AGAR
18015*	BIGGY (NICKERSON) / MALT AGAR
18017	COLUMBIA CNA BLOOD/CHROMAGAR
18017*	COLUMBIA CNA BLOOD/CHROMAGAR
18018	MAC CONKEY/ SABOURAUD CAF
18020	EMB LEVINE / TSA BLOOD
18020*	EMB LEVINE / TSA BLOOD
18021	Chromatic™ CRE / Chromatic™ ESBL
18021*	Chromatic™ CRE / Chromatic™ ESBL
18022	TSA Blood/Columbia CNA
18327	COLUMBIA CNA / MAC CONKEY
18327*	COLUMBIA CNA / MAC CONKEY
18379	GARDNERELLA V. / THAYER MARTIN
18379*	GARDNERELLA V. / THAYER MARTIN
18380	MAC CONKEY / TSA BLOOD
18380*	MAC CONKEY / TSA BLOOD
18390	BAIRD PARKER / SABOURAUD CAF
18390*	BAIRD PARKER / SABOURAUD CAF
18391	HEKTOEN ENTERIC / YERSINIA
18391*	HEKTOEN ENTERIC / YERSINIA
18422	COLUMBIA CNA / GARDNERELLA
18422*	COLUMBIA CNA / GARDNERELLA

18500	BAIRD PARKER / MAC CONKEY
18500*	BAIRD PARKER / MAC CONKEY
18502	CLED / MAC CONKEY
18502*	CLED / MAC CONKEY
18503	HEKTOEN ENTERIC / SS
18503*	HEKTOEN ENTERIC / SS
18505	MAC CONKEY / S.S.AGAR
18505*	MAC CONKEY / S.S.AGAR
18507	COLUMBIA CNA / CHOCOLATE
18507*	COLUMBIA CNA / CHOCOLATE
18595	D.T.M. / SABOURAUD
18595*	D.T.M. / SABOURAUD
18700	Group A Selective/TSA II + Sheep Blood 5%
18703	CHOCOLATE AGAR /THAYER MARTIN
20075	MAC CONKEY BROTH(7516MC2) 20x5ml
20077	PHYSIOLOGICAL SOLUTION 2.5 ml
20079	PHYSIOLOGICAL SOLUTION 4.5 ML
20081	INOCULUM SOLUTION 5 ML
20089	SUSPENSION BROTH
20090	HELICOBACTER PYLORI TEST
20095	PHYSIOLOGICAL SOLUTION
20098	PEPTONE WATER
20105	Glucose Broth
20121	INOCULUM BROTH 7 ML
20129	TRYPTIC SOY BROTH 15 ml
20136	TRYPTONE WATER
20140	PURPLE LACTOSE BROTH
20156	SUSPENSION MEDIUM 7 ML
20158	MYCOPLASMA TRANSPORT BROTH
20159	TRICHOMONAS BROTH w/o CLORAMPHENICOL
20171	Thioglycollate Medium w Vit.K1 & Hemin
20340	VAGITUBE
21104	TRYPTIC SOY BROTH
21110	SELENITE BROTH
21241	Fluid Thioglycollate Medium
22130	SCHAEDLER BROTH
23001	F.B. FASTIDIOUS BROTH
23002	MUELLER HINTON BROTH w HORSE BLOOD (11ml)
23003	MUELLER HINTON BROTH
24070	MYCOSEL BROTH 20PV
24071	Cooked Meat Medium
24091	HAEMOPHILUS TEST BROTH 20 PV
24098	PEPTONE WATER 20PV
24100	ALKALINE PEPTONE WATER 20PV
24103	NUTRIENT BROTH 20PV
24104	BRAIN HEART INFUSION BROTH 20PV
20105	Glucose Broth
24107	MUELLER HINTON II BROTH 20 PV
24108	MULLER KAUFFMANN BROTH 20PV
24109	SABOURAUD BROTH (Harm.EP) 20PV
24110	SELENITE BROTH 20PV
24111	TODD HEWITT BROTH 20PV
24112	TRYPTOSE BROTH 20PV
24115	TRICHOMONAS BROTH 20PV
24117	Pergola Broth
24119	GN HAJNA BROTH 20PV
24120	BILE AESCULIN BROTH 20PV
24124	Fluid Thioglycollate Medium
24125	SERUM BROTH 20PV
24127	Fluid Thioglycollate Medium + 1% Tween 80

24128	TRYPTIC SOY BROTH + TWEEN 80 1% 20PV
24135	SALMONELLA DIFFERENTIAL BROTH 20PV
24136	TRYPTONE WATER 20PV
24137	MALONATE BROTH 20PV
24139	LYSINE DECARBOXYLASE BROTH 20PV
24141	BRAIN HEART INFUSION BROTH 2 ml 20PV
24142	PHYSIOLOGICAL SOLUTION 3ml 20PV
24144	TODD HEWITT w Gentam/Nalidixic acid 20PV
24145	TODD HEWITT B. w Colistin/Nalid.a. 20PV
24146	THIOGLYCOLLATE M w/o INDICATOR acc.USP 20PV
24147	Thiogycollate Bile
24149	MR-VP MEDIUM 20PV
24161	Sabouraud Dextrose Broth + CAF
24241	Fluid Thioglycollate Medium
24342	MOTILITY TEST MEDIUM 20PV
24345	O.F. Medium with Glucose
24400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH 20PV
24403	BIOTONE BROTH 20PV
24404	CAMPYLOBACTER BROTH 20PV
24411	S.F. BROTH 20PV
24412	STREPTOCOCCUS BROTH 20PV
24413	MOSSEL AND MARTIN w MANNITOL 20PV
24416	UREA BROTH 20PV
24417	Wilkins Chalgren Broth
24430	SCHAEDLER BROTH 20PV
24432	YERSINIA BROTH 20PV
24433	EUGON BROTH 20PV
24436	MIDDLEBROOK 7H9 BROTH 20PV
24446	PHENOL RED BROTH 20PV
24450	Rappaport Broth w/o Soy
24451	Tetrathionate Broth
24459	CASO BROTH (Double Concentration) CE 20PV
24461	RPMI Broth
24462	RPMI Broth (double strength)
24513	TRYPTIC SOY BROTH (Harm.EP)
24514	TRYPTIC SOY BROTH
24516	UREA BROTH
26105	Glucose Broth
26124	Fluid Thioglycollate Medium 100 x 10 ml
26400	RAPPAPORT VASSILIADIS SOY (RSV) BROTH
26513	Tryptic Soy Broth
27001	GESA MEDIUM
27500	Triptic Soy Broth
27501	Todd Hewitt Broth
27502	Brain Heart Infusion Broth
27503	Nutrient Broth
29000	CHECK-SET BROTH Irradiated 20 Tests
30007	CAMPYLOBACTER SELECTIVE THIOGLYCOLLATE MEDIUM
30008	CLOSTRIDIUM AGAR (Sheep Blood 5%)
30009	HELICOBACTER PYLORI AGAR
30010	STREPTOCOCCAL KF + TTC AGAR
30011	SIMMONS CITRATE AGAR
30013	NITRATI AGAR
30014	MOSSEL AGAR
30022	T.C.B.S. AGAR
30023	SABOURAUD CAF AGAR
30024	SABOURAUD CAF + ACTIDIONE AGAR
30030	M.R.S. AGAR
30080	BORDET GENGOU AGAR (Sheep Blood 15%)
30081	CHRISTENSEN UREA AGAR

30082	TRYPTIC SOY AGAR
30083	NUTRIENT AGAR
30084	BRAIN HEART INFUSION AGAR
30085	PHENYLALANINE AGAR
30087	KLIGLER IRON AGAR
30088	KLIGLER IRON AGAR + NaCl 2%
30090	Mueller Hinton II Agar
30091	BIGGY (NICKERSON) AGAR
30093	SABOURAUD AGAR
30095	SIM MEDIUM
30096	T.S.I. AGAR
30097	Tryptose Agar
30098	LYSINE IRON AGAR
30099	Chocolate Agar
30116	LOEFFLER MEDIUM
30117	PERGOLA MEDIUM
30118	Lowenstein Jensen Medium
30119	LOWENSTEIN JENSEN MEDIUM w/o GLYCEROL
30121	Stonebrink Medium
30125	DORSET EGG MEDIUM
30368	MIDDLEBROOK 7H10 AGAR
31065	SPS Agar
31075	Mueller Hinton II Agar
31090	Mueller Hinton II Agar
31097	Tryptose Agar
31099	Chocolate Agar
31121	Stonebrink Medium
33040	THAYER MARTIN AGAR
33055	MYCOSEL AGAR
33060	SERUM TELLURITE AGAR
33066	O.N.P.G. AGAR
33085	BILE AESCULIN AGAR
33086	DERMATHOPHYTE (D.T.M.) AGAR
33118	I.U.T.M. MEDIUM
33120	PETRAGNANI MEDIUM
34070	CAMPYLOBACTER AGAR
34071	CYSTINE TRYPTIC AGAR (CTA)
34075	Mueller Hinton II Agar
34121	LOWENSTEIN JENSEN + RIFAMPICIN 15 µg/mL
34121/1	LOWENSTEIN JENSEN + RIFAMPICIN 5 µg/mL
34121/2	LOWENSTEIN JENSEN + RIFAMPICIN 10 µg/mL
34121/3	LOWENSTEIN JENSEN + RIFAMPICIN 25 µg/mL
34121/4	LOWENSTEIN JENSEN + RIFAMPICIN 50 µg/mL
34121/5	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
34121/6	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL
34122	LOWENSTEIN JENSEN + RIFAPENTIN 9 µg/mL
34123	LOWENSTEIN JENSEN + ISONIAZID 0.1 µg/mL
34123/1	LOWENSTEIN JENSEN + ISONIAZID 0.2 µg/mL l
34123/2	LOWENSTEIN JENSEN + ISONIAZID 1 µg/mL
34123/3	LOWENSTEIN JENSEN + ISONIAZID 5 µg/mL
34123/4	LOWENSTEIN JENSEN + ISONIAZID 10 µg/mL
34124/1	LOWENSTEIN JENSEN + PYRAZINAMIDE 5 µg/mL
34124/2	LOWENSTEIN JENSEN + PYRAZINAMIDE 15 µg/mL
34124/3	LOWENSTEIN JENSEN + PYRAZINAMIDE 20 µg/mL
34124/4	LOWENSTEIN JENSEN+PYRAZINAMIDE 200 µg/mL
34125/1	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
34125/2	LOWENSTEIN JENSEN + STREPTOMYCIN 10 µg/mL
34125/3	LOWENSTEIN JENSEN + STREPTOMYCIN 25 µg/mL
34125/4	LOWENSTEIN JENSEN + STREPTOMYCIN 2 µg/mL
34125/5	LOWENSTEIN JENSEN + STREPTOMYCIN 50 µg/mL

34126/1	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
34126/2	LOWENSTEIN JENSEN + ETHAMBUTOL 4 µg/mL
34126/3	LOWENSTEIN JENSEN + ETHAMBUTOL 5 µg/mL
34126/4	LOWENSTEIN JENSEN + ETHAMBUTOL 1 µg/mL
34126/5	LOWENSTEIN JENSEN + ETHAMBUTOL 3 µg/mL
34126/6	LOWENSTEIN JENSEN + ETHAMBUTOL 10 µg/mL
34127	LOWENSTEIN JENSEN + AMIKACIN 5 µg/mL
34127/1	LOWENSTEIN JENSEN + AMIKACIN 40 µg/mL
34128/1	LOWENSTEIN JENSEN + OFLOXACIN 5 µg/mL
34128/2	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/mL
34128/3	LOWENSTEIN JENSEN + OFLOXACIN 25 µg/mL
34128/4	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/mL
34128/5	LOWENSTEIN JENSEN + OFLOXACIN 20 µg/mL
34129/1	LOWENSTEIN JENSEN + PAS 1 µg/mL
34129/2	LOWENSTEIN JENSEN + PAS 10 µg/mL
34129/3	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
34129/4	LOWENSTEIN JENSEN + PAS 0.1 µg/mL
34129/5	LOWENSTEIN JENSEN + PAS 5 µg/mL
34130/1	LOWENSTEIN JENSEN + RIFABUTIN 10 µg/mL
34130/2	LOWENSTEIN JENSEN + RIFABUTIN 30 µg/mL
34130/3	LOWENSTEIN JENSEN + RIFABUTIN 50 µg/mL
34131/1	LOWENSTEIN JENSEN+CLARITHROMICIN 4 µg/mL
34131/2	LOWENSTEIN JENSEN+CLARITHROMYCIN 32 µg/mL
34132/1	LOWENSTEIN JENSEN + ETHIONAMIDE 10 µg/mL
34132/2	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
34132/3	LOWENSTEIN JENSEN + ETHIONAMIDE 30 µg/mL
34132/4	LOWENSTEIN JENSEN + ETHIONAMIDE 40 µg/mL
34135/1	LOWENSTEIN JENSEN + NICOTINAMIDE 10 µg/mL
34135/2	LOWENSTEIN JENSEN + NICOTINAMIDE 20 µg/mL
34135/3	LOWENSTEIN JENSEN + NICOTINAMIDE 30 µg/mL
34136	LOWENSTEIN JENSEN + PEFLOXACIN 2 µg/mL
34137/1	LOWENSTEIN JENSEN + CYCLOSERINE 30 µg/mL
34137/2	LOWENSTEIN JENSEN + CYCLOSERINE 10 µg/mL
34137/3	LOWENSTEIN JENSEN + CYCLOSERINE 20 µg/mL
34137/4	LOWENSTEIN JENSEN + CYCLOSERINE 40 µg/mL
34137/5	LOWENSTEIN JENSEN + CYCLOSERINE 50 µg/mL
34138/1	LOWENSTEIN JENSEN + CAPREOMYCIN 10 µg/mL
34138/2	LOWENSTEIN JENSEN + CAPREOMYCIN 40 µg/mL
34138/3	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/mL
34138/4	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/mL
34139/1	LOWENSTEIN JENSEN + CLOFAZIMINE 5 µg/mL
34139/2	LOWENSTEIN JENSEN + CLOFAZIMINE 10 µg/mL
34143/1	LOWENSTEIN JENSEN + KANAMYCIN 10 µg/mL
34143/2	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
34143/3	LOWENSTEIN JENSEN + KANAMYCIN 30 µg/mL
34144	LOWENSTEIN JENSEN + PYRUVATE 0.2%
34145	LOW.JENSEN + PACT
34146/1	Lowenstein Jensen + Levofloxacin 2 µg/ml
35000	LOWENSTEIN JENSEN MEDIUM
35001	LOWENSTEIN JENSEN + ISONIAZID 0.20 µg/mL
35002	LOWENSTEIN JENSEN + ISONIAZID 1 µg/ml
35010	LOWENSTEIN JENSEN + RIFAMPICIN 40 µg/mL
35011	LOWENSTEIN JENSEN + RIFAMPICIN 20 µg/mL
35020	LOWENSTEIN JENSEN + STREPTOMYCIN 4 µg/mL
35021	LOWENSTEIN JENSEN + STREPTOMYCIN 10µg/ml
35030	LOWENSTEIN JENSEN + ETHAMBUTOL 2 µg/mL
35040	LOWENSTEIN JENSEN + ETHIONAMIDE 20 µg/mL
35041	LOWENSTEIN JENSEN + ETHIONAMIDE 30µg/ml
35050	LOWENSTEIN JENSEN + PYRAZINAMIDE 1 µg/mL
35060	LOWENSTEIN JENSEN + KANAMYCIN 20 µg/mL
35061	LOWENSTEIN JENSEN + KANAMYCIN 30µg/ml
35070	LOWENSTEIN JENSEN + PAS 1 µg/mL
35071	LOWENSTEIN JENSEN + PAS 0.5 µg/mL
35080	LOWENSTEIN JENSEN + OFLOXACIN 2 µg/ml
35081	LOWENSTEIN JENSEN + OFLOXACIN 10 µg/ml
35082	LOWENSTEIN JENSEN + OFLOXACIN 40 µg/ml
35090	LOWENSTEIN JENSEN + CAPREOMYCIN 30 µg/ml
35091	LOWENSTEIN JENSEN + CAPREOMYCIN 20 µg/ml
35147	LOWENSTEIN JENSEN + PNB 500 µg/ml
35148	LOWENSTEIN JENSEN + TCH 2 µg/ml
36001/1	IUTM + STREPTOMYCIN 2 µg/mL
36001/2	IUTM + STREPTOMYCIN 4 µg/mL
36001/3	IUTM + STREPTOMYCIN 10 µg/mL
36001/4	IUTM + STREPTOMYCIN 25 µg/mL
36001/5	IUTM + STREPTOMYCIN 50 µg/mL
36002/1	IUTM + ISONIAZID 0.1 µg/mL
36002/2	IUTM + ISONIAZID 0.2 µg/mL
36002/3	IUTM + ISONIAZID 1 µg/mL
36002/4	IUTM + ISONIAZID 5 µg/mL
36002/5	IUTM + ISONIAZID 10 µg/mL
36003/1	IUTM + ETHAMBUTOL 1 µg/mL
36003/2	IUTM + ETHAMBUTOL 2 µg/mL
36003/3	IUTM + ETHAMBUTOL 3 µg/mL
36003/4	IUTM + ETHAMBUTOL 5 µg/mL
36003/5	IUTM + ETHAMBUTOL 10 µg/mL
36004/1	IUTM + RIFAMPICIN 5 µg/mL
36004/2	IUTM + RIFAMPICIN 10 µg/mL l
36004/3	IUTM + RIFAMPICIN 20 µg/mL
36004/4	IUTM + RIFAMPICIN 40 µg/mL
36004/5	IUTM + RIFAMPICIN 50 µg/mL
36005/1	IUTM + RIFABUTIN 10 µg/mL
36005/2	IUTM + RIFABUTIN 20 µg/mL
36005/3	IUTM + RIFABUTIN 30 µg/mL
36005/4	IUTM + RIFABUTIN 40 µg/mL
36005/5	IUTM + RIFABUTIN 50 µg/mL
36006/1	IUTM + CYCLOSERINE 10 µg/mL
36006/2	IUTM + CYCLOSERINE 20 µg/mL
36006/3	IUTM + CYCLOSERINE 30 µg/mL
36006/4	IUTM + CYCLOSERINE 40 µg/mL
36006/5	IUTM + CYCLOSERINE 50 µg/mL
36007/1	IUTM + OFLOXACIN 1.25 µg/mL
36007/2	IUTM + OFLOXACIN 2.5 µg/mL
36007/3	IUTM + OFLOXACIN 10 µg/mL
36007/4	IUTM + OFLOXACIN 25 µg/mL
36007/5	IUTM + OFLOXACIN 50 µg/mL
36008/1	IUTM + PAS 0.1 µg/mL
36008/2	IUTM + PAS 0.5 µg/mL
36008/3	IUTM + PAS 1 µg/mL
36008/4	IUTM + PAS 5 µg/mL
36008/5	IUTM + PAS 10 µg/mL
36009/1	IUTM + PYRAZINAMIDE 10 µg/mL
36009/2	IUTM + PYRAZINAMIDE 30 µg/mL
36009/3	IUTM + PYRAZINAMIDE 50 µg/mL
36009/4	IUTM + PYRAZINAMIDE 70 µg/mL
36009/5	IUTM + PYRAZINAMIDE 90 µg/mL
37000	MIDDLEBROOK 7H11
37001	MIDDLEBROOK 7H11 + AMIKACIN 2 µg/mL
37002	MIDDLEBROOK 7H11 + AMIKACIN 4 µg/mL
37006	MIDDLEBROOK 7H11 + ETHAMBUTOL 7.5 µg/mL
37011	MIDDLEBROOK 7H11 + ETHIONAMIDE 10 µg/mL

37016	MIDDLEBROOK 7H11 + ISONIAZIDE 0.2 µg/mL
37017	MIDDLEBROOK 7H11 + ISONIAZIDE 1 µg/mL
37021	MIDDLEBROOK 7H11 + KANAMYCIN 6 µg/mL
37026	MIDDLEBROOK 7H11 + PAS 8 µg/mL
37031	MIDDLEBROOK 7H11 + PYRAZINAMIDE 25 µg/mL
37036	MIDDLEBROOK 7H11 + RIFABUTIN 1 µg/mL
37037	MIDDLEBROOK 7H11 + RIFABUTIN 0.5 µg/mL
37041	MIDDLEBROOK 7H11 + RIFAMPICIN 1 µg/mL
37046	MIDDLEBROOK 7H11 + STREPTOMYCIN 2 µg/mL
37051	MIDDLEBROOK 7H11 + OFLOXACIN 2 µg/mL
37056	MIDDLEBROOK 7H11 + CYCLOSERINE 30 µg/mL
400020	Fluid Thioglycollate Medium 6 x 100 ml
400120	Fluid Thioglycollate Medium 6 x 300 ml
400220	Fluid Thioglycollate Medium 6 x 1000 ml
401890	BUFFER SOLUTION pH 7 6X100 ml
401930	SPS Agar 6X150 ml
401980	TRYPTONE WATER 6X100 ml
401990	ALKALINE PEPTONE WATER 6X100 ml
402000	NUTRIENT BROTH 6X100 ml
402020	MUELLER HINTON II BROTH 6X100 ml
402030	MULLER KAUFFMANN BROTH 6X100 ml
402040	SABOURAUD BROTH 6X100 ml
402050	Selenite Broth 6X100 ml
402060	SALMONELLA DIFF.BROTH 6X90 ml
402070	TRYPTOSE BROTH 6X100 ml
402120	MRS AGAR 6X100 ml
402130	PEPTONE WATER 6X100 ml
402140	BLOOD AGAR BASE 6X100 ml
402170	AZIDE BLOOD AGAR BASE 6X100 ml
402180	CLED AGAR 6X100 ml
402190	NUTRIENT AGAR 6X100 ml
402200	DERMATHOPHYTE (D.T.M.) AGAR 6X100 ml
402210	COLUMBIA CNA AGAR BASE 6X100 ml
402220	DRIGALSKI LACTOSE AGAR 6X100 ml
402230	HEKTOEN ENTERIC AGAR 6X100 ml
402240	MAC CONKEY AGAR 6X100 ml
402250	MUELLER HINTON II AGAR 6X100 ml
402270	PSEUDOMONAS CETRIMIDE AGAR 6X100 ml
402280	SABOURAUD AGAR 6X100 ml
402290	MANNITOL SALT AGAR 6X100 ml
402300	S.S. AGAR 6X100 ml
402320	TRYPTOSE AGAR 6X100 ml
402330	BRILLIANT GREEN AGAR 6X100 ml
402340	DESOXYCHOLATE AGAR 6X100 ml
402350	E.M.B. LEVINE AGAR 6X100 ml
402360	SALMONELLA RAPID TEST 6X100 ml
402370	SABOURAUD CAF AGAR 6X100 ml
402380	BRAIN HEART INFUSION AGAR 6X100 ml
402430	PEPTONE DILUITIONS 6X100 ml
402450	MAC CONKEY SORBITOL AGAR 6X100 ml
402500	Fluid Thioglycollate Medium + 1% Tween 80
402570	X.L.D. AGAR 6X100 ml
403030	BIOTONE BROTH 6X100 ml
403050	S.I.M. MEDIUM 6X100 ml
403060	UREA INDOLE BROTH 6X100 ml
412010	BRAIN HEART INFUSION BROTH 6X200 ml
412030	SIMMONS CITRATE AGAR 6X200 ml
412040	LYSINE IRON AGAR 6X200 ml
412050	Selenite Broth 6X200 ml
412060	TODD HEWITT BROTH 6X200 ml
412080	TRICHOMONAS BROTH 6X200 ml
412100	CHRISTENSEN UREA AGAR 5X200 ml
412110	TRYPTIC SOY BROTH + TWEEN80 1% 6x200ml
412130	PSEUDOMONAS AGAR BASE 6x200ml
412150	AZIDE BLOOD AGAR BASE 6X200 ml
412170	PHENILALANINE AGAR 6X200 ml
412180	CLED AGAR 6X200 ml
412190	NUTRIENT AGAR 6X200 ml
412210	COLUMBIA CNA AGAR BASE 6X200 ml
412230	HEKTOEN ENTERIC AGAR 6X200 ml
412240	MAC CONKEY AGAR 6X200 ml
412250	MUELLER HINTON II AGAR 6X200 ml
412270	PSEUDOMONAS CETRIMIDE AGAR 6X200 ml
412280	SABOURAUD AGAR 6X200 ml
412290	MANNITOL SALT AGAR 6X200 ml
412300	S.S. AGAR 6X200 ml
412370	SABOURAUD CAF AGAR 6X200 ml
413010	ISOSENSITEST AGAR 6X200 ml
413030	CAMPYLOBACTER AGAR 6X200 ml
413040	CLOSTRIDIUM AGAR BASE 6X200 ml
413080	NUTRIENT AGAR acc. to ISO 6579
414010	PEPTONE WATER pH 8.4 + NaCl 1% 6X225 ml
432050	SELENITE BROTH (DOUBLE CONCENT.) 6X200ml
432080	TRYPTIC SOY BROTH 6X225 ml
432250	D-Nase TEST AGAR 6X200 ml
432290	TRYPTIC SOY AGAR 6X200 ml
442080	TRYPTIC SOY BROTH 6X200 ml
442220	Chocolate Agar 6x 100 ml
442280	SABOURAUD MODIFIED AGAR 6X100 ml
442290	TRYPTIC SOY AGAR 6X100 ml
442300	WURTZ LACTOSE AGAR 6X100 ml
442320	BILE AESCULIN AGAR 6X100 ml
442350	BIGGY (NICKERSON) AGAR 6X100 ml
442490	SPS AGAR 6X100 ml
452060	Fluid Thioglycollate Medium 6 x 100 ml
452080	TRYPTIC SOY BROTH 6X100 ml
452210	COLUMBIA AGAR BASE 6X200 ml
452500	Fluid Thioglycollate Medium + 1% Tween 80 25 x 100 ml
453060	Fluid Thioglycollate Medium 25 x 100 ml
463100	Fluid Thioglycollate Medium 6 x 900 ml
463130	Selenite Broth 6X1000 ml
470010	TRYPTIC SOY AGAR 6X500 ml
470020	Selenite Broth 6X500 ml
470030	DESOXYCHOLATE AGAR 6X500 ml
470040	SABOURAUD AGAR 6X500 ml
470050	NUTRIENT BROTH 6X500 ml
470060	NUTRIENT AGAR 6X500 ml
470070	Mueller Hinton II Agar 6X500 ml
470080	MANNITOL SALT AGAR 6X500 ml
470090	MAC CONKEY AGAR 6X500 ml
470100	COLUMBIA AGAR BASE 6X500 ml
470110	CLED AGAR 6X500 ml
470120	Chocolate Agar 6 x 500 ml
470130	BLOOD AGAR BASE 6X500 ml
470140	BILE AESCULIN AGAR 6X500 ml
470150	TRICHOMONAS BROTH 6X500 ml
470160	DESOXYCHOLATE CITRATE AGAR 6X500 ml
470210	ALKALINE PEPTONE WATER 6X500 ml
470220	CZAPEK DOX AGAR 6X500 ml
470280	DRIGALSKI LACTOSE AGAR 6X500 ml

470290	CARY BLAIR TRANSPORT MEDIUM 6X500 ml
470300	Fluid Thioglycollate Medium 6 x 500 ml
470320	PEPTONE WATER 6X500 ml
470370	TRYPTIC SOY BROTH 6 x 500 ml
471070	SABOURAUD BROTH 6X500 ml
471120	PHYSIOLOGICAL SOLUTION 6X240 ml
473000	PHYSIOLOGICAL SOLUTION 6X500 ml
481110	CHROMATIC™ CANDIDA 6X100 ml
481130	CHROMATIC™ DETECTION 6X100 ml
481140	CHROMATIC™ SALMONELLA 6X100 ml
481160	CHROMATIC™ STAPH AUREUS 6X100 ml
481180	CHROMATIC™ STREP B 6X100ml
482190	Chromatic™ E.coli O157 6 x 200 ml
490010	HEMO-AEROBIC culturing 6X80 ml
490020	HEMO-ANAEROBIC culturing 6X80 ml
490030	HEMO-AEROBIC culturing-Pediatric 6X40 ml
490040	HEMO-ANAEROBIC culturing-Pediatric 6X40ml
490050	HEMO-AEROBIC culturing NEONATAL 6x9 ml
490060	HEMO-ANAEROBIC culturing NEONATAL 6x9 ml
493000	Fluid Thioglycollate Medium 6 x 100 ml
495010	TRYPTIC SOY BROTH 6x100 ml
495020	Fluid Thioglycollate Medium 6 x 100 ml
500142	URITEST PENTA
500152	URITEST
500182	URITEST M
500702	URITEST EF
50020	VAGITEST
50021	DERMATEST
500232	URITEST N
500302	URITEST 2
500402	URITEST MALTO
500412	URITEST EC
51014	URITEST PENTA
51015	URITEST
51018	URITEST M
51020	VAGITEST 120 slide
51021	DERMATEST
51023	URITEST N
51024	URITEST C
51030	URITEST 2
51040	URITEST MALTO
51041	URITEST EC
51070	URITEST EF
51118	URITEST M
51123	URITEST N 500 slide
51130	URITEST 2 500 slide
51140	URITEST MALTO
51170	CLED/MAC CONKEY/ BILE AESCULIN
52115	CLED/MAC CONKEY/SLANETZ 120 slide
52119	URITEST SF 500 slide
610001	BILE AESCULIN AZIDE AGAR
610002	DEXTROSE AGAR
610005	BLOOD AGAR BASE
610006	BORDET GENGOU AGAR BASE
610007	BRAIN HEART INFUSION AGAR
610008	BRAIN HEART INFUSION BROTH
6100085	BRAIN HEART INFUSION BROTH
610009	BRILLIANT GREEN AGAR
610012	CLED AGAR
6100125	CLED AGAR

610013	COLUMBIA AGAR BASE
6100135	COLUMBIA AGAR BASE
610014	DESOXYCHOLATE AGAR
6100145	DESOXYCHOLATE AGAR
610015	DESOXYCHOLATE CITRATE AGAR
610016	DRIGALSKI LACTOSE AGAR
610019	E.M.B. LEVINE AGAR
610021	HEKTOEN ENTERIC AGAR
6100215	HEKTOEN ENTERIC AGAR
610022	G.C. MEDIUM
610023	KLIGLER IRON AGAR
610024	M.R.S. AGAR (ISO/FDIS 15214)
610025	M.R.S. BROTH (ISO/FDIS 15214)
610026	LOWENSTEIN JENSEN MEDIUM
6100265	LOWENSTEIN JENSEN MEDIUM
610027	LYSINE IRON AGAR
610028	MAC CONKEY AGAR
6100285	MAC CONKEY AGAR
610029	MANNITOL SALT AGAR
6100295	MANNITOL SALT AGAR
610032	MR-VP BROTH
610033	MUELLER HINTON AGAR
6100335	MUELLER HINTON AGAR
610034	MUELLER HINTON BROTH
610035	MULLER KAUFFMANN BROTH
610036	NUTRIENT AGAR
610037	NUTRIENT BROTH
6100375	NUTRIENT BROTH
610038	PEPTONE WATER
610039	PHENYLALANINE AGAR
610041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
6100415	PSEUDOMONAS CETRIMIDE AGAR
610042	SS AGAR (MODIFIED)
6100425	SS AGAR (MODIFIED)
610043	SCHAEDLER AGAR BASE
610044	PURPLE LACTOSE AGAR
610046	SIMMONS CITRATE AGAR
610047	MONSUR AGAR
610048	AEROMONAS AGAR BASE
610049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
610050	Fluid Thioglycollate Medium
6100505	Fluid Thioglycollate Medium
610051	TODD HEWITT BROTH
6100515	TODD HEWITT BROTH
610052	TRYPTIC SOY AGAR
6100525	TRYPTIC SOY AGAR (Harm.EP) 5 KG
610053	TRYPTIC SOY BROTH
6100535	TRYPTIC SOY BROTH
610055	T.S.I. AGAR USP
610056	CLOSTRIDIUM BROTH
6100565	CLOSTRIDIUM BROTH
610057	MAC CONKEY AGAR No.2
6100575	MAC CONKEY AGAR No.2 5 KG
610060	X.L.D. AGAR (ISO 6579)
6100605	X.L.D. AGAR
610061	TRICHOMONAS BROTH
610065	GSB AGAR BASE (ISLAM)
610070	YEAST GLUCOSE CHLORAMPHENICOL AGAR
6100705	YEAST GLUCOSE CHLORAMPHENICOL AGAR 5 Kg
610071	PSEUDOMONAS AGAR BASE

610072	CZAPEK DOX BROTH
610074	TRYPTONE SULFITE NEOMYCIN AGAR
610075	PHENYLALANINE MALONATE BROTH
610079	BRUCELLA AGAR BASE
610080	WORT BROTH W/O NaCl
610092	XLT 4 AGAR
610095	CZAPEK DOX AGAR
610096	REINFORCED CLOSTRIDIAL AGAR
610097	STAPHYLOCOCCUS BROTH
610098	ALKALINE PEPTONE WATER
610101	MALT AGAR
610103	SABOURAUD AGAR
6101035	SABOURAUD AGAR
610104	SABOURAUD BROTH
610107	UREA AGAR BASE (ISO 6785)
610108	MAC CONKEY SORBITOL AGAR
610109	P.P.L.O. BROTH
610110	MUELLER HINTON AGAR MODIFIED
610111	YERSINIA SELECTIVE AGAR BASE
610112	CLED ANDRADE AGAR
610113	COLUMBIA CNA AGAR BASE
610114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
610115	CLOSTRIDIUM DIFFICILE AGAR BASE
610117	TRYPTONE YEAST AGAR
610118	ANDRADE LACTOSE PEPTONE WATER
610123	CORN MEAL AGAR
610125	LEGIONELLA CYE AGAR BASE
610128	MAC CONKEY AGAR w/o BILE SALT
610130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
610131	CAMPYLOBACTER ENRICHMENT BROTH BASE
610132	MOTILITY TEST AGAR
610134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
610135	BIGGY (NICKERSON) AGAR
610136	BACILLUS CEREUS AGAR BASE (PEMBA)
610137	SCHAEDLER BROTH
610140	E.M.B. AGAR w LACTOSE + SUCROSE
610143	LIVER BROTH
610144	MRS BROTH w/o GLUCOSE
610145	SELENITE BROTH
6101455	SELENITE BROTH
610146	SABOURAUD MALTOSE AGAR
610147	SLANETZ AND BARTLEY AGAR + TTC
6101475	SLANETZ AND BARTLEY AGAR + TTC
610148	SPS AGAR
610151	BILE AESCULIN BROTH
610152	AMIES TRANSPORT MEDIUM + CHARC.
6101525	AMIES TRANSPORT MEDIUM + CHARC.
610153	AZIDE BLOOD AGAR BASE
610155	AZIDE VIOLET BLOOD AGAR BASE
610157	BIOTONE AGAR
610158	BIOTONE BROTH
610159	CPLM SELECTIVE WITH CAF
610160	DERMATOPHYTE (D.T.M.) AGAR
610161	DEXTROSE BROTH
610163	G.N. HAJNA BROTH
610164	HERELLEA AGAR
6101645	HERELLEA AGAR
610165	KOSER CITRATE MEDIUM
610168	LISTERIA PALCAM AGAR
610169	I.U.T.M. MEDIUM
610170	MAC CONKEY MMG AGAR
6101705	MAC CONKEY MMG AGAR
610172	MALONATE BROTH
610174	PHENOL RED BROTH BASE
610175	RAPPAPORT VASSILIADIS BROTH (ISO 6785-6579)
610176	ROGOSA AGAR
610177	ROGOSA BROTH
610179	SABOURAUD CAF AGAR + ACTIDIONE
610180	S.F. BROTH
610181	S.I.M. MEDIUM
610182	STUART TRANSPORT MEDIUM
610183	TETRATHIONATE BROTH BASE
610185	TRYPTIC (CTA) MEDIUM
610186	VOGEL JOHNSON AGAR
610188	BLOOD AGAR BASE N. 2
610191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
6101915	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
610193	TRYPTOSE AGAR
610195	MAC CONKEY AGAR w/o CRYSTAL VIOLET
610196	TRYPTIC BILE AGAR
610197	TRYPTOFAN BROTH
610200	CAMPYLOBACTER KARMALI AGAR BASE
610203	SABOURAUD CAF AGAR
6102035	SABOURAUD CAF AGAR 5 KG
610205	DNase TEST AGAR
610206	TRYPTONE WATER (ISO/DIS 3811)
610207	CLOSTRIDIUM PERFRIGENS AGAR BASE
610210	BILE AESCULIN AGAR
610211	KLIGLER IRON AGAR MOD.
610214	MIDDLEBROOK 7H9 BROTH BASE
610217	NUTRIENT BROTH N.2
610218	Mueller Hinton II Broth
610221	ANTIBIOTIC TEST MEDIUM
610222	CLOSTRIDIUM BROTH w/o AGAR
6102225	CLOSTRIDIUM BROTH w/o AGAR
610223	MAC CONKEY AGAR w/o Salt
610227	PHENOL RED AGAR BASE
610229	ANTIBIOTIC MEDIUM E
610230	OXIDATIVE/FERMENTATIVE MEDIUM
610233	TRYPTOSE BROTH
610235	MANNITOL MOTILITY TEST MEDIUM
610236	MOTILITY INDOLE UREA AGAR (M.I.U.)
610241	TRYPTONE SOYA YEAST EXTRACT BROTH
610245	LB AGAR
610301	BISMUTH SULPHITE AGAR
610303	Lysine Decarboxylase Broth
610304	OF BASAL MEDIUM
610305	ORNITHINE DECARBOXYLASE BROTH
610306	ARGININE DECARBOXYLASE BROTH
610308	PHENOL RED AGAR BASE
610309	PSEUDOMONAS AGAR F
610310	PSEUDOMONAS AGAR P
610311	UREA BROTH
610315	ANTIBIOTIC AGAR N.11
610319	PFIZER SELECTIVE ENTEROCOCCUS AGAR
610322	NITRATE BROTH
610331	DIAGNOSTIC SENSITIVITY TEST AGAR (D.S.T.)
610339	T.S.I. AGAR acc.EP
610341	EMGON BROTH
610343	MANNITOL SALT BROTH

610363	Yeast Extract Sodium Lactate medium
610364	Tryptose Phosphate Broth
6103645	Tryptose Phosphate Broth
610372	Cooked Meat Medium
610492	POLYPEPTONE
610495	BRAIN HEART INFUSION
6104955	BRAIN HEART INFUSION
610496	ACID HYDROLISATE OF CASEIN
610497	BEEF EXTRACT
6104975	BEEF EXTRACT
610498	LACTOSE
6104985	LACTOSE
610506	CYSTINE HEART AGAR
610611	CHROMATIC™ SALMONELLA
610612	CHROMATIC™ DETECTION
6106125	CHROMATIC™ DETECTION
610613	CHROMATIC™ CANDIDA
610614	Chromatic™ E.coli O157
610615	CHROMATIC™ MRSA
610616	CHROMATIC™ STAPH AUREUS
610617	CHROMATIC™ STREP B
610625	SABOURAUD CAF (50 mg/L) AGAR
610627	MUELLER HINTON II AGAR
6106275	MUELLER HINTON II AGAR
610629	CHROMATIC™ ESBL
611000	SODIUM CHLORIDE
611001	AGAR
6110015	AGAR
611002	GELATIN BACTERIOLOGICAL
6110025	GELATIN BACTERIOLOGICAL
611003	SODIUM SELENITE
6110035	SODIUM SELENITE
611004	TRYPTONE
6110045	TRYPTONE
611005	YEAST EXTRACT
6110055	YEAST EXTRACT
611006	MALT EXTRACT
6110065	MALT EXTRACT
611007	CAMPYLOBACTER AGAR BASE
611008	TRYPTOSE
6110085	TRYPTOSE
611009	GLUCOSIO
611010	T.C.B.S. AGAR
611015	SIERRA LIPOLYTIC AGAR
611016	YEAST EXTRACT AGAR (ISO 6222)
611021	HEART INFUSION BROTH
6110215	HEART INFUSION BROTH
611022	MIDDLEBROOK 7H10 AGAR BASE
611203	SABOURAUD CAF (1g/l) AGAR
611210	WURTZ LACTOSE AGAR
611265	ISOSENSITEST AGAR
611366	STAPHYLOCOCCUS 110 AGAR
611367	BILE BACTERIOLOGICAL
611401	IRON SULPHITE AGAR
611402	CARY BLAIR TRANSPORT MEDIUM
611502	CASEIN PEPTONE
611601	GLUCOSE
6116015	GLUCOSE
611618	CHROMATIC™ MH
611619	CHROMATIC™ CRE AGAR BASE

611701	PEPTONE BACTERIOLOGICAL
6117015	PEPTONE BACTERIOLOGICAL
611801	SUCROSE
6118015	SUCROSE
611901	BILE SALT N.3
6119015	BILE SALT N.3
612001	LIVER EXTRACT
6120015	LIVER EXTRACT
612101	PEPTONE MYCOLOGICAL
6121015	PEPTONE MYCOLOGICAL
612201	PROTEOSE PEPTONE
6122015	PROTEOSE PEPTONE
612202	STREPTOCOCCUS SELECTIVE AGAR
612203	STREPTOCOCCUS BROTH
612501	SOY PEPTONE
6125015	SOY PEPTONE
620001	BILE AESCULIN AZIDE AGAR
620002	DEXTROSE AGAR
620005	BLOOD AGAR BASE
620006	BORDET GENGOU AGAR BASE
620007	BRAIN HEART INFUSION AGAR
620008	BRAIN HEART INFUSION BROTH
620009	BRILLIANT GREEN AGAR
620012	CLED AGAR
620013	COLUMBIA AGAR BASE
620014	DESOXYCHOLATE AGAR
620015	DESOXYCHOLATE CITRATE AGAR
620016	DRIGALSKY LACTOSE AGAR
620019	E.M.B. LEVINE AGAR
620021	HEKTOEN ENTERIC AGAR
620022	G.C. MEDIUM
620023	KLIGLER IRON AGAR
620024	M.R.S. AGAR (ISO/FDIS 15214)
620025	M.R.S. BROTH (ISO/FDIS 15214)
620026	LOWENSTEIN JENSEN MEDIUM
620027	LYSINE IRON AGAR
620028	MAC CONKEY AGAR
620029	MANNITOL SALT AGAR
620032	MR-VP BROTH
620033	MUELLER HINTON AGAR
620034	MUELLER HINTON BROTH
620035	MULLER KAUFFMANN BROTH
620036	NUTRIENT AGAR
620037	NUTRIENT BROTH
620038	PEPTONE WATER
620039	PHENYLALANINE AGAR
620041	PSEUDOMONAS CETRIMIDE AGAR (ISO 8360-1)
620042	SS AGAR (MODIFIED)
620043	SCHAEDLER AGAR BASE
620044	PURPLE LACTOSE AGAR
620046	SIMMONS CITRATE AGAR
620047	MONSUR AGAR
620048	AEROMONAS AGAR BASE
620049	LEGIONELLA BCYE AGAR BASE (ISO 11731)
620050	Fluid Thioglycollate Medium
620051	TODD HEWITT BROTH
620052	TRYPTIC SOY AGAR
620053	TRYPTIC SOY BROTH
620055	T.S.I. AGAR USP
620056	CLOSTRIDIUM BROTH

620057	MAC CONKEY AGAR No.2
620060	X.L.D. AGAR (ISO 6579)
620061	TRICHOMONAS BROTH
620065	GSB AGAR BASE (ISLAM)
620070	YEAST GLUCOSE CHLORAMPHENICOL AGAR
620071	PSEUDOMONAS AGAR BASE
620072	CZAPEK DOX BROTH
620074	TRYPTONE SULFITE NEOMYCIN AGAR
620075	PHENYLALANINE MALONATE BROTH
620079	BRUCELLA AGAR BASE
620092	XLT 4 AGAR
620095	CZAPEK DOX AGAR
620096	REINFORCED CLOSTRIDIAL AGAR
620097	STAPHYLOCOCCUS BROTH
620098	ALKALINE PEPTONE WATER
620101	MALT AGAR
620103	SABOURAUD AGAR
620104	SABOURAUD BROTH
620107	UREA AGAR BASE (ISO 6785)
620108	MAC CONKEY SORBITOL AGAR
620109	P.P.L.O. BROTH
620110	MUELLER HINTON AGAR MODIFIED
620111	YERSINIA SELECTIVE AGAR BASE
620112	CLED ANDRADE AGAR
620113	COLUMBIA CNA AGAR BASE
620114	BACILLUS CEREUS AGAR BASE (MOSSEL) ISO 7932
620115	CLOSTRIDIUM DIFFICILE AGAR BASE
620117	TRYPTONE YEAST AGAR
620118	ANDRADE LACTOSE PEPTONE WATER
620122	MIDDLEBROOK 7H10 AGAR BASE
620123	CORN MEAL AGAR
620125	LEGIONELLA CYE AGAR BASE
620130	CAMPYLOBACTER BLOOD FREE MEDIUM BASE
620131	CAMPYLOBACTER ENRICHMENT BROTH BASE
620132	MOTILITY TEST AGAR
620134	SLANETZ BARTLEY AGAR BASE ISO 7899-2
620135	BIGGY (NICKERSON) AGAR
620136	BACILLUS CEREUS AGAR BASE (PEMBA)
620137	SCHAEDLER BROTH
620140	E.M.B. AGAR w LACTOSE + SUCROSE
620143	LIVER BROTH
620144	MRS BROTH w/o GLUCOSE
620145	SELENITE BROTH
620146	SABOURAUD MALTOSE AGAR
620147	SLANETZ AND BARTLEY AGAR + TTC
620148	SPS AGAR
620151	BILE AESCULIN BROTH
620152	AMIES TRANSPORT MEDIUM + CHARC.
620153	AZIDE BLOOD AGAR BASE
620155	AZIDE VIOLET BLOOD AGAR BASE
620157	BIOTONE AGAR
620158	BIOTONE BROTH
620159	CPLM SELECTIVE WITHCAF
620160	DERMATOPHYTE (D.T.M.) AGAR
620161	DEXTROSE BROTH
620163	G.N. HAJNA BROTH
620164	HERELLEA AGAR
620165	KOSER CITRATE BROTH
620168	LISTERIA PALCAM AGAR
620169	I.U.T.M. MEDIUM
620170	MAC CONKEY MMG AGAR
620172	MALONATE BROTH
620174	PHENOL RED BROTH BASE
620175	RAPPAPORT VASSILIADIS BROTH
620176	ROGOSA AGAR
620177	ROGOSA BROTH
620179	SABOURAUD CAF AGAR + ACTIDIONE
620180	S.F. BROTH
620181	S.I.M. MEDIUM
620182	STUART TRANSPORT MEDIUM
620183	TETRATHIONATE BROTH BASE
620185	TRYPTIC (CTA) MEDIUM
620186	VOGEL JOHNSON AGAR
620188	BLOOD AGAR BASE N. 2
620191	AMIES TRANSPORT MEDIUM (w/o CHARCOAL)
620193	TRYPTOSE AGAR
620195	MAC CONKEY AGSAR w/o CRYSTAL VIOLET
620196	TRYPTIC BILE AGAR
620197	TRYPTOFAN BROTH
620200	CAMPYLOBACTER KARMALI AGAR BASE
620203	SABOURAUD CAF AGAR
620205	DNase TEST AGAR
620206	TRYPTONE WATER (ISO/DIS 3811)
620207	CLOSTRIDIUM PERFRIGENS AGAR BASE
620210	BILE AESCULIN AGAR
620211	KLIGLER IRON AGAR MOD.
620214	MIDDLEBROOK 7H9 BROTH BASE
620217	NUTRIENT BROTH N.2
620218	Mueller Hinton II Broth
620227	PHENOL RED AGAR BASE
620229	ANTIBIOTIC MEDIUM E
620233	TRYPTOSE BROTH
620235	MANNITOL MOTILITY TEST MEDIUM
620241	TRYPTONE SOYA YEAST EXTRACT BROTH
620303	Lysine Decarboxylase Broth
620309	PSEUDOMONAS AGAR F
620311	UREA BROTH
620495	BRAIN HEART INFUSION
620496	ACID HYDROLISATE OF CASEIN
620497	BEEF EXTRACT
620498	LACTOSE
620611	CHROMATIC™ SALMONELLA
620612	CHROMATIC™ DETECTION
620613	CHROMATIC™ CANDIDA
620614	Chromatic™ E.coli O157
620615	CHROMATIC™ MRSA
620616	CHROMATIC™ STAPH AUREUS
620617	CHROMATIC™ STREP B
620627	MUELLER HINTON II AGAR
620629	CHROMATIC™ ESBL
621000	SODIUM CHLORIDE
621001	AGAR
621003	SODIUM SELENITE
621004	TRYPTONE
621005	YEAST EXTRACT
621006	MALT EXTRACT
621007	CAMPYLOBACTER AGAR BASE
621010	TCBS AGAR
621015	SIERRA LIPOLYTIC AGAR
621016	YEAST EXTRACT AGAR (ISO 6222)

621021	HEART INFUSION BROTH
621022	MIDDLEBROOK 7H10 AGAR BASE
621210	WURTZ LACTOSE AGAR
621265	ISOSENSITEST AGAR
621367	BILE BACTERIOLOGICAL
621401	IRON SULPHITE AGAR
621402	CARY BLAIR TRANSPORT MEDIUM
621601	GLUCOSE
621618	CHROMATIC™ MH
621619	CHROMATIC™ CRE AGAR BASE
621701	PEPTONE BACTERIOLOGICAL
622202	STREPTOCOCCUS SELECTIVE AGAR
630026	LOWENSTEIN JENSEN MEDIUM w GLYCEROL 1 litre
71618	ENTEROSYSTEM 18R 20 Tests
71630	STAF SYSTEM 18 R 20 Tests
71670	COPRO SYSTEM 40 Tests
71675	COPRO SYSTEM Plus 20 Tests
71678	PATHOGENIC SYSTEM DOUBLE 40 Tests
71679	PATHOGENIC SYSTEM 20 Tests
71681	PATHOGENIC SYSTEM AST
71714	INTEGRAL SYSTEM ENTEROBATTERI 20 Tests
71718	INTEGRAL SYSTEM STAFILOCOCCHI 20 Tests
71720	INTEGRAL SYSTEM STREPTOCOCCHI 20 Tests
71724	INTEGRAL SYSTEM GARDNERELLA 20 TESTS
71822	INTEGRAL SYSTEM YEASTS Plus 20 Tests
72560	STREPTO SYSTEM 12 R 40 Tests
72592	MYCOPLASMA SYSTEM Plus 20 Tests
74156	A.F. GENITAL SYSTEM 20 Tests
74160	URIN SYSTEM Plus 20 Tests
74161	URIN SYSTEM Chrom 20 Tests
76010	Sensi Test gram-negative 20 Tests
76020	Sensi Test gram-positive 20 Tests
76031	SensiQuattro Gram-negative 20 Tests
76032	SensiQuattro Gram-positive 20 Tests
76033	SensiQuattro Candida EU 20 Tests
78618	ENTERO PLURI TEST 10 Tests
78619	ENTERO PLURI TEST 25 Tests
78620	OXI/FERM PLURI TEST 10 Tests
78621	OXI/FERM PLURI TEST 25 Tests
79010	Sensi Test gram-negative 4 Tests
79020	Sensi Test gram-positive 4 Tests
79031	SensiQuattro Gram-negative 4 Tests
79032	SensiQuattro Gram-positive 4 Tests
79033	SensiQuattro Candida EU 4 Tests
79156	A.F. GENITAL SYSTEM 4 Tests
79160	URIN SYSTEM Plus 4 Tests
79161	URIN SYSTEM Chrom 4 Tests
79560	STREPTO SYSTEM 12 R 8 Tests
79592	MYCOPLASMA SYSTEM Plus 4 Tests
79618	ENTEROSYSTEM 18R 4 Tests
79630	STAF SYSTEM 18 R 4 Tests
79670	COPRO SYSTEM 8 Tests
79675	COPRO SYSTEM Plus 4 Tests
79678	PATHOGENIC SYSTEM DOUBLE 8 Tests
79679	PATHOGENIC SYSTEM 4 Tests
79681	PATHOGENIC SYSTEM AST
79714	INTEGRAL SYSTEM ENTEROBATTERI 4 Tests
79718	INTEGRAL SYSTEM STAFILOCOCCHI 4 Tests
79720	INTEGRAL SYSTEM STREPTOCOCCHI 4 Tests
79724	INTEGRAL SYSTEM GARDNERELLA 4 Tests
79822	INTEGRAL SYSTEM YEASTS Plus 4 Tests
80009	IODINE MKTT SOLUTION 10 x 10 ml
80010	XLT 4 supplement 2 x 50 ml
80021	GLYCEROL supplement 4 x 50 ml
80022	POTASSIUM TELLURITE 1% suppl. 5 x 10 ml
80031	TWEEN 80 supplement 2 x 50 ml
80040	CHROMATIC™ SALMONELLA Supplement 2x50 ml
80047	MULLER KAUFFMANN 3X50 ml (Iodio/B.G.0.1%)
80053	VITAMIN K 1% supplement 5 x 5 ml
80056	LEGIONELLA growth supplement 10 vials
80057	H2O2 REAGENT 1 x 10 ml
80060	DECONTAM-KIT
80110	UREA 40% 6X100 ml
80219	EGG YOLK emulsion 4 x 50 ml
80252	ENTEROSYSTEM 18R REAGENT 100/200 Tests
80253	COPRO SYSTEM REAGENTS (antisera)
80257	LISTERIA SYSTEM 18R -REAG 100/200 Tests
80258	AF GENITAL SYSTEM REAGENT
80260	IDENTIF. SYSTEM-REAGENT 100/200 Tests
80271	KOVAC'S REAGENT 4x25 ml
80272	FERRIC CHLORIDE 10% 2x 25 ml
80273	NINHYDRIN 7% 10 ml
80275	MIF COLOR KIT 50 Tests
80276	ZIEHL-NEELSEN 3 x 250 ml
80277	METHYLENE BLUE Solution 250 ml
80279	VASELINE OIL 4 x 50 ml
80280	V.P. TEST-Reagent 10x10ml
80281	V.P. TEST EP 10 x 10 mL
80282	Kit May-Grünwald Giemsa
80290	SAFRANIN SOLUTION 1000 ml
80291	POTASSIUM TELLURITE 3.5% suppl.5x10 ml
80292	UREA 40 % supplement 10 x 5 ml
80293	GRAM COLOR KIT 4 x 250 ml
80294	KIT COLOR ALBERT 2 x 250 ml
80295	DECOLOURIZING SOLUTION 1000 ml
80296	LUGOL PVP SOLUTION 1000 ML
80297	SAFRANIN SOLUTION 500 ml
80298	LUGOL PVP SOLUTION 250 ml
80299	CRYSTAL VIOLET SOLUTION 1000 ml
80300	TTC 1% supplement 5 x 10 ml
80350	ANTIBIOTIC TEST
80351	RAPID ANTIBIOTIC TEST 50 Tests
80380	KINYOUN COLOR KIT 2 x 250 ml
80390	FIXUR 1
80409	IODINE SOLUTION 10 x 10 ml
80410	XLT 4 SUPPLEMENT 4 x 50 ml
80422	POTASSIUM TELLURITE 1% Supplement 10 x 10 ml
80430	TTC 1% supplement 10 x 10 ml
80431	TWEEN 80 Supplement 4 x 50 ml
80453	VITAMIN K 1% SUPPLEMENT 10 x 5 ml
80491	POTASSIUM TELLURITE 3,5% Supplement 10 x 10
81001	AMPICILLIN supplement 10 vials
81002	LEGIONELLA (BMPA) supplement 10 vials
81003	BRUCELLA supplement 10 vials
81004	CAMPYLOBACTER Preston supplem 10 vials
81006	CN (Pseudomonas) supplement 10 vials
81007	CLOSTRIDIUM difficile suppleme 10 vials
81008	LEGIONELLA (GVPC) supplement 10 vials
81009	IODINE solution 5 x 10 ml
81011	CLOSTRIDIUM perfrigens (T.S.C.) sup.10 v.

81012	LCAT supplement 10 vials
81013	BORDETELLA supplement 10 vials
81014	HAEMOPHILUS supplement 10 vials
81015	CAMPYLOBACTER Butzler supplement 10 vials
81016	BACILLUS Cereus Supplement 10 Vials
81017	CHLORAMPHENICOL supplement 10 vials
81019	LEGIONELLA (MWY) supplement 10 vials
81020	MMG Supplement 10 vials
81022	V.C.N. supplement 10 vials
81023	VITALEX growth supplement 10 vials
81024	V.C.N.T. supplement 10 vials
81025	DERMATOPHYTE supplement 10 vials
81026	LISTERIA PALCAM supplement 10 vials
81032	ONPG 1.5% Supplement 10 vials
81033	GENTAMYCIN supplement 10 vials
81035	MIDDLEBROOK 7H 10 supplement 4 x 50 ml
81036	CAMPYLOBACTER KARMALI Supplement 10 vials
81037	CAMPYLOBACTER CCDA supplement 10 vials
81038	CAMPYLOBACTER C.T.V.N. Supplement 10 vials
81039	YERSINIA supplement 10 vials
81040	GARDNERELLA vaginalis Supplement 10vials
81041	V.C.A.T. supplement 10 vials
81042	LISTERIA FRASER supplement (1125mg)10 vials
81048	CNA (Staf/Strep) supplemet 10 vials
81050	CAMPYLOBACTER growth supplement 10 vials
81051	CAMPYLOBACTER Blaser Wang supp 10 vials
81054	SCHAEDLER supplement 10 vials
81055	CAMPYLOBACTER Skirrow supple 10 vials
81056	LEGIONELLA (BCYE) growth suppl.10 vials
81062	VANCOMYCIN Supplement for VRE 10 vials
81077	CAMPYLOBACTER C.T.V.A. Supplement 10 vials
81078	CHROMATIC™ MRSA Supplement
81079	UREA-ARGININE SCREEN
81082	CEFIXIME TELLURITE Supplement
81083	MEROPENEM Supplement
81084	NEOMYCIN Solution
81085	CHROMATIC™ STAPH AUREUS Supplement
81086	VCC MOD SELECTIVE Supplement
81088	CHROMATIC™ CRE Supplement
81089	Chromatic™ ESBL Supplement
81090	CHROMATIC™ ESBL+AmpC Supplement
81091	Legionella BCYE Growth Supplement w/o L-Cysteine
83810	HORSE SERUM 1 x 100 ml
85501	COPRO KIT (SELENITE BROTH)
85502	COPRO KIT 2 (SALMONELLA BROTH)
87001	KOVAC'S Reagent
87002	VP (NaOH) Reagent
87003	CATALASE Reagent
87004	PHENYLALANINE Reagent
87005	OXIDASE Reagent
87006	Vaseline Oil
87007	VP (KOH) Reagent
87008	Lactophenol Cotton Blue Droppers
87101	GRAM COLOR KIT
88001	BETA LACTAMASE TEST 30 Tests
88003	OXIDASE TEST SWABS 30 Tests
88004	OXIDASE TEST DISCS 30 Discs
88005	O.N.P.G. TEST 30 Tests
88006	E.COLI TEST 30 Tests
88007	HIPPURATE TEST 30 Tests

88008	AESCULIN BILE TEST 30 Tests
88009	NITRATI TEST 30 Tests 30 Tests
88010	LISTERIA MONO TEST 20 Tests
88011	UREA RAPID TEST 30 Tests
88013	H2S RAPID TEST 30 Tests
88014	LYSINE DECARBOXYLASE TEST 30 Tests
88015	ORNITHINE DECARBOXYLASE TEST 30 Tests
88016	ARGININE DECARBOXYLASE TEST 30 Tests
88017	INDOLE TEST 30 Tests
88020	S F RAPID TEST 30 Tests
88021	CAMP TEST-S 30 Tests
88023	CATALASI/OXY TEST 30 Tests
88024	UREA / INDOLO TEST 30 Tests
88027	CAMP TEST-R 30 Tests
88028	PEPTIDASE A TEST 30 Tests
88029	OXIDASE TEST STICKS 50 Tests
88030	COAGULASE TEST 40 Tests
88031	GRAM TEST STICK 30 Tests
88032	INDOLO TEST STICK 30 Tests
88033	BETA LACTAMASE STICKS 30 Tests
88034	PEPTIDASE A STICKS 30 Tests
88035	VP TEST KIT
88040	C 390 50 Discs
88041	Brilliant Green 100 µg
88042	CITRATE TEST
88043	O129 Disc 150 µg
88044	O129 Disc 10 µg
88105	O.N.P.G. TEST
88201	GALACTOSE TEST 30 Tests
88202	GLUCOSE TEST 30 Tests
88203	LACTOSE TEST 30 Tests
88204	MALTOSE TEST 30 Tests
88205	RAFFINOSE TEST 30 Tests
88206	SUCROSE TEST 30 Tests
88207	ARABITOL TEST 30 Tests
88208	ADONITOL TEST 30 Tests
88209	ARABINOSE TEST 30 Tests
88210	DULCITOL TEST 30 Tests
88211	INOSITOL TEST 30 Tests
88212	INULIN TEST 30 Tests
88213	LEVULOSE TEST 30 Tests
88214	MANNITOL TEST 30 Tests
88215	MANNOSE TEST 30 Tests
88216	RHAMNOSE TEST 30 Tests
88217	SALICIN TEST 30 Tests
88218	SORBITOL TEST 30 Tests
88219	TREHALOSE TEST 30 Tests
88220	XYLOSE TEST 30 Tests
89021	CultiControl™ Aspergillus brasiliensis ATCC® 16404™
89022	CultiControl™ Bacillus Cereus ATCC® 11778™
89023	CultiControl™ Bacillus subtilis ATCC® 6633™
89024	CultiControl™ Candida albicans ATCC® 10231™
89025	CultiControl™ Enterococcus faecalis ATCC® 19433™
89026	CultiControl™ Enterococcus faecalis ATCC® 29212™
89027	CultiControl™ Escherichia coli ATCC® 25922™
89028	CultiControl™ Escherichia coli ATCC® 8739™
89029	CultiControl™ Listeria innocua ATCC® 33090™
89030	CultiControl™ Listeria ivanovii ATCC® 19119™
89031	CultiControl™ Listeria monocytogenes ATCC® 19111™
89032	CultiControl™ Proteus mirabilis ATCC® 25933™

89033	CultiControl™ Pseudomonas aeruginosa ATCC® 27853™
89034	CultiControl™ Pseudomonas aeruginosa ATCC® 9027™
89035	CultiControl™ Rhodococcus equi ATCC® 6939™
89036	CultiControl™ Saccharomyces cerevisiae ATCC® 9763™
89037	CultiControl™ Salmonella typhimurium ATCC® 14028™
89038	CultiControl™ Shigella flexneri ATCC® 12022™
89039	CultiControl™ Staphylococcus aureus NCTC 12493
89040	CultiControl™ Staphylococcus aureus ATCC® 25923™
89041	CultiControl™ Staphylococcus aureus ATCC® 29213™
89042	CultiControl™ Staphylococcus aureus ATCC® 33862™
89043	CultiControl™ Staphylococcus aureus ATCC® 43300™
89044	CultiControl™ Staphylococcus aureus ATCC® 6538™
89045	CultiControl™ Staphylococcus epidermidis ATCC® 12228™
89046	CultiControl™ Streptococcus agalactiae ATCC® 13813™
89047	CultiControl™ Streptococcus pneumoniae ATCC® 49619™
89048	CultiControl™ Streptococcus pyogenes ATCC® 19615™
89049	CultiControl™ Proteus mirabilis ATCC® 12453™
89050	CultiControl™ Yersinia enterocolitica ATCC® 9610™
89051	CultiControl™ Listeria monocytogenes ATCC® 19115™
89052	CultiControl™ Legionella pneumophila subsp. pneumophila ATCC® 33152™
89053	CultiControl™ Clostridium perfringens ATCC® 13124™
89054	CultiControl™ Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 13311™
89055	CultiControl™ Lactobacillus paracasei subsp. paracasei ATCC ® BAA-52™
89056	CultiControl™ Vibrio parahaemolyticus ATCC ® 17802™
89057	CultiControl™ Aspergillus fumigatus ATCC ® 204305™
89058	CultiControl™ Shigella sonnei ATCC ® 25931™
89059	CultiControl™ Clostridium sordellii ATCC ® 9714™
89060	CultiControl™ Listeria monocytogenes ATCC ® 7644™
89061	CultiControl™ Streptococcus bovis ATCC ® 33317™
89062	CultiControl™ Streptococcus mutans ATCC ® 25175™
89063	CultiControl™ Streptococcus pneumoniae ATCC ® 27336™
89064	CultiControl™ Streptococcus sanguinis ATCC ® 10556™
89065	CultiControl™ Enterobacter cloacae subsp. cloacae ATCC ® BAA-1143™
89066	CultiControl™ Enterococcus faecalis ATCC ® 49532™
89067	CultiControl™ Enterococcus faecalis ATCC ® 49533™
89068	CultiControl™ Escherichia coli NCTC 11954™
89069	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-2146™
89070	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 700603™
89071	CultiControl™ Candida parapsilosis ATCC ® 22019™
89072	CultiControl™ Candida albicans ATCC ® 90028™
89073	CultiControl™ Issatchenkia orientalis ATCC ® 6258™
89074	CultiControl™ Neisseria gonorrhoeae ATCC ® 19424™
89075	CultiControl™ Neisseria gonorrhoeae ATCC ® 31426™
89076	CultiControl™ Haemophilus influenzae ATCC® 49766™
89077	CultiControl™ Haemophilus influenzae ATCC® 49247™
89078	CultiControl™ Bacteroides fragilis ATCC® 25285™
89079	CultiControl™ Bacteroides thetaiotaomicron ATCC® 29741™
89080	CultiControl™ Lactobacillus acidophilus ATCC ® 4356™
89081	CultiControl™ Lactobacillus leichmannii ATCC ® 4797™
89082	CultiControl™ Lactococcus lactis ATCC ® 19435™
89083	CultiControl™ Proteus mirabilis ATCC ® 29906™
89084	CultiControl™ Salmonella enterica subsp. enterica serovar Enteritidis ATCC ® 13076™
89085	CultiControl™ Listeria monocytogenes ATCC ® 13932™
89086	CultiControl™ Campylobacter jejuni ATCC ® 33291™
89087	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-1706™
89088	CultiControl™ Klebsiella pneumoniae ATCC ® BAA-1705™
89089	CultiControl™ Klebsiella pneumoniae subsp. pneumoniae ATCC ® 13883™
89090	CultiControl™ Clostridium difficile ATCC ® 9689™
89091	CultiControl™ Aggregatibacter aphrophilus ATCC ® 7901™
89092	CultiControl™ Staphylococcus aureus subsp. aureus ATCC® 700698™
89093	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 700699™
89094	CultiControl™ Plesiomonas shigelloides ATCC ® 14029™
89095	CultiControl™ Clostridium sporogenes ATCC ® 19404™
89096	CultiControl™ Micrococcus luteus ATCC ® 10240™
89097	CultiControl™ Candida tropicalis ATCC ® 750™
89098	CultiControl™ Candida krusei ATCC ® 14243™
89099	CultiControl™ Gardnerella vaginalis ATCC ® 14018™
89100	CultiControl™ Lactobacillus fermentum ATCC ® 9338™
89101	CultiControl™ Listeria grayi ATCC ® 25401™
89102	CultiControl™ Micrococcus luteus ATCC ® 4698™
89103	CultiControl™ Moraxella (Branhamella) catarrhalis ATCC ® 25238™
89104	CultiControl™ Neisseria gonorrhoeae ATCC ® 49226™
89105	CultiControl™ Proteus mirabilis ATCC ® 35659™
89106	CultiControl™ Proteus mirabilis ATCC ® 43071™
89107	CultiControl™ Proteus vulgaris ATCC ® 6380™
89108	CultiControl™ Pseudomonas aeruginosa ATCC ® 10145™
89109	CultiControl™ Pseudomonas aeruginosa ATCC ® 15442™
89110	CultiControl™ Pseudomonas fluorescens ATCC ® 13525™
89111	CultiControl™ Bacteroides ovatus ATCC ® 8483™
89112	CultiControl™ Clostridium histolyticum ATCC ® 19401™
89113	CultiControl™ Bacteroides fragilis ATCC ® 23745™
89114	CultiControl™ Actinomyces odontolyticus ATCC ® 17929™
89115	CultiControl™ Enterococcus faecalis ATCC ® 33186™
89116	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 33591™
89117	CultiControl™ Enterococcus faecium ATCC ® 51559™
89118	CultiControl™ Fusobacterium nucleatum ATCC ® 25586™
89119	CultiControl™ Aeromonas hydrophila ATCC ® 7966™
89120	CultiControl™ Haemophilus influenzae ATCC ® 10211™
89121	CultiControl™ Serratia marcescens ATCC ® 8100™
89122	CultiControl™ Neisseria gonorrhoeae ATCC ® 49981™
89123	CultiControl™ Haemophilus haemolyticus ATCC ® 33390™
89124	CultiControl™ Haemophilus influenzae ATCC ® 33533™
89125	CultiControl™ Providencia stuartii ATCC ® 33672™
89126	CultiControl™ Staphylococcus haemolyticus ATCC ® 29970™
89127	CultiControl™ Streptococcus anginosus ATCC ® 33397™
89128	CultiControl™ Streptococcus dysgalactiae subsp.equisimilis ATCC ® 12388™
89129	CultiControl™ Streptococcus mitis ATCC ® 6249™
89130	CultiControl™ Streptococcus pyogenes ATCC ® 49399™
89131	CultiControl™ Streptococcus salivarius ATCC® 13419™
89132	CultiControl™ Salmonella enterica subsp. enterica serovar Abony NCTC 6017
89133	CultiControl™ Staphylococcus xylosus ATCC ® 29971™
89135	CultiControl™ Propionibacterium acnes ATCC® 11827™
89136	CultiControl™ Haemophilus influenzae NCTC 8468
89137	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® 19095™
89138	CultiControl™ Cronobacter sakazakii ATCC ® 29544™
89139	CultiControl™ Bordetella bronchiseptica ATCC ® 4617™
89140	CultiControl™ Trichophyton mentagrophytes ATCC ® 9533™

89141	CultiControl™ Acinetobacter baumannii ATCC ® BAA-747™
89144	CultiControl™ Vibrio alginolyticus ATCC ® 17749™
89145	CultiControl™ Campylobacter jejuni subsp. jejuni ATCC ® 33560™
89146	CultiControl™ Citrobacter freundii ATCC ® 43864™
89147	CultiControl™ Burkholderia cepacia ATCC ® 25416™
89148	CultiControl™ Listeria monocytogenes ATCC ® 35152™
89149	CultiControl™ Stenotrophomonas maltophilia ATCC® 13637™
89151	CultiControl™ Legionella pneumophila subsp. fraseri ATCC ® 33156™
89152	CultiControl™ Enterococcus faecium ATCC ® 6057™
89154	CultiControl™ Salmonella enterica subsp. arizonae ATCC ® 13314™
89156	CultiControl™ Enterobacter aerogenes ATCC ® 13048™
89160	CultiControl™ Haemophilus influenzae ATCC ® 19418™
89163	CultiControl™ Escherichia coli ATCC ® 35218™
89164	CultiControl™ Neisseria meningitidis ATCC ® 13090™
89165	CultiControl™ Peptostreptococcus anaerobius ATCC ® 27337™
89170	CultiControl™ Staphylococcus aureus subsp. aureus ATCC ® BAA-44™
89171	CultiControl™ Enterococcus faecium ATCC ® 19434™
89172	CultiControl™ Enterococcus faecium ATCC ® BAA-2319™
89173	CultiControl™ Enterococcus faecalis ATCC ® 51299™
89174	CultiControl™ Acinetobacter baumannii ATCC ® 19606™
89175	CultiControl™ Streptococcus pneumoniae ATCC ® 700671™
89176	CultiControl™ Haemophilus influenzae ATCC ® 33391™
89177	CultiControl™ Candida albicans ATCC ® 18804™
89178	CultiControl™ Candida albicans ATCC ® 64124™
9001	NALIDIXIC ACID NA 30 µg 250 Discs
9001/1	NALIDIXIC ACID NA 30 µg 50 Discs
9002	Oxolinic acid OA 2 µg 250 Discs
9002/1	Oxolinic acid OA 2 µg 50 Discs
9003	PIPEMIDIC ACID PI 20 µg 250 Discs
9003/1	PIPEMIDIC ACID PI 20 µg 50 Discs
9004	AMIKACIN AK 30 µg 250 Discs
9004/1	AMIKACIN AK 30 µg 50 Discs
9005	AMOXICILLIN AML 30 µg 250 Discs
9005/1	AMOXICILLIN AML 30 µg 50 Discs
9006	AMPICILLIN AMP 10 µg 250 Discs
9006/1	AMPICILLIN AMP 10 µg 50 Discs
9007	AZLOCILLIN AZL 75 µg 250 Discs
9007/1	AZLOCILLIN AZL 75 µg 50 Discs
9008	AZTREONAM ATM 30 µg 250 Discs
9008/1	AZTREONAM ATM 30 µg 50 Discs
9009	CARBENICILLIN CAR 100 µg 250 Discs
9009/1	CARBENICILLIN CAR 100 µg 50 Discs
9010	CEFACLOR CEC 30 µg 250 Discs
9010/1	CEFACLOR CEC 30 µg 50 Discs
9011	CEPHALEXIN CL 30 µg 250 Discs
9011/1	CEPHALEXIN CL 30 µg 50 Discs
9013	CEPHALOTHIN KF 30 µg 250 Discs
9013/1	CEPHALOTHIN KF 30 µg 50 Discs
9014	CEFAMANDOLE MA 30 µg 250 Discs
9014/1	CEFAMANDOLE MA 30 µg 50 Discs
9015	CEFAZOLIN KZ 30 µg 250 Discs
9015/1	CEFAZOLIN KZ 30 µg 50 Discs
9016	CEFOPERAZONE CFP 30 µg 250 Discs
9016/1	CEFOPERAZONE CFP 30 µg 50 Discs
9017	CEFOTAXIME CTX 30 µg 250 Discs
9017/1	CEFOTAXIME CTX 30 µg 50 Discs
9018	CEFOXITIN FOX 30 µg 250 Discs
9018/1	CEFOXITIN FOX 30 µg 50 Discs
9019	CEFTAZIDIME CAZ 30 µg 250 Discs
9019/1	CEFTAZIDIME CAZ 30 µg 50 Discs
9020	CEFTRIAXONE CRO 30 µg 250 Discs
9020/1	CEFTRIAXONE CRO 30 µg 50 Discs
9021	CEFUROXIME CXM 30 µg 250 Discs
9021/1	CEFUROXIME CXM 30 µg 50 Discs
9022	CHLORAMPHENICOL C 30 µg 250 Discs
9022/1	CHLORAMPHENICOL C 30 µg 50 Discs
9023	COLISTIN SULFATE CS 10 µg 250 Discs
9023/1	COLISTIN SULFATE CS 10 µg 50 Discs
9024	ERYTHROMYCIN E 15 µg 250 Discs
9024/1	ERYTHROMYCIN E 15 µg 50 Discs
9025	FOSFOMYCIN FOS 50 µg 250 Discs
9025/1	FOSFOMYCIN FOS 50 µg 50 Discs
9026	GENTAMICIN CN 10 µg 250 Discs
9026/1	GENTAMICIN CN 10 µg 50 Discs
9027	KANAMYCIN K 30 µg 250 Discs
9027/1	KANAMYCIN K 30 µg 50 Discs
9028	LINCOMYCIN MY 2 µg 250 Discs
9028/1	LINCOMYCIN MY 2 µg 50 Discs
9029	METHICILLIN MET 5 µg 250 Discs
9029/1	METHICILLIN MET 5 µg 50 Discs
9030	MINOCYCLINE MN 30 µg 250 Discs
9030/1	MINOCYCLINE MN 30 µg 50 Discs
9031	AMPICILLIN-SULBACTAM AMS 20 µg 250 Discs
9031/1	AMPICILLIN-SULBACTAM AMS 20µg 50 DISCS
9032	NEOMYCIN N 30 µg 250 Discs
9032/1	NEOMYCIN N 30 µg 50 Discs
9033	NETILMICIN NET 30 µg 250 Discs
9033/1	NETILMICIN NET 30 µg 50 Discs
9034	NITROFURANTOIN F 300 µg 250 Discs
9034/1	NITROFURANTOIN F 300 µg 50 Discs
9035	NORFLOXACIN NOR 10µg 250 Discs
9035/1	NORFLOXACIN NOR 10 µg 50 Discs
9036	OXACILLIN OX 1µg 250 Discs
9036/1	OXACILLIN OX 1 µg 50 Discs
9037	PENICILLIN G P 10 IU 250 Discs
9037/1	PENICILLIN G P 10 IU 50 Discs
9038	PIPERACILLIN PRL 100 µg 250 Discs
9038/1	PIPERACILLIN PRL 100 µg 50 Discs
9039	RIFAMPICIN RD 30 µg 250 Discs
9039/1	RIFAMPICIN RD 30 µg 50 Discs
9040	STREPTOMYCIN S 10 µg 250 Discs
9040/1	STREPTOMYCIN S 10 µg 50 Discs
9041	SULFAFURAZOLE SF 300 µg 250 Discs
9041/1	SULFAFURAZOLE SF 300 µg 50 Discs
9042	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 250 Discs
9042/1	TRIMETHOPRIM-SULFAMETHOXAZOLE SXT 25 µg 50 Discs
9043	TETRACYCLINE TE 30 µg 250 Discs
9043/1	TETRACYCLINE TE 30 µg 50 Discs
9044	TOBRAMYCIN TOB 10 µg 250 Discs
9044/1	TOBRAMYCIN TOB 10 µg 50 Discs
9045	VANCOMYCIN VA 30 µg 250 Discs
9045/1	VANCOMYCIN VA 30 µg 50 Discs
9046	SISOMYCIN SIS 30µg 250 Discs
9046/1	SISOMYCIN SIS 30 µg 50 Discs
9047	CLINDAMYCIN CD 2 µg 250 Discs
9047/1	CLINDAMYCIN CD 2 µg 50 Discs

9048	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 250 Discs
9048/1	AMOXICILLIN-CLAVULANIC ACID AUG 30 µg 50 Discs
9049	FUSIDIC ACID FC 10 µg 250 Discs
9049/1	FUSIDIC ACID FC 10 µg 50 Discs
9050	TEICOPLANIN TEC 30 µg 250 Discs
9050/1	TEICOPLANIN TEC 30 µg 50 Discs
9051	BACITRACIN BA 10 IU 250 Discs
9051/1	BACITRACIN BA 10 IU 50 Discs
9052	CEFADROXIL CDX 30 µg 250 Discs
9052/1	CEFADROXIL CDX 30 µg 50 Discs
9053	CEFSULODIN CSD 30 µg 250 Discs
9053/1	CEFSULODIN CSD 30 µg 50 Discs
9054	CEFTIZOXIME CZX 30 µg 250 Discs
9054/1	CEFTIZOXIME CZX 30 µg 50 Discs
9055	CEPHRADINE CE 30 µg 250 Discs
9055/1	CEPHRADINE CE 30 µg 50 Discs
9056	CIPROFLOXACIN CIP 5 µg 250 Discs
9056/1	CIPROFLOXACIN CIP 5 µg 50 Discs
9057	CINOXACIN CIN 100 µg 250 Discs
9057/1	CINOXACIN CIN 100 µg 50 Discs
9058	CLOXACILLIN CX 5 µg 250 Discs
9058/1	CLOXACILLIN CX 5 µg 50 Discs
9059	DOXYCYCLINE DXT 30 µg 250 Discs
9059/1	DOXYCYCLINE DXT 30 µg 50 Discs
9060	ROXITROMYCIN RXT 15 µg 250 Discs
9060/1	ROXITROMYCIN RXT 15 µg 50 Discs
9061	ERTAPENEM ETP 10 µg 250 Discs
9061/1	ERTAPENEM ETP 10 µg 50 Discs
9062	MEZLOCILLIN MEZ 75 µg 250 Discs
9062/1	MEZLOCILLIN MEZ 75 µg 50 Discs
9063	NOVOBIOCIN NO 30 µg 250 Discs
9063/1	NOVOBIOCIN NO 30 µg 50 Discs
9064	CEFPODOXIME PX 10 ug 250 Discs
9064/1	CEFPODOXIME PX 10 ug 50 Discs
9065	OXYTETRACYCLINE OT 30 µg 250 Discs
9065/1	OXYTETRACYCLINE OT 30 µg 50 Discs
9066	POLYMYXIN B PB 100 IU 250 Discs
9066/1	POLYMYXIN B PB 100 IU 50 Discs
9067	SPECTINOMYCIN SPC 100 µg 250 Discs
9067/1	SPECTINOMYCIN SPC 100 µg 50 Discs
9068	MEROPENEM MRP 10 µg 250 Discs
9068/1	MEROPENEM MRP 10 µg 50 Discs
9069	FLUCONAZOLE FLU 100 µg 250 Discs
9069/1	FLUCONAZOLE FLU 100 µg 50 Discs
9070	TICARCILLIN TC 75 µg 250 Discs
9070/1	TICARCILLIN TC 75 µg 50 Discs
9071	AMPHOTERICIN B AMB 20 µg 250 Discs
9071/1	AMPHOTERICIN B AMB 20 µg 50 Discs
9072	ECONAZOLE ECN 10 µg 250 Discs
9072/1	ECONAZOLE ECN 10 µg 50 Discs
9073	FLUCYTOSINE AFY 1 µg 250 Discs
9073/1	FLUCYTOSINE AFY 1 µg 50 Discs
9074	GRISEOFULVIN AGF 10 µg 250 Discs
9074/1	GRISEOFULVIN AGF 10 µg 50 Discs
9075	KETOCONAZOLE KCA 10 µg 250 Discs
9075/1	KETOCONAZOLE KCA 10 µg 50 Discs
9076	METRONIDAZOLE MTZ 5 µg 250 Discs
9076/1	METRONIDAZOLE MTZ 5 µg 50 Discs
9077	MICONAZOLE MCL 10 µg 250 Discs
9077/1	MICONAZOLE MCL 10 µg 50 Discs

9078	NYSTATIN NY 100 IU 250 Discs
9078/1	NYSTATIN NY 100 IU 50 Discs
9079	IMIPENEM IMI 10 µg 250 Discs
9079/1	IMIPENEM IMI 10 µg 50 Discs
9080	OFLOXACIN OFX 5 µg 250 Discs
9080/1	OFLOXACIN OFX 5 µg 50 Discs
9081	CEFOTETAN CTT 30 µg 250 Discs
9081/1	CEFOTETAN CTT 30 µg 50 Discs
9082	TYLOSIN TY 30 µg 250 Discs
9082/1	TYLOSIN TY 30 µg 50 Discs
9083	TRIMETHOPRIM TM 2.5 µg 250 Discs
9083/1	TRIMETHOPRIM TM 2.5 µg 50 Discs
9084	SULFAMETHOXAZOLE SMX 50 µg 250 Discs
9084/1	SULFAMETHOXAZOLE SMX 50µg 50 Discs
9085	Imipenem + Phenylboronic acid IMI + BO 250 Discs
9085/1	Imipenem + Phenylboronic acid IMI + BO 50 Discs
9086	Imipenem + Cloxacillin IMI + CL 250 Discs
9086/1	Imipenem + Cloxacillin IMI + CL 50 Discs
9087	EDTA ED 250 Discs
9087/1	EDTA ED 50 Discs
9088	SPIRAMYCIN SP 100 µg 250 Discs
9088/1	SPIRAMYCIN SP 100 µg 50 Discs
9089	CEFIXIME CFM 5 µg 250 Discs
9089/1	CEFIXIME CFM 5 µg 50 Discs
9090	Daptomycin DAP 30 µg 250 Discs
9090/1	Daptomycin DAP 30 µg 50 Discs
9091	PEFLOXACIN PEF 5 µg 250 Discs
9091/1	PEFLOXACIN PEF 5 µg 50 Discs
9093	DICLOXACILLIN DCX 1 µg 250 Discs
9093/1	DICLOXACILLIN DCX 1 µg 50 Discs
9094	TIAMULIN T 30 µg 250 Discs
9094/1	TIAMULIN T 30 µg 50 Discs
9095	IMIPENEM/CILASTATIN IMC 20 µg 250 Discs
9095/1	IMIPENEM/CILASTATIN IMC 20 µg 50 Discs
9096	TICARCILLIN-CLAVULINC ACID TTC 85 µg 250 Discs
9096/1	TICARCILLIN-CLAVULINC ACID TTC 85 µg 50 Discs
9097	CLOTRIMAZOLE CLO 50 µg 250 Discs
9097/1	CLOTRIMAZOLE CLO 50 µg 50 Discs
9098	CLARITHROMYCIN CLR 15 µg 250 Discs
9098/1	CLARITHROMYCIN CLR 15 µg 50 Discs
9099	FURAZOLIDON FR 50 µg 250 Discs
9099/1	FURAZOLIDON FR 50 µg 50 Discs
9100	PIPERACILLIN-TAZOBACTAM TZP 110 µg 250 Discs
9100/1	PIPERACILLIN-TAZOBACTAM TZP 110 µg 50 Disc
9101	CEFTIBUTEN CTB 30 µg 250 Discs
9101/1	CEFTIBUTEN CTB 30 µg 50 Discs
9102	LEVOFLOXACIN LEV 5 µg 250 Discs
9102/1	LEVOFLOXACIN LEV 5 µg 50 Discs
9103	MOXIFLOXACIN MOX 5 µg 250 Discs
9103/1	MOXIFLOXACIN MOX 5 µg 50 Discs
9104	CEFEPIME FEP 30 µg 250 Discs
9104/1	CEFEPIME FEP 30 µg 50 Discs
9105	AZITHROMYCIN AZM 15 µg 250 Discs
9105/1	AZITHROMYCIN AZM 15 µg 50 Discs
9106	MYOKAMYCIN MK 15 µg 250 Discs
9106/1	MYOKAMYCIN MK 15 µg 50 Discs
9107	ITRACONAZOLE ITC 50 µg 250 Discs
9107/1	ITRACONAZOLE ITC 50 µg 50 Discs
9108	CEFOPERAZONE CFP 75 µg 250 Discs
9108/1	CEFOPERAZONE CFP 75 µg 50 Discs

9109	FOSFOMYCIN (includes G-6-p) FOS 200 µg 250 Discs
9109/1	FOSFOMYCIN (includes G-6-p) FOS 200 µg 50 Discs
9110	TRIMETHOPRIM TM 5 µg 250 Discs
9110/1	TRIMETHOPRIM TM 5 µg 50 Discs
9111	FUSIDIC ACID FC 30 µg 250 Discs
9111/1	FUSIDIC ACID FC 30 µg 50 Discs
9112	CEFPROZIL CPR 30 µg 250 Discs
9112/1	CEFPROZIL CPR 30 µg 50 Discs
9113	LOMEFLOXACIN LOM 10 µg 250 Discs
9113/1	LOMEFLOXACIN LOM 10 µg 50 Discs
9115	AMPICILLIN AMP 2 µg 250 Discs
9115/1	AMPICILLIN AMP 2 µg 50 Discs
9116	LINCOMYCIN MY 15 µg 250 Discs
9116/1	LINCOMYCIN MY 15 µg 50 Discs
9117	NOVOBIOCIN NO 5 µg 250 Discs
9117/1	NOVOBIOCIN NO 5 µg 50 Discs
9118	RIFAMPICIN RD 5 µg 250 Discs
9118/1	RIFAMPICIN RD 5µg 50 Discs
9119	METRONIDAZOLE MTZ 50 µg 250 Discs
9119/1	METRONIDAZOLE MTZ 50 µg 50 Discs
9120	POLYMYXIN B PB 300 UI 250 Discs
9120/1	POLYMYXIN B PB 300 UI 50 Discs
9121	FOSFOMYCIN (includes G-6-p) FOS 100 µg 250 Discs
9121/1	FOSFOMYCIN (includes G-6-p) FOS 100 µg 50 Discs
9122	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 250 Discs
9122/1	AMPLICLOX (Ampicillin-Cloxacillin) ACL 30 µg 50 Discs
9124	GENTAMICIN CN 120 µg 250 Discs
9124/1	GENTAMICIN CN 120 µg 50 Discs
9125	GENTAMICIN CN 30 µg 250 Discs
9125/1	GENTAMICIN CN 30 µg 50 Discs
9126	SULFONAMIDE S3 300 µg 250 Discs
9126/1	SULFONAMIDE S3 300 µg 50 Discs
9127	PENICILLIN G P 2 IU 250 Discs
9127/1	PENICILLIN G P 2 IU 50 Discs
9128	CHLORAMPHENICOL C 10 µg 250 Discs
9128/1	CHLORAMPHENICOL C 10 µg 50 Discs
9129	SULBACTAM SU 20µg 250 Discs
9129/1	SULBACTAM SU 20µg 50 Discs
9130	PENICILLIN G P 1 IU 250 Discs
9130/1	PENICILLIN G P 1 IU 50 Discs
9131	SODIUM FUSIDATE FC 30 250 Discs
9132	SULFAPRIM SXT 50 µg 250 Discs
9132/1	SULFAPRIM SXT 50 µg 50 Discs
9133	AMOXICILLIN AML 10 µg 250 Discs
9133/1	AMOXICILLIN AML 10 µg 50 Discs
9134	CEFOTAXIME CTX 75 µg 250 Discs
9134/1	CEFOTAXIME CTX 75 µg 50 Discs
9135	OXACILLIN OX 5µg 250 Discs
9135/1	OXACILLIN OX 5µg 50 Discs
9136	LINEZOLID LNZ 30µg 250 Discs
9136/1	LINEZOLID LNZ 30µg 50 Discs
9137	AMPHOTERICIN B AMB 10 µg 250 Discs
9137/1	AMPHOTERICIN B AMB 10 µg 50 Discs
9139	ITRACONAZOLE ITC 8 µg 250 Discs
9139/1	ITRACONAZOLE ITC 8 µg 50 Discs
9140	KETOCONAZOLE KCA 15 µg 250 Discs
9140/1	KETOCONAZOLE KCA 15 µg 50 Discs
9141	COLISTIN SULFATE CS 30 UI 250 Discs
9141/1	COLISTIN SULFATE CS 30 UI 50 Discs
9142	STREPTOMYCIN S 300 µg 250 Discs
9142/1	STREPTOMYCIN S 300 µg 50 Discs
9143	CEFEPIME+CLAVULANIC ACID FEL 40 µg 250 Discs
9144	Cefoxitin+Cloxacillin FOC 230 µg 250 Discs
9144/1	Cefoxitin+Cloxacillin FOC 230 µg 50 Discs
9145	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 250 Discs
9145/1	CEFTAZIDIME+CLAVULANIC ACID CAL 40 µg 50 Discs
9146	CLINDAMYCIN CD 10 µg 250 Discs
9146/1	CLINDAMYCIN CD 10 µg 50 Discs
9147	TIGECYCLIN TGC 15 µg 250 Discs
9147/1	TIGECYCLIN TGC 15 µg 50 Discs
9148	FLUCYTOSINE AFY 10 µg 250 Discs
9148/1	FLUCYTOSINE AFY 10 µg 50 Discs
9150	SULFADIAZINE SUZ 300 ug 250 Discs
9150/1	SULFADIAZINE SUZ 300 ug 50 Discs
9151	AMOXICILLIN AML 2 µg 250 Discs
9151/1	AMOXICILLIN AML 2 µg 50 Discs
9152	CEFOTAXIME CTX 5 µg 250 Discs
9152/1	CEFOTAXIME CTX 5 µg 50 Discs
9153	CEFTAZIDIME CAZ 10 µg 250 Discs
9153/1	CEFTAZIDIME CAZ 10 µg 50 Discs
9154	DORIPENEM DOR 10 µg 250 Discs
9154/1	DORIPENEM DOR 10 µg 50 Discs
9155	LINEZOLID LNZ 10 µg 250 Discs
9155/1	LINEZOLID LNZ 10 µg 50 Discs
9156	MECILLINAM MEC 10 µg 250 Discs
9156/1	MECILLINAM MEC 10 µg 50 Discs
9157	MUPIROCIN MUP 200 µg 250 Discs
9157/1	MUPIROCIN MUP 200 µg 50 Discs
9158	NITROFURANTOIN F 100 µg 250 Discs
9158/1	NITROFURANTOIN F 100 µg 50 Discs
9159	PIPERACILLIN PRL 30 µg 250 Discs
9159/1	PIPERACILLIN PRL 30 µg 50 Discs
9160	PIPERACILLIN-TAZOBACTAM TZP 36 µg 250 Discs
9160/1	PIPERACILLIN-TAZOBACTAM TZP 36 µg 50 Discs
9161	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 250 Discs
9161/1	QUINUPRISTIN-DALFOPRISTIN QDA 15 µg 50 Discs
9162	STREPTOMYCIN S 300 µg 250 Discs
9162/1	STREPTOMYCIN S 300 µg 50 Discs
9163	TOBRAMYCIN TOB 30 ug 250 Discs
9163/1	TOBRAMYCIN TOB 30 ug 50 Discs
9164	VANCOMYCIN VA 5 µg 250 Discs
9164/1	VANCOMYCIN VA 5 µg 50 Discs
9165	CASPOFUNGIN CAS 5 µg 250 Discs
9165/1	CASPOFUNGIN CAS 5 µg 50 Discs
9166	FLUCONAZOLE FLU 25 µg 250 Discs
9166/1	FLUCONAZOLE FLU 25 µg 50 Discs
9167	POSACONAZOLE POS 5 µg 250 Discs
9167/1	POSACONAZOLE POS 5 µg 50 Discs
9168	VORICONAZOLE VO 1 µg 250 Discs
9168/1	VORICONAZOLE VO 1 µg 50 Discs
9169	GATIFLOXACIN GAT 5 µg 250 Discs
9169/1	GATIFLOXACIN GAT 5 µg 50 Discs
9170	NETILMICIN NET 10 µg 250 Discs
9170/1	NETILMICIN NET 10 µg 50 Discs
9171	PHENOXYMETHYLPENICILLIN PV 10 µg 250 Discs
9171/1	PHENOXYMETHYLPENICILLIN PV 10 µg 50 Discs
9172	TELITHROMYCIN TEL 15 µg 250 Discs
9172/1	TELITHROMYCIN TEL 15 µg 50 Discs
9173	LORACARBEF LOR 30 µg 250 Discs
9173/1	LORACARBEF LOR 30 µg 50 Discs

9174	NAFCILLIN NAF 1 µg 250 Discs
9174/1	NAFCILLIN NAF 1 µg 50 Discs
9175	MEROPENEM+CLOXACILLIN MR+CL 250 Discs
9175/1	MEROPENEM+CLOXACILLIN MR+CL 50 Discs
9176	Meropenem + Phenylboronic acid MR + BO 250 Discs
9176/1	Meropenem + Phenylboronic acid MR + BO 50 Discs
9177	MEROPENEM+DIPICOLINIC ACID MR+DP 250 Discs
9177/1	MEROPENEM+DIPICOLINIC ACID MR+DP 50 Discs
9178	Meropenem + EDTA MR + ED 250 Discs
9178/1	Meropenem + EDTA MR + ED 50 Discs
9179	AMOXICILLIN AML 25 µg 250 Discs
9179/1	AMOXICILLIN AML 25 µg 50 Discs
9181	NITROFURANTOIN F 50 µg 250 Discs
9181/1	NITROFURANTOIN F 50 µg 50 Discs
9182	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 250 Discs
9182/1	CEFOTAXIME+CLAVULANIC ACID CTL 40 µg 50 Discs
9183	Imipenem + EDTA IMI + ED 250 Discs
9183/1	Imipenem + EDTA IMI + ED 50 Discs
9184	COLISTIN SULFATE CS 25 µg 250 Discs
9184/1	COLISTIN SULFATE CS 25 µg 50 Discs
9185	CEFPIROME CR 30 µg 250 Discs
9185/1	CEFPIROME CR 30 µg 50 Discs
9186	TEMOCILLIN TMO 30 µg 250 Discs
9186/1	TEMOCILLIN TMO 30 µg 50 Discs
9187	Sulfamethoxazole SMX 100 µg 250 Discs
9187/1	Sulfamethoxazole SMX 100 µg 50 Discs
9188	Metronidazole MTZ 10 µg 250 Discs
9188/1	Metronidazole MTZ 10 µg 50 Discs
9189	MUPIROCIN MUP 5 µg 250 Discs
9190	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 250 Discs
9190/1	CEFPODOXIME+CLAVULANIC ACID PXL 11 µg 50 Discs
9191	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 250 Discs
9191/1	AMOXICILLIN-CLAVULANIC ACID AUG 3 µg 50 Discs
9192	ROKITAMYCIN ROK 30 µg 250 Discs
9192/1	ROKITAMYCIN ROK 30 µg 50 Discs
9193	Phenylboronic acid BO 250 Discs
9193/1	Phenylboronic acid BO 50 Discs
9194	DIPICOLINIC ACID DP 250 Discs
9194/1	DIPICOLINIC ACID DP 50 Discs
9195	CEFTAROLINE CPT 5 µg 250 Discs
9195/1	CEFTAROLINE CPT 5 µg 50 Discs
9198	CEFTAROLINE CPT 30 µg 250 Discs
9198/1	CEFTAROLINE CPT 30 µg 50 Discs
9199	ERTAPENEM+CLOXACILLIN ET+CL 250 Discs
9199/1	ERTAPENEM+CLOXACILLIN ET+CL 50 Discs
9201	ORITAVANCIN ORI 25 µg 250 Discs
9201/1	ORITAVANCIN ORI 25 µg 50 Discs
9202	Ertapenem+Phenylboronic acid ET+BO 250 Discs
9202/1	Ertapenem+Phenylboronic acid ET+BO 50 Discs
9203	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 250 Discs
9203/1	Cefotaxime+Clavulanic acid+Cloxacillin CTLC 50 Discs
9204	Ceftazidime+Clavulanic acid+Cloxacillin CALC 250 Discs
9204/1	Ceftazidime+Clavulanic acid+Cloxacillin CALC 50 Discs
9205	Ceftazime-avibactam CZA 50 µg 250 Discs
9205/1	Ceftazime-avibactam CZA 50 µg 50 Discs
9206	Ceftazime-avibactam CZA 14 µg 250 Discs
9206/1	Ceftazime-avibactam CZA 14 µg 50 Discs
9207	Ulifloxacin ULI 5 µg 250 Discs
9207/1	Ulifloxacin ULI 5 µg 50 Discs

91200	DISC DISPENSER 8 CARTRIDGES
91203	DISC DISPENSER 6 CARTRIDGES
92000	AMOX*/SULB 2/1 AXS 0.016-256* 30 MIC Tests
920000	AMOX*/SULB 2/1 AXS 0.016-256* 100 MIC Tests
92001	RIFAMPICIN RD 0.002-32 30 MIC Tests
920010	RIFAMPICIN RD 0.002-32 100 MIC Tests
920011	RIFAMPICIN RD 0.002-32 10 MIC Tests
92002	FUSIDIC ACID FU 0.016-256 30 MIC Tests
920020	FUSIDIC ACID FU 0.016-256 100 MIC Tests
920021	FUSIDIC ACID FU 0.016-256 10 MIC Tests
92003	AMPICILLIN AMP 0.016-256 30 MIC Tests
920030	AMPICILLIN AMP 0.016-256 100 MIC Tests
920031	AMPICILLIN AMP 0.016-256 10 MIC Tests
92004	POLYMYXIN B PB 0.064-1024 30 MIC Tests
920040	POLYMYXIN B PB 0.064-1024 100 MIC Tests
920041	POLYMYXIN B PB 0.064-1024 10 MIC Tests
92005	CEFPODOXIME PX 0.016-256 30 MIC Tests
920050	CEFPODOXIME PX 0.016-256 100 MIC Tests
920051	CEFPODOXIME PX 0.016-256 10 MIC Tests
92006	CEFOTAXIME CTX 0.016-256 30 MIC Tests
920060	CEFOTAXIME CTX 0.016-256 100 MIC Tests
920061	CEFOTAXIME CTX 0.016-256 10 MIC Tests
92007	CEFOTAXIME CTX 0.002-32 30 MIC Tests
920070	CEFOTAXIME CTX 0.002-32 100 MIC Tests
920071	CEFOTAXIME CTX 0.002-32 10 MIC Tests
92008	CEFPIROME CR 0.016-256 30 MIC Tests
920080	CEFPIROME CR 0.016-256 100 MIC Tests
920081	CEFPIROME CR 0.016-256 10 MIC Tests
92009	GENTAMICIN CN 0.016-256 30 MIC Tests
920090	GENTAMICIN CN 0.016-256 100 MIC Tests
920091	GENTAMICIN CN 0.016-256 10 MIC Tests
92010	GENTAMICIN CN 0.064-1024 30 MIC Tests
920100	GENTAMICIN CN 0.064-1024 100 MIC Tests
920101	GENTAMICIN CN 0.064-1024 10 MIC Tests
92011	GATIFLOXACIN GAT 0.002-32 30 MIC Tests
920110	GATIFLOXACIN GAT 0.002-32 100 MIC Tests
920111	GATIFLOXACIN GAT 0.002-32 10 MIC Tests
92012	TEICOPLANIN TEC 0.016-256 30 MIC Tests
920120	TEICOPLANIN TEC 0.016-256 100 MIC Tests
920121	TEICOPLANIN TEC 0.016-256 10 MIC Tests
92013	ENROFLOXACIN ENR 0.002-32 30 MIC Tests
920130	ENROFLOXACIN ENR 0.002-32 100 MIC Tests
920131	ENROFLOXACIN ENR 0.002-32 10 MIC Tests
92014	SPECTINOMYCIN SPC 0.064-1024 30 MIC Tests
920140	SPECTINOMYCIN SPC 0.064-1024 100 MIC Tests
920141	SPECTINOMYCIN SPC 0.064-1024 10 MIC Tests
92015	OXACILLIN OX 0.016-256 30 MIC Tests
920150	OXACILLIN OX 0.016-256 100 MIC Tests
920151	OXACILLIN OX 0.016-256 10 MIC Tests
92016	CEFTIZOXIME CZX 0.016-256 30 MIC Tests
920160	CEFTIZOXIME CZX 0.016-256 100 MIC Tests
920161	CEFTIZOXIME CZX 0.016-256 10 MIC Tests
92017	MECILLINAM MEC 0.002-32 30 MIC Tests
920170	MECILLINAM MEC 0.002-32 100 MIC Tests
920171	MECILLINAM MEC 0.002-32 10 MIC Tests
92018	AMIKACIN AK 0.016-256 30 MIC Tests
920180	AMIKACIN AK 0.016-256 100 MIC Tests
920181	AMIKACIN AK 0.016-256 10 MIC Tests
92019	BACITRACIN BA 0.016-256 30 MIC Tests
920190	BACITRACIN BA 0.016-256 100 MIC Tests

920191	BACITRACIN BA 0.016-256 10 MIC Tests
92020	CEFOTETAN CTT 0.016-256 30 MIC Tests
920200	CEFOTETAN CTT 0.016-256 100 MIC Tests
920201	CEFOTETAN CTT 0.016-256 10 MIC Tests
92021	AMOXICILLIN AML 0.016-256 30 Tests
920210	AMOXICILLIN AML 0.016-256 100 MIC Tests
920211	AMOXICILLIN AML 0.016-256 10 MIC Tests
92022	NITROFURANTOIN F 0.032-512 30 MIC Tests
920220	NITROFURANTOIN F 0.032-512 100 MIC Tests
920221	NITROFURANTOIN F 0.032-512 10 MIC Tests
92023	CEFOB*/SULB 2/1 CPS 0.016-256* 30 MIC Tests
920230	CEFOB*/SULB 2/1 CPS 0.016-256* 100 MIC Tests
920231	CEFOB*/SULB 2/1 CPS 0.016-256* 10 MIC Tests
92024	AMOX*/CLAV 2/1 AMG 0.016-256* 30 MIC Tests
920240	AMOX*/CLAV 2/1 AMG 0.016-256* 100 MIC Tests
920241	AMOX*/CLAV 2/1 AMG 0.016-256* 10 MIC Tests
92025	RIFAMPICIN RD 0.016-256 30 MIC Tests
920250	RIFAMPICIN RD 0.016-256 100 MIC Tests
920251	RIFAMPICIN RD 0.016-256 10 MIC Tests
92026	QUIN-DALFOPRIST QDA 0.002-32 30 MIC Tests
920260	QUIN-DALFOPRIST QDA 0.002-32 100 MIC Tests
920261	QUIN-DALFOPRIST QDA 0.002-32 10 MIC Tests
92027	AMPIC*/SULB 2/1 AMS 0.016-256* 30 MIC Tests
920270	AMPIC*/SULB 2/1 AMS 0.016-256* 100 MIC Tests
920271	AMPIC*/SULB 2/1 AMS 0.016-256* 10 MIC Tests
92028	SULBACTAM SUL 0.016-256 30 MIC Tests
920280	SULBACTAM SUL 0.016-256 100 MIC Tests
920281	SULBACTAM SUL 0.016-256 10 MIC Tests
92029	TEMOCILLIN TMO 0.064-1024 30 MIC Tests
920290	TEMOCILLIN TMO 0.064-1024 100 MIC Tests
920291	TEMOCILLIN TMO 0.064-1024 10 MIC Tests
92030	AZITHROMYCIN AZM 0.016-256 30 MIC Tests
920300	AZITHROMYCIN AZM 0.016-256 100 MIC Tests
920301	AZITHROMYCIN AZM 0.016-256 10 MIC Tests
92031	SULFAMETOXAZOLE SMX 0.064-1024 30 MIC Tests
920310	SULFAMETOXAZOLE SMX 0.064-1024 100 MIC Tests
920311	SULFAMETOXAZOLE SMX 0.064-1024 10 MIC Tests
92032	MINOCYCLINE MN 0.016-256 30 MIC Tests
920320	MINOCYCLINE MN 0.016-256 100 MIC Tests
920321	MINOCYCLINE MN 0.016-256 10 MIC Tests
92033	AZTREONAM ATM 0.016-256 30 MIC Tests
920330	AZTREONAM ATM 0.016-256 100 MIC Tests
920331	AZTREONAM ATM 0.016-256 10 MIC Tests
92034	KANAMYCIN K 0.016-256 30 MIC Tests
920340	KANAMYCIN K 0.016-256 100 MIC Tests
920341	KANAMYCIN K 0.016-256 10 MIC Tests
92035	GEMIFLOXACIN GEM 0.002-32 30 MIC Tests
920350	GEMIFLOXACIN GEM 0.002-32 100 MIC Tests
920351	GEMIFLOXACIN GEM 0.002-32 10 MIC Tests
92036	CEFACLOR CEC 0,016-256 30 MIC Tests
920360	CEFACLOR CEC 0,016-256 100 MIC Tests
920361	CEFACLOR CEC 0,016-256 10 MIC Tests
92037	TRIMETHOPRIM TM 0.002-32 30 MIC Tests
920370	TRIMETHOPRIM TM 0.002-32 100 MIC Tests
920371	TRIMETHOPRIM TM 0.002-32 10 MIC Tests
92038	MUPIROCIN MUP 0.064-1024 30 MIC Tests
920380	MUPIROCIN MUP 0.064-1024 100 MIC Tests
920381	MUPIROCIN MUP 0.064-1024 10 MIC Tests
92039	CEPHALOTHIN KF 0.016-256 30 MIC Tests
920390	CEPHALOTHIN KF 0.016-256 100 MIC Tests
920391	CEPHALOTHIN KF 0.016-256 10 MIC Tests
92040	DORIPENEM DOR 0.002-32 30 MIC Tests
920400	DORIPENEM DOR 0.002-32 100 MIC Tests
920401	DORIPENEM DOR 0.002-32 10 MIC Tests
92041	Pefloxacin PEF 0.016-256 mg/L 30 MIC Tests
920410	Pefloxacin PEF 0.016-256 mg/L 100 MIC Tests
920411	Pefloxacin PEF 0.016-256 mg/L 10 MIC Tests
92042	CEFTRIAXONE CRO 0.016-256 30 MIC Tests
920420	CEFTRIAXONE CRO 0.016-256 100 MIC Tests
920421	CEFTRIAXONE CRO 0.016-256 10 MIC Tests
92043	CEFTRIAXONE CRO 0.002-32 30 MIC Tests
920430	CEFTRIAXONE CRO 0.002-32 100 MIC Tests
920431	CEFTRIAXONE CRO 0.002-32 10 MIC Tests
92044	CLOXACILLIN CX 0.016-256 30 MIC Tests
920440	CLOXACILLIN CX 0.016-256 100 MIC Tests
920441	CLOXACILLIN CX 0.016-256 10 MIC Tests
92045	CIPROFLOXACIN CIP 0.002-32 30 MIC Tests
920450	CIPROFLOXACIN CIP 0.002-32 100 MIC Tests
920451	CIPROFLOXACIN CIP 0.002-32 10 MIC Tests
92046	SPIRAMYCIN SP 0.002-32 30 MIC Tests
920460	SPIRAMYCIN SP 0.002-32 100 MIC Tests
920461	SPIRAMYCIN SP 0.002-32 10 MIC Tests
92048	CLARITHROMYCIN CLR 0.016-256 30 MIC Tests
920480	CLARITHROMYCIN CLR 0.016-256 100 MIC Tests
920481	CLARITHROMYCIN CLR 0.016-256 10 MIC Tests
92049	CEFTAROLINE CPT 0.016-256 30 MIC Test
920490	CEFTAROLINE CPT 0.016-256 100 MIC Test
920491	CEFTAROLINE CPT 0.016-256 10 MIC Test
92050	FOSMIDOMYCIN FOM 0.016-256 30 MIC Tests
920500	FOSMIDOMYCIN FOM 0.016-256 100 MIC Tests
920501	FOSMIDOMYCIN FOM 0.016-256 10 MIC Tests
92051	ERYTHROMYCIN E 0.016-256 30 MIC Tests
920510	ERYTHROMYCIN E 0.016-256 100 MIC Tests
920511	ERYTHROMYCIN E 0.016-256 10 MIC Tests
92052	TELAVANCIN TLV 0.002-32 30 MIC Tests
920520	TELAVANCIN TLV 0.002-32 100 MIC Tests
920521	TELAVANCIN TLV 0.002-32 10 MIC Tests
92053	TELAVANCIN TLV 0.016-256 30 MIC Tests
920530	TELAVANCIN TLV 0.016-256 100 MIC Tests
920531	TELAVANCIN TLV 0.016-256 10 MIC Tests
92054	IMIPENEM IMI 0.002-32 30 MIC Tests
920540	IMIPENEM IMI 0.002-32 100 MIC Tests
920541	IMIPENEM IMI 0.002-32 10 MIC Tests
92056	Ceftaroline CPT 0.002-32 30 MIC Tests
920560	Ceftaroline CPT 0.002-32 100 MIC Tests
920561	Ceftaroline CPT 0.002-32 10 MIC Tests
92057	VANCOMYCIN VA 0.016-256 30 MIC Tests
920570	VANCOMYCIN VA 0.016-256 100 MIC Tests
920571	VANCOMYCIN VA 0.016-256 10 MIC Tests
92058	CEFTIBUTEN CTB 0.002-32 30 MIC Tests
920580	CEFTIBUTEN CTB 0.002-32 100 MIC Tests
920581	CEFTIBUTEN CTB 0.002-32 10 MIC Tests
92060	CEFIXIME CFM 0,016-256 30 MIC Tests
920600	CEFIXIME CFM 0,016-256 100 MIC Tests
920601	CEFIXIME CFM 0,016-256 10 MIC Tests
92066	CEFOXITIN FOX 0.016-256 30 MIC Tests
920660	CEFOXITIN FOX 0.016-256 100 MIC Tests
920661	CEFOXITIN FOX 0.016-256 10 MIC Tests
92072	CLINDAMYCIN CD 0.016-256 30 MIC Tests
920720	CLINDAMYCIN CD 0.016-256 100 MIC Tests

920721	CLINDAMYCIN CD 0.016-256 10 MIC Tests
92075	CHLORAMPHENICOL C 0,016-256 30 MIC Tests
920750	CHLORAMPHENICOL C 0,016-256 100 MIC Tests
920751	CHLORAMPHENICOL C 0,016-256 10 MIC Tests
92078	FOSFOMYCIN FOS 0,016-256 30 MIC Tests
920780	FOSFOMYCIN FOS 0,016-256 100 MIC Tests
920781	FOSFOMYCIN FOS 0,016-256 10 MIC Tests
92079	FOSFOMYCIN FOS 0,064-1024 30 MIC Tests
920790	FOSFOMYCIN FOS 0,064-1024 100 MIC Tests
920791	FOSFOMYCIN FOS 0,064-1024 10 MIC Tests
92081	LEVOFLOXACIN LEV 0.002-32 30 MIC Tests
920810	LEVOFLOXACIN LEV 0.002-32 100 MIC Tests
920811	LEVOFLOXACIN LEV 0.002-32 10 MIC Tests
92084	MEROPENEM MRP 0.002-32 30 MIC Tests
920840	MEROPENEM MRP 0.002-32 100 MIC Tests
920841	MEROPENEM MRP 0.002-32 10 MIC Tests
92087	METRONIDAZOLE MTZ 0.016-256 30 MIC Tests
920870	METRONIDAZOLE MTZ 0.016-256 100 MIC Tests
920871	METRONIDAZOLE MTZ 0.016-256 10 MIC Tests
92090	MOXIFLOXACIN MXF 0,002-32 30 MIC Tests
920900	MOXIFLOXACIN MXF 0,002-32 100 MIC Tests
920901	MOXIFLOXACIN MXF 0,002-32 10 MIC Tests
92093	NETILMICIN NET 0.016-256 30 MIC Tests
920930	NETILMICIN NET 0.016-256 100 MIC Tests
920931	NETILMICIN NET 0.016-256 10 MIC Tests
92096	NORFLOXACIN NOR 0.016-256 30 MIC Tests
920960	NORFLOXACIN NOR 0.016-256 100 MIC Tests
920961	NORFLOXACIN NOR 0.016-256 10 MIC Tests
92099	OFLOXACIN OFX 0.002-32 30 MIC Tests
920990	OFLOXACIN OFX 0.002-32 100 MIC Tests
920991	OFLOXACIN OFX 0.002-32 10 MIC Tests
92102	PENICILLIN G P 0.016-256 30 MIC Tests
921020	PENICILLIN G P 0.016-256 100 MIC Tests
921021	PENICILLIN G P 0.016-256 10 MIC Tests
92103	PENICILLIN G P 0.002-32 30 MIC Tests
921030	PENICILLIN G P 0.002-32 100 MIC Tests
921031	PENICILLIN G P 0.002-32 10 MIC Tests
92105	PIPERACILLIN PIP 0.016-256 30 MIC Tests
921050	PIPERACILLIN PIP 0.016-256 100 MIC Tests
921051	PIPERACILLIN PIP 0.016-256 10 MIC Tests
92108	PIPERAC*/TAZOB TZP 0.016-256* 30 MIC Tests
921080	PIPERAC*/TAZOB TZP 0.016-256* 100 MIC Tests
921081	PIPERAC*/TAZOB TZP 0.016-256* 10 MIC Tests
92111	STREPTOMYCIN S 0.064-1024 30 Tests
921110	STREPTOMYCIN S 0.064-1024 100 MIC Tests
921111	STREPTOMYCIN S 0.064-1024 10 MIC Tests
92112	Streptomycin S 0.016-256 mg/L 30 Tests
921120	Streptomycin S 0.016-256 mg/L 100 MIC Tests
921121	Streptomycin S 0.016-256 mg/L 10 MIC Tests
92114	TETRACYCLINE TE 0.016-25 30 MIC Tests
921140	TETRACYCLINE TE 0.016-25 100 MIC Tests
921141	TETRACYCLINE TE 0.016-25 10 MIC Tests
92117	TICARC*/CLAV TTC 0,016-256* 30MICTests
921170	TICARC*/CLAV TTC 0,016-256* 100 MIC Test
921171	TICARC*/CLAV TTC 0,016-256* 10 MIC Test
92120	TOBRAMYCIN TOB 0,064-1024 30 MIC Tests
921200	TOBRAMYCIN TOB 0,064-1024 100 MIC Tests
921201	TOBRAMYCIN TOB 0,064-1024 10 MIC Tests
92121	TOBRAMYCIN TOB 0,016-256 30 Tests
921210	TOBRAMYCIN TOB 0,016-256 100 Tests
921211	TOBRAMYCIN TOB 0,016-256 10 Tests
92123	TRIM*/SULFAM SXT 0,002-32 30 MIC Tests
921230	TRIM*/SULFAM SXT 0,002-32 100 MIC Tests
921231	TRIM*/SULFAM SXT 0,002-32 10 MIC Tests
92126	CEFEPIME FEP 0.016-256 30 MIC Tests
921260	CEFEPIME FEP 0.016-256 100 MIC Tests
921261	CEFEPIME FEP 0.016-256 10 MIC Tests
92127	CEFEPIME FEP 0.002-32 µg/ml 30 MIC Tests
921270	CEFEPIME FEP 0.002-32 µg/ml 100 MIC Tests
921271	CEFEPIME FEP 0.002-32 µg/ml 10 MIC Tests
92129	CEFUROXIME CXM 0.016-256 30 MIC Tests
921290	CEFUROXIME CXM 0.016-256 100 MIC Tests
921291	CEFUROXIME CXM 0.016-256 10 MIC Tests
92132	NALIDIXIC ACID NA 0,016-256 30 MIC Tests
921320	NALIDIXIC ACID NA 0,016-256 100 MIC Tests
921321	NALIDIXIC ACID NA 0,016-256 10 MIC Tests
92135	LINEZOLID LNZ 0.016-256 30 MIC Tests
921350	LINEZOLID LNZ 0.016-256 100 MIC Tests
921351	LINEZOLID LNZ 0.016-256 10 MIC Tests
92136	TEDIZOLID TZD 0.002-32 30 MIC Tests
921360	TEDIZOLID TZD 0.002-32 100 MIC Tests
921361	TEDIZOLID TZD 0.002-32 10 MIC Tests
92137	Dalbavancin DAL 0.002-32 30 MIC Tests
921370	Dalbavancin DAL 0.002-32 100 MIC Tests
921371	Dalbavancin DAL 0.002-32 10 MIC Tests
92138	CEFTAZIDIME CAZ 0.016-256 30 MIC Tests
921380	CEFTAZIDIME CAZ 0.016-256 100 MIC Tests
921381	CEFTAZIDIME CAZ 0.016-256 10 MIC Tests
92140	Ceftobiprole BPR 0.002-32 mg/L 30 MIC Tests
921400	Ceftobiprole BPR 0.002-32 mg/L 100 MIC Tests
921401	Ceftobiprole BPR 0.002-32 mg/L 10 MIC Tests
92141	COLISTIN CS 0.016-256 30 MIC Tests
921410	COLISTIN CS 0.016-256 100 MIC Tests
921411	COLISTIN CS 0.016-256 10 MIC Tests
92142	COLISTIN CS 0.064-1024 30 MIC Tests
921420	COLISTIN CS 0.064-1024 100 MIC Tests
921421	COLISTIN CS 0.064-1024 10 MIC Tests
92144	TIGECYCLIN TGC 0.016-256 30 MIC Tests
921440	TIGECYCLIN TGC 0.016-256 100 MIC Tests
921441	TIGECYCLIN TGC 0.016-256 10 MIC Tests
92145	DAPTOMYCIN DAP 0.016-256 30 MIC Tests
921450	DAPTOMYCIN DAP 0.016-256 100 MIC Tests
921451	DAPTOMYCIN DAP 0.016-256 10 MIC Tests
92146	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 30 MIC Tests
921460	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 100 MIC Tests
921461	Ceftolozane*-tazobactam C/T 0.016-256* mg/L 10 MIC Tests
92147	FLUCONAZOLE FLU 0.016-256 30 MIC Tests
921470	FLUCONAZOLE FLU 0.016-256 100 MIC Tests
921471	FLUCONAZOLE FLU 0.016-256 10 MIC Tests
92148	ITRACONAZOLE ITC 0.002-32 30 MIC Tests
921480	ITRACONAZOLE ITC 0.002-32 100 MIC Tests
921481	ITRACONAZOLE ITC 0.002-32 10 MIC Tests
92149	FLUCYTOSIN FC 0.002-32 30 MIC Tests
921490	FLUCYTOSIN FC 0.002-32 100 MIC Tests
921491	FLUCYTOSIN FC 0.002-32 10 MIC Tests
92150	VORICONAZOLE VO 0.002-32 30 MIC Tests
921500	VORICONAZOLE VO 0.002-32 100 MIC Tests
921501	VORICONAZOLE VO 0.002-32 10 MIC Tests
92151	KETOCONAZOLE KE 0.002-32 30 MIC Tests

921510	KETOCONAZOLE KE 0.002-32 100 MIC Tests
921511	KETOCONAZOLE KE 0.002-32 10 MIC Tests
92152	POSACONAZOLE POS 0,002-32 30 MIC Tests
921520	POSACONAZOLE POS 0,002-32 100 MIC Tests
921521	POSACONAZOLE POS 0,002-32 10 MIC Tests
92153	AMPHOTERICIN B AMB 0,002-32 30 MIC Tests
921530	AMPHOTERICIN B AMB 0,002-32 100 MIC Tests
921531	AMPHOTERICIN B AMB 0,002-32 10 MIC Tests
92154	CASPOFUNGIN CAS 0,002-32 30 MIC Tests
921540	CASPOFUNGIN CAS 0,002-32 100 MIC Tests
921541	CASPOFUNGIN CAS 0,002-32 10 MIC Tests
92155	ANIDULAFUNGIN AND 0.002-32 30 MIC Tests
921550	ANIDULAFUNGIN AND 0.002-32 100 MIC Tests
921551	ANIDULAFUNGIN AND 0.002-32 10 MIC Tests
92156	DOXYCYCLINE DXT 0,016-256 30 MIC Tests
921560	DOXYCYCLINE DXT 0,016-256 100 MIC Tests
921561	DOXYCYCLINE DXT 0,016-256 10 MIC Tests
92157	ERTAPENEM ETP 0,002-32 30 MIC Tests
921570	ERTAPENEM ETP 0,002-32 100 MIC Tests
921571	ERTAPENEM ETP 0,002-32 10 MIC Tests
92159	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 30 Tests
921590	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 100 Tests
921591	CEFTAZ/CEFTAZ+CLAV. CAZ/CAL MIC 10 Tests
92160	CEFOT./CEFOT.+ CLAV. CTX/CTL 30 MIC Tests
921600	CEFOT./CEFOT.+ CLAV. CTX/CTL 100 MIC Tests
921601	CEFOT./CEFOT.+ CLAV. CTX/CTL 10 MIC Tests
92161	CEFEP./CEFEP.+CLAV. FEP/FEL 30 MIC Tests
921610	CEFEP./CEFEP.+CLAV. FEP/FEL 100 MIC Tests
921611	CEFEP./CEFEP.+CLAV. FEP/FEL 10 MIC Tests
92162	IMIPEN./IMIP.+ EDTA IMI/IMD 30 MIC Tests
921620	IMIPEN./IMIP.+ EDTA IMI/IMD 100 MIC Tests
921621	IMIPEN./IMIP.+ EDTA IMI/IMD 10 MIC Tests
92163	VANCOM/TEICOPLANINA VA/TEC 30 MIC Tests
921630	VANCOM/TEICOPLANINA VA/TEC 100 MIC Tests
921631	VANCOM/TEICOPLANINA VA/TEC 10 MIC Tests
92164	CEFOT/CEFOT+CLOX CTT/CXT0,5-32/0,5-32 30 MIC Tests
921640	CEFOT/CEFOT+CLOX CTT/CXT 0,5-32/0,5-32 100 MIC Tests
921641	CEFOT/CEFOT+CLOX CTT/CXT 0,5-32/0,5-32 10 MIC Tests
92165	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 30 MIC Tests
921650	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 100 MIC Tests
921651	MEROPENEM/MEROPENEM + EDTA MRP/MRD 0.125-8/0.032-2 µg/ml 10 MIC Tests
92166	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 30 MIC Tests
921660	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 100 MIC Tests
921661	IMIPEN/IMIP+EDTA IMI/IMD 0.125-8/0.032-2 10 MIC Tests
92167	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 30 MIC Tests
921670	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 100 MIC Tests
921671	MEROPENEM / MEROPENEM + PHENYLBORONIC ACID MRP/MBO 0.125-8 / 0.032-2 10 MIC Tests
92168	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 30 MIC Tests
921680	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 100 MIC Tests
921681	ERTAPENEM / ERTAPENEM + PHENYLBORONIC ACID ETP/EBO 0.125-8 / 0.032-2 10 MIC Tests
92169	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 30 MIC Tests
921690	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 100 MIC Tests
921691	ERTAP/ERTAP+CLOXACILLIN ETP/ECX 0.125-8/0.032-2 10 MIC Tests

92170	ETHAMBUTOL EB 0.016-256 30 MIC Tests
921700	ETHAMBUTOL EB 0.016-256 100 MIC Tests
921701	ETHAMBUTOL EB 0.016-256 10 MIC Tests
92171	ISONIAZIDE IZ 0.016-256 30 MIC Tests
921710	ISONIAZIDE IZ 0.016-256 100 MIC Tests
921711	ISONIAZIDE IZ 0.016-256 10 MIC Tests
92172	ETHIONAMIDE ET 0.016-256 30 MIC Tests
921720	ETHIONAMIDE ET 0.016-256 100 MIC Tests
921721	ETHIONAMIDE ET 0.016-256 10 MIC Tests
92173	AZTREONAM ATM 0.064-1024 30 MIC Tests
921730	AZTREONAM ATM 0.064-1024 100 MIC Tests
921731	AZTREONAM ATM 0.064-1024 10 MIC Tests
92174	CEFAZOLIN KZ 0.016-256 30 MIC Tests
921740	CEFAZOLIN KZ 0.016-256 100 MIC Tests
921741	CEFAZOLIN KZ 0.016-256 10 MIC Tests
92180	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 30 MIC Tests
921800	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 100 MIC Tests
921801	AMOX*/CLAV 2 µg/mL AMC 0.016-256* 10 MIC Tests
92181	AMPIC*/SULB 4 µg/mL SAM 0.016-256* 30 MIC Tests
921810	AMPIC*/SULB 4 µg/mLSAM 0.016-256* 100 MIC Tests
921811	AMPIC*/SULB 4 µg/mL SAM 0.016-256* 10 MIC Tests
92182	MICAFUNGIN MYC 0,002-32 30 MIC Tests
921820	MICAFUNGIN MYC 0,002-32 100 MIC Tests
921821	MICAFUNGIN MYC 0,002-32 10 MIC Tests
92183	Ticarcillin TC 0.016-256 mg/L 30 MIC Tests
921830	Ticarcillin TC 0.016-256 mg/L 100 MIC Tests
921831	Ticarcillin TC 0.016-256 mg/L 10 MIC Tests
92184	Isavuconazole IVU 0.002-32 mg/L 30 MIC Tests
921840	Isavuconazole IVU 0.002-32 mg/L 100 MIC Tests
921841	Isavuconazole IVU 0.002-32 mg/L 10 MIC Tests
92200	Tiamulin TIA 0.002-32 30 MIC Tests
922000	Tiamulin TIA 0.002-32 100 MIC Tests
922001	Tiamulin TIA 0.002-32 10 MIC Tests
92201	TILMICOSIN TIL 0.002-32 30 MIC Tests
922010	TILMICOSIN TIL 0.002-32 100 MIC Tests
922011	TILMICOSIN TIL 0.002-32 10 MIC Tests
93001	EASY RID h-IgG
93002	EASY RID h-IgA
93003	EASY RID h-IgM
93004	EASY RID h-C3c
93005	EASY RID h-C4
93006	EASY RID h-Transferrin
93007	EASY RID h-Albumin
93008	EASY RID h-Apolipoprotein A1
93009	EASY RID h-Apolipoprotein B
93010	EASY RID h-Alfa 1 Acid Glicoprotein
93011	EASY RID h-Fibrinogen
93012	EASY RID h-Antitrombin III
93013	EASY RID h-Ig Light Chain K
93014	EASY RID h-Ig Light Chain Lambda
93015	Anti h-alfa 1 Antitrypsin
93016	Anti h-Ceruloplasmin
93018	Anti h-Haptoglobin
93104	Multiplate h-IgG/IgA/IgM
93106	MULTIPLATE h-C3c/C4
93110	MULTIPLATE h-Apo A1/Apo B
93115	MULTIPLATE h-Kappa Chain/Lambda Chain
93201	BENCE JONES TEST
940010	RID CONTROL SERUM
9501	OPTOCHINE OPT 100 Discs

9502	Bacitracin Test 100 Discs
9503	X FACTOR TEST 100 Discs
9504	V FACTOR TEST 100 Discs
9505	V+X FACTOR TEST 100 Discs
9508	METRONIDAZOLE TEST 100 Discs
9511	SULPHONAMIDE TEST 100 Discs
95200	ANAEROBES
95210	ENTEROCOCCI
95220	ENTEROBACTERIA 1
95230	ENTEROBACTERIA URINE
95240	ENTEROBACTERIA 2
95250	PSEUDOMONAS
95260	STAPH
95270	ACINETOBACTER
95280	YEASTS
95290	Strepto
95380	ENTEROBACTERIA
95390	PSEUDOMONAS ACINETOBACTER
95400	ENTEROCOCCI
95410	ANAEROBES
95420	STAPH/STREP
95430	ENTEROBACTERIA URINE
95440	ENTEROBACTERIA FROM URINE AND OTHER SAMPLE
95500	YEASTS
9555	MT-HAEMOPHILUS
9562	URIN-2
9563	MICE
9564	KGL I (Gram + ve) 1 x 100 Test
9565	KGL II (Gram - ve) 1 x 100 Test
9566	KGL III 100 Test
9567	MULTODISC A
9568	MULTODISC B
9569	MULTODISC C
9570	MULTODISC D
9571	MULTODISC A (100 Pz) (Tender106/2003)
9573	MULTODISC C (100 Pz) (Tender106/2003)
9574	MULTODISC D (100 Pz) (Tender106/2003)
9575	URINE RING (Tender238/2006)
9576	PSEUDOMONAS RING (Tender238/2006)
9577	GRAM NEGATIVE RING (Tender238/2006)
9578	GRAM POSITIVE RING (Tender238/2006)
96001	SALMONELLA TYPHI H 20 ml
96002	SALMONELLA TYPHI O 20 ml
96003	SALMONELLA PARATYPHI AH 20 ml
96004	SALMONELLA PARATYPHI AO 20 ml
96005	SALMONELLA PARATYPHI BH 20 ml
96006	SALMONELLA PARATYPHI BO 20 ml
96007	BRUCELLA TOTALE 20 ml
96008	BRUCELLA ABORTUS 20 ml
96009	SALMONELLA TYPHI TOTALE 20 ml CE
96010	SALMONELLA PARATYPHI A TOTALE 20 ml
96011	PROTEUS OX2 20 ml
96012	PROTEUS OXK 20 ml
96013	PROTEUS OX19 20 ml
96015	FEBRILE MULTITEST KIT
96016	STREP-CHECK KIT
96017	STAPH LATEX KIT
96018	SALMONELLA PARATYPHI B TOTALE 20 ml
96019	SALMONELLA PARATYPHI CH 20 ml
96020	SALMONELLA PARATYPHI CO 20 ml
96021	SALMONELLA PARATYPHI C TOTALE 20 ml
96022	BRUCELLA MELITENSIS 20 ml
96023	BRUCELLA SUIS 20 ml
96031	SALMONELLA TYPHI H SLIDE 5 ml
96032	SALMONELLA TYPHI O SLIDE 5 ml
96033	SALMONELLA TYPHI TOTALE 5 ml SLIDE
96034	SALMONELLA PARATYPHI AH SLIDE 5 ml
96035	SALMONELLA PARATYPHI AO 5 ml SLIDE
96036	SALMONELLA PARATYPHI A TOTALE 5ml SLIDE
96037	SALMONELLA PARATYPHI BH 5 ml SLIDE
96038	SALMONELLA PARATYPHI BO 5 ml SLIDE
96039	SALMONELLA PARATYPHI B TOTALE 5ml SLIDE
96040	SALMONELLA PARATYPHI CH 5 ml SLIDE
96041	SALMONELLA PARATYPHI CO 5 ml SLIDE
96042	SALMONELLA PARATYPHI C TOTALE 5 ml SLIDE
96043	BRUCELLA TOTALE SLIDE 5 ml SLIDE
96044	BRUCELLA ABORTUS 5 ml SLIDE
96045	BRUCELLA MELITENSIS SLIDE 5 ml
96046	BRUCELLA BENGAL ROSE SLIDE 5 ml
96047	PROTEUS OX2 5 ml SLIDE
96048	PROTEUS OX19 5 ml SLIDE
96049	PROTEUS OXK 5 ml SLIDE
96093	CONTROLLO NEGATIVO/NEGATIVE CONTROL 0.5ml
96096	POSITIVE CONTROL FOR SALMONELLA 0.5ml
96097	POSITIVE CONTROL FOR PROTEUS 0.5ml
96098	POSITIVE CONTROL FOR BRUCELLA 0.5ml
96142	Legionella Latex Kit
96143	CAMPYLOBACTER LATEX KIT
96144	CLOSTRIDIUM DIFFICILE LATEX KIT
96148	SHIGELLA ANTISERUM
96150	E. COLI O157 LATEX KIT
96151	SALMONELLA LATEX KIT
96153	STREPTO B LATEX KIT
96154	STREPTO A LATEX KIT
96155	BENCE JONES LATEX TEST
96316	Clostridium difficile GDH Card
96317	Clostridium Difficile Toxin A+B Card
96318	Giardia Card
96319	Listeria Monocytogenes Card
96320	Salmonella Ag Card
96321	O157 E.coli Card
96401	ONE STEP AMP DRMG SCREEN 20 CARDS
96404	ONE STEP COC DRMG SCREEN
96405	ONE STEP THC DRMG SCREEN
96406	ONE STEP M-AMP DRMG SCREEN 20 CARDS
96411	ONE STEP BRUPRENORPHINE DRMG SCREEN 20 CARDS
96415/20	FECAL OCCULT BLOOD CARD
96418	STREPTO A CARD 30 CARDS
96441	Gonorrea Ag Card
96442	Gardnerella Vaginalis Card
96443	Trichomonas Vaginalis Card
96444	B.J. Free Kappa/Lambda Dipstick
96455	H.PYLORI CARD 20 CARD
96460	HCG URINE/SERUM CARD 50 CARD
96461	HCG URINE/SERUM CARD 100 CARD
96462	MICROALBUMIN CARD URINE 20 Cards
96465	AFP -ALFA FETO CARD 20 CARDS
96468	TUBERCOLOSI CARD 20 CARDS
96480	IgE TOTAL CARD
96485	CEA CARD 20 Cards

96487	MYOGLOBIN
96488	TROPONIN 20 CARDS
96490	FERRITIN CARD
96495	SIFILIDE CARD 20 CARDS
96498	IM MONONUCLEOSIS INFECTION 20 CARDS
96590	URINE STRIP
96900	GIOTTO READER
96909	BIOMIC V3
96914	BIOMIC V3 AST
96915	BIOMIC V3 ID
96916	BIOMIC V3 CC
96919	AST Software
96931	ID Software
96932	CC Software
96933	Micropiastre 96 pozzetti Software

97800	ROTASTICK ONE STEP KIT 20 Tests
97801	RSV STICK ONE STEP 20 Tests
97802	ROTA/ADENO COMBI STICK ONE STEP 20 Tests
97803	H.PYLORI FECAL Ag ONE STEP 20 Tests
97805	STREP B STICK ONE STEP ASSAY 20 Tests
97807	ADENOSTICK ONE STEP ASSAY 20 Tests
9999	Blank Discs
99003	KPC&MBL disc kit (acc. to EUCAST)
99004	ESBL disc kit (acc. to EUCAST)
99005	ESBL disc kit (acc. to CLSI)
99006	ESBL (Chromos. Ind. AmpC) disc kit (acc. to EUCAST)
99007	KPC&MBL&OXA-48 disc kit (acc. to EUCAST)
99008	ESBL+AmpC screen disc kit
99009	AmpC disc kit

Direttore Tecnico/ Technical Director
Dr.Silvio Brocco

Italia

CERTIFICATO

Nr. 50 100 11497 Rev.005

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE:
REGISTERED OFFICE:

VIA SCOZIA - ZONA INDUSTRIALE
IT - 64026 ROSETO DEGLI ABRUZZI (TE)

SEDI OPERATIVE: **VEDI ALLEGATO 1** / *OPERATIONAL SITES:* ***SEE ANNEX 1***

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura per microbiologia, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro (IAF 12, 29)

Design and development, production and sales of in-vitro diagnostic medical devices: culture media for microbiology, identification and susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices (IAF 12, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità / *Validity*

Dal / From: **2022-02-11**

Al / To: **2025-02-10**

Data emissione /
Issuing Date

2022-01-26

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2022-02-10
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2022-02-10*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 11497 Rev.005**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 11497 Rev.005***
pagina 1 di 1 / *page 1 of 1*

IL CERTIFICATO NR 50 100 11497 Rev.005 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N *50 100 11497 Rev.005 COVERS ALSO THE FOLLOWING OFFICES:*

LIOFILCHEM S.r.l.

VIA SCOZIA - ZONA INDUSTRIALE IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine

Production and sales of in-vitro diagnostic medical devices: dehydrated and ready-to-use culture media for microbiology

VIA URUGUAY IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura pronti per microbiologia, reagenti e supplementi, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro. Progettazione e sviluppo e commercializzazione di terreni di coltura disidratati per microbiologia

Design and development, production and sales of in-vitro: diagnostic medical devices: ready-to-use culture media for microbiology, reagents and supplements, microbial identification and antimicrobial susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, plasma protein determination kits. Distribution of other in-vitro diagnostic medical devices. Design and development and distribution of dehydrated culture media for microbiology

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità /*Validity*

Dal / From: **2022-02-11**

Al / To: **2025-02-10**

Data emissione /
Issuing Date

2022-01-26

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2022-02-10
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2022-02-10*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

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

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

Product Service

Certificate

No. Q5 071067 0006 Rev. 02

Holder of Certificate: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

Certification Mark:

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

Scope of Certificate: **Design and development, production and sales of in-vitro diagnostic medical devices: culture media for microbiology, identification and susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 071067 0006 Rev. 02

Report No.: ITA 1775694

Valid from: 2021-12-19
Valid until: 2024-12-18

Date, 2021-12-10

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

TÜV SÜD Product Service

Certificate

No. Q5 071067 0006 Rev. 02

Applied Standard(s):

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

Facility(ies):

Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Production and sales of in-vitro diagnostic medical devices: dehydrated and ready-to-use culture media for microbiology.

Liofilchem S.r.l.
Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALY

Design and development, production and sales of in-vitro:diagnostic medical devices: ready-to-use culture media for microbiology, reagents and supplements, microbial identification and antimicrobial susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, plasma protein determination kits. Distribution of other in-vitro diagnostic medical devices. Design and development and distribution of dehydrated culture media for microbiology.

/

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

TÜV®

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

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Thromboplastin L

REF 5265HL
REF 5265L
REF 5267L

CE IVD

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Web: www.helena-biosciences.com

HL-2-3035P 2015/10 (1)

Thromboplastin L
Instructions for use — en

INTENDED PURPOSE

The Thromboplastin L kit is intended for carrying out clot based haemostasis assays.

The first standardised one-stage prothrombin time test was developed by Dr. Armand Quick in 1935. It has now become the basic coagulation screening test for the diagnosis of congential and acquired deficiencies of clotting factors from the extrinsic pathway (factors II, V, VII and X)[1,2]. It is also used for the induction and monitoring of oral anticoagulant therapy[3,4] and can be used to assess the protein synthesis capability of the liver in chronic or acute hepatic disorders.
Thromboplastin L is of rabbit brain origin but resembles human preparations in its low International Sensitivity Index (ISI). The ISI of Thromboplastin L is approximately 1.1 and is calibrated against the WHO international reference preparation[5]. Thromboplastin L is particularly suited to the monitoring of oral anticoagulant therapy and, in conjunction with the appropriate factor deficient plasma, the measurement of factor activity in the extrinsic pathway. Tissue thromboplastin, in the presence of calcium ions, is an activator which initiates the extrinsic pathway of coagulation. When a mixture of tissue thromboplastin and calcium ions is added to normal citrated plasma, the clotting mechanism is activated, leading to a fibrin clot. If a deficiency exists within the extrinsic pathway, the time required for clot formation will be prolonged depending on the severity of the deficiency.

WARNINGS AND PRECAUTIONS

The reagents contained in this kit are for *in vitro* diagnostic use only – DO NOT INGEST. Wear appropriate personal protective equipment when handling all kit components. Refer to the product safety declaration for the link to appropriate hazard and precautionary statements where applicable. Dispose of components in accordance with local regulations.

COMPOSITION

Composition	Content	Description	Preparation
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Liquid Rabbit Brain Thromboplastin containing Calcium Chloride, stabilisers and preservatives.	The liquid, calcified thromboplastin is ready-for-use. No further calcium is required to carry out standard PT Assays. The contents of the vial should be mixed well before use. (5 minutes on roller).
Each kit contains Instructions For Use.			
Each kit contains lot specific reference values insert.			

ITEMS REQUIRED BUT NOT PROVIDED

The below products can be used in conjunction with Thromboplastin L:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

STORAGE, SHELF-LIFE AND STABILITY

Unopened reagents are stable until the given expiry date when stored under conditions indicated on the vial or kit label.

Thromboplastin L	Opened vials are stable for 2 months at $^{+}$2 – $^{+}$8°C, 5 days at $^{+}$15°C (on-board Sysmex CA-1500) and 6 hours at $^{+}$37°C (on-board AC-4 including reagent container and cap). A shift-use stability of 7 days (Sysmex CA-1500) can be achieved. DO NOT FREEZE. Large clumps of particles or changes in expected values may indicate product deterioration.

SAMPLE COLLECTION AND PREPARATION

Plastic or siliconised glass should be used throughout. Blood (9 parts) should be collected into 3.2% or 3.8% sodium citrate anticoagulant (1 part). Separate plasma after centrifugation at 1500 x g for 15 minutes. Plasma should be kept at $^{+}$18 –$^{+}$24°C. Testing should be completed within 4 hours of sample collection, or plasma can be stored frozen at -20°C for 2 weeks or -70°C for 6 months. Thaw quickly at $^{+}$37°C prior to testing. Do not keep at $^{+}$37°C for more than 5 minutes[6].

PROCEDURE

For accurate INR reporting, it is recommended to determine the laboratory specific ISI of the reagent with the testing system in use. The Helena Biosciences Europe ISI Calibrant Plasma Set (REF 5519) is recommended for this purpose[7,8]. This should be performed for each new reagent batch. The Helena Biosciences Europe INR Reference Set (REF 5490) should be used to check for shifts in the local system ISI which have been noted with changes in laboratory temperature and post instrument servicing, amongst other local variances.

Manual Method

1. Mix sufficient Thromboplastin L to complete the anticipated testing for the day and incubate at $^{+}$37°C for no more than 4 hours.
2. Pre-warm 0.1 mL of the test plasma at $^{+}$37°C for 2 minutes.
3. Add 0.2 mL of freshly mixed thromboplastin reagent to the plasma while simultaneously starting a stopwatch.
4. Note the time for clot formation to the nearest 0.1 seconds.

Automated Method

Refer to the appropriate instrument operator manual for detailed instructions or contact Helena Biosciences Europe for instrument specific application guides.

INTERPRETATION OF RESULTS

Results should be reported to the nearest 0.1 seconds and duplicates should agree within 5% of each other. %PT values can be interpolated from the calibration graph (%PT of PT Calibration plasmas versus measured clot time), which should be a straight line when plotted on log-log graph paper.

INR values can be calculated using the following formula: INR = (PT Time Patient / Mean Normal PT Time)^{ISI}

For clear guidance on the indications for and management of patients on warfarin, please refer to The British Society for Haematology, for their most current edition of 'Guidelines on oral anticoagulation with warfarin'. At time of printing this is the 2011 fourth edition[9].

LIMITATIONS

The use of serial dilutions of a reference plasma for the %PT curve is not recommended as this can lead to discrepancies caused by the low fibrinogen in the reference plasma dilutions which are not reflected in patient samples having predominantly normal fibrinogen levels. Helena Biosciences Europe advise use of the 5504R %PT/Direct INR kit for this purpose.

QUALITY CONTROL

Each laboratory should establish a quality control program. Normal and abnormal control plasmas should be tested prior to each batch of patient samples, to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid.
Helena Biosciences Europe supplies the following controls available for use with this product:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

REFERENCE VALUES

Reference values can vary between laboratories depending on the techniques and systems in use. For this reason each laboratory should establish its own reference ranges. This is particularly important for local ISI calibration. Using the Sysmex series of instruments, normal values ranging from 11.50 - 14.60 seconds; 0.930 - 1.160 INR; 79.10 - 112.80 %PT are typical.

PERFORMANCE CHARACTERISTICS

The following performance characteristics have been determined by Helena Biosciences Europe or their representatives using a Sysmex CA-1500 coagulation instrument. Each laboratory should establish its own performance data.

Reproducibility

Sample	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Repeatability	0.07	0.59	0.24	1.09	0.45	1.11
Between-run	0.10	0.83	0.16	0.75	0.49	1.20
Between-day	0.04	0.32	0.06	0.27	0.25	0.62
Within-device / Laboratory	0.12	1.07	0.29	1.35	0.72	1.75

Interferences

Helena Thromboplastin L is insensitive to Heparin levels of up to 2 U/mL. Using a 5% interference threshold, there is no significant interference from Haemoglobin at concentrations up to 10 g/L. Using a 5% interference threshold, there is no significant interference from Bilirubin at concentrations up to 0.5 g/L for Thromboplastin L. Lipid interference testing demonstrates that lipid levels do not directly affect the clot time of the reagent up to 3.75g/L. Lipid concentrations in excess of this prevent clot detection.

Method Comparison

Comparison of clot time in seconds and INR values were determined using Thromboplastin L and Thromboplastin LI on 268 samples. The following correlations were obtained:

Thromboplastin L (Seconds) = 0.9911x + 0.1038	r^2 = 0.9941	n = 268
Thromboplastin L (INR) = 0.9853x + 0.0261	r^2 = 0.9500	n = 268

BIBLIOGRAPHY

1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice, *Am. J. Med. Sci,* **190:** 501.
2. Biggs R (1976) Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Edition, Blackwell Scientific Publications, London.
3. Hirsh J, Poller L, Deykin D, Levine J, Dalen JE (1989) Optimal Therapeutic Range for Oral Anticoagulants, *Chest,* **95:** 5S-11S.
4. Poller L (1986) Laboratory Control of Anticoagulant Therapy, *Sem. Thromb. Haemostasis,* **12:** 13-19.
5. World Health Organisation (1984) Expert Committee on Biological Standards, *Technical Series,* **700:** 19.
6. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5.
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9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition, *British Journal of Haematology,* **154(3):** 311-324.

Thromboplastin L
Fiche technique — fr

UTILISATION

Le kit Thromboplastin L est destiné à la réalisation des analyses de l'hémostase basées sur la formation de caillots.

La première méthode de détermination standardisée du temps de prothrombine en une étape a été développée en 1935 par le Dr. Armand Quick. Cette méthode de Quick constitue désormais l'analyse de base de la coagulation servant à diagnostiquer des anomalies des facteurs de coagulation, congénitales ou acquises, à partir de la voie extrinsèque (facteurs II, V, VII et X)[1,2]. Elle sert aussi à l'induction et au monitorage des thérapies avec anticoagulants oraux[3,4] et elle peut être utilisée pour évaluer la capacité de synthèse des protéines du foie chez les patients souffrants de troubles hépatiques chroniques ou aigus.
Le Thromboplastin L provient de cerveaux de lapin mais il ressemble au BCT humain en raison de son indice de sensibilité international (ISI) faible. L'ISI du Thromboplastin L est d'environ 1,1 et est étalonné en comparaison avec la préparation internationale de référence de l'OMS[5]. Le Thromboplastin L convient tout particulièrement au monitorage des thérapies avec anticoagulants oraux et, utilisé conjointement au plasma carencé en un facteur approprié, à la détermination de l'activité du facteur de la voie extrinsèque. La thromboplastine tissulaire, en présence d'ions calcium, est un activateur qui démarre la voie extrinsèque de la coagulation. Quand un mélange de thromboplastine tissulaire et d'ions calcium est ajouté à un plasma citraté normal, le processus de coagulation, qui doit conduire à la production d'un caillot fibreux, s'active. Si la voie extrinsèque présente une anomalie, le temps nécessaire à la formation du caillot est allongé suivant la gravité du trouble de la coagulation.

AVERTISSEMENTS ET PRÉCAUTIONS

Les réactifs du kit sont à usage diagnostique *in vitro* uniquement – NE PAS INGÉRER. Porter un équipement de protection individuelle approprié lors de la manipulation de tous les composants du kit. Consulter la fiche de données de sécurité du produit pour obtenir le lien vers les phrases de risque et les conseils de prudence le cas échéant. Éliminer les composants conformément aux églementations locales.

COMPOSITION

Composant	Contient	Description	Préparation
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Thromboplastine liquide de cerveau de lapin contenant du chlorure de calcium, des stabilisateurs et des conservateurs.	La thromboplastine liquide calcifiée est prête à l'emploi. Aucun calcium supplémentaire n'est nécessaire pour réaliser des déterminations standard du TP. Le contenu du flacon doit être bien mélangé avant utilisation (5 minutes sur un mélangeur à rouleaux).
Chaque kit contient une fiche technique.			
Chaque kit contient valeurs de référence spécifiques du lot.			

MATÉRIEL NÉCESSAIRE NON FOURNI

Les produits ci-dessous peuvent être utilisés en conjonction avec la Thromboplastin L :

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

CONSERVATION, DURÉE DE VIE UTILE ET STABILITÉ

Les flacons de réactif non ouverts sont stables jusqu'à la date de péremption indiquée s'ils sont conservés dans les conditions indiquées sur l'étiquette du kit ou du flacon.

Thromboplastin L	Les flacons ouverts sont stables pendant 2 mois à $^{+}$2 °C – $^{+}$8 °C, pendant 5 jours à $^{+}$15 °C (à bord du Sysmex CA-1500) et pendant 6 heures à $^{+}$37 °C (à bord de l'AC-4, récipient de réactif et capuchon inclus). Il est possible d'obtenir une stabilité de période de travail de 7 jours (Sysmex CA-1500). NE PAS CONGELER. La présence de d'amas de particules ou un écart par rapport aux valeurs prévues indique une détérioration du produit.

PRÉLÈVEMENT ET PRÉPARATION DES ÉCHANTILLONS

Utiliser tout au long du prélèvement du plastique ou du verre siliconé. Mélanger 9 volumes de sang et 1 volume de citrate de sodium à 3,2% ou 3,8%. Séparer le plasma après centrifugation à 1500 x g pendant 15 minutes. Conserver le plasma entre $^{+}$18 –$^{+}$24°C. L'analyse doit être terminée dans les 4 heures suivant le prélèvement de l'échantillon ; sinon, il est possible de congeler le plasma 2 semaines à -20°C ou 6 mois à -70°C. Décongeler rapidement à $^{+}$37°C avant de réaliser l'analyse. Ne pas laisser à $^{+}$37°C plus de 5 minutes[6].

PROCÉDURE

Pour obtenir un RNI (rapport normalisé international) précis, il est recommandé à chaque laboratoire de déterminer l'ISI spécifique du réactif avec le système d'analyse utilisé. Il est conseillé d'utiliser le ISI Calibrant Plasma Set Helena Biosciences Europe (REF 5519) pour cela[7,8]. Cette opération doit être réalisée pour chaque nouveau lot de réactif. Le kit RNI de référence Helena Biosciences Europe (REF 5490) doit être utilisé pour vérifier l'existence d'un décalage de l'ISI du système local déterminé en raison d'une variation de la température du laboratoire, suite à une opération de maintenance réalisée sur l'instrument ou toute autre variable locale.

Méthode Manuelle

1. Mélanger du Thromboplastin L en quantité suffisante pour réaliser les analyses prévues dans la journée et incuber à $^{+}$37 °C pendant 4 heures au maximum.
2. Préchauffer 0,1 mL de plasma à $^{+}$37°C pendant 2 minutes.
3. Ajouter 0,2 mL de réactif de thromboplastine fraîchement mélangé au plasma et démarrer à ce moment un chronomètre.
4. Relever le temps de formation du caillot en arrondissant au dixième de seconde.

Méthodes Automatisées

Consulter le manuel d'utilisation de l'instrument approprié pour obtenir des instructions détaillées ou contacter Helena Biosciences Europe pour obtenir des notes d'application spécifiques à l'instrument.

INTERPRÉTATION DES RÉSULTATS

Les résultats doivent être indiqués en arrondissant au dixième de seconde et l'écart maximal entre eux est de 5%. Il est possible d'interpoler les valeurs de %TP à partir de la courbe d'étalonnage (%TP des plasmas d'étalonnage du TP par rapport au temps de coagulation mesuré), qui doit correspondre à une ligne droite quand elle est représentée sur du papier logarithmique.

La formule suivante permet de calculer les valeurs du RNI: RNI = (Temps TP patient / Temps TP moyen normal)^{ISI}

Pour obtenir des informations claires quant aux indications et à la prise en charge des patients sous warfarine, consulter la British Society for Haematology pour obtenir la dernière édition des Guidelines on oral anticoagulation with warfarin (Recommandations relatives à l'anticoagulothérapie orale avec la warfarine). Au moment de l'impression du présent document, il s'agit de la quatrième édition de 2011[9].

LIMITES

Il est déconseillé de réaliser des dilutions du plasma de référence pour la courbe de %TP, car cela risquerait d'entraîner des divergences dues au faible taux de fibrinogène présent dans les dilutions du plasma de référence, ce qui ne serait pas représentatif des échantillons patients qui ont principalement des taux de fibrinogène normaux. Helena Biosciences Europe conseille l'utilisation du kit 5504R %PT/Direct INR dans ce but.

CONTRÔLE QUALITÉ

Chaque laboratoire doit établir un programme de contrôle qualité. Les plasmas de contrôle, normaux et anormaux, doivent être testés avant chaque lot d'échantillons patients afin de s'assurer que l'instrument et l'opérateur offrent des performances satisfaisantes. Si les contrôles ne donnent pas les résultats prévus, les résultats du patient doivent être considérés comme non valables.
Helena Biosciences Europe distribue les contrôles suivants à utiliser avec ce produit:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

VALEURS DE RÉFÉRENCE

Les valeurs de référence peuvent varier d'un laboratoire à l'autre suivant les techniques et les systèmes utilisés. C'est pour cette raison qu'il appartient à chaque laboratoire de déterminer ses propres plages de référence. Ceci est particulièrement important pour l'étalonnage de l'ISI local. Avec les instruments de la série Sysmex, l'intervalle type des valeurs normales est de 11,50 - 14,60 secondes; 0.930 - 1.160 INR; 79.10 - 112.80 %PT .

CARACTÉRISTIQUES DE PERFORMANCES

Helena Biosciences Europe ou ses mandataires ont déterminé les caractéristiques de performance suivantes en utilisant un instrument de coagulation Sysmex CA-1500. Chaque laboratoire doit établir ses propres données de performance.

Reproductibilité

Échantillon	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Répétabilité	0,07	0,59	0,24	1,09	0,45	1,11
Inter-séries	0,10	0,83	0,16	0,75	0,49	1,20
Inter-jours	0,04	0,32	0,06	0,27	0,25	0,62
Intra-dispositif/laboratoire	0,12	1,07	0,29	1,35	0,72	1,75

Interférences

Thromboplastin L (ISI faible) d'Helena ne présente pas d'interférences avec un taux d'héparine jusqu'à 2 U/mL. En utilisant un seuil d'interférence de 5 %, il n'y a pas d'interférences significatives de l'hémoglobine à une concentration jusqu'à 10 g/L. En utilisant un seuil d'interférence de 5 %, il n'y a pas d'interférences significatives de la bilirubine à une concentration jusqu'à 0,5 g/L pour la Thromboplastin L. Une évaluation de l'interférence des lipides montre que les taux de lipides n'affectent pas le temps de coagulation du réactif jusqu'à 3,75 g/L. Une concentration en lipides dépassant cette limite empêche la détection du caillot.

Comparaison de la méthode

Des comparaisons du temps de coagulation en secondes et en valeurs de RNI ont été déterminées en utilisant les produits Thromboplastin L et Thromboplastin LI avec 268 échantillons. Les corrélations suivantes ont été obtenues:

Thromboplastin L (seconde) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

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1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice, *Am. J. Med. Sci,* **190:** 501.
2. Biggs R (1976) Human Blood Coagulation, Haemostasis and Thrombosis, 2nd Edition, Blackwell Scientific Publications, London.
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6. Clinical and Laboratory Standards Institute (2008) Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Haemostasis Assays: Approved Guideline, 5th edn. CLSI: H21-A5.
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9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition, *British Journal of Haematology,* **154(3):** 311-324.

Thromboplastin L
Anleitung — de

VERWENDUNGSZWECK

Das Thromboplastin L Kit ist für koagulometrische Gerinnungstests vorgesehen.

Die erste standardisierte Prothrombinzeit als Einstufen-Test wurde 1935 von Dr. Armand Quick entwickelt. Mittlerweile ist er der Standard-Screeningtest in der Gerinnung zur Diagnose eines vererbten oder erworbenen Gerinnungsfaktormangels des extrinsischen Systems (Faktor II, V, VII und X)[1,2]. Er wird auch zur Einstellung und Überwachung von oralen Antikoagulanztherapien[3,4] verwendet und kann bei chronischen und akuten Lebererkrankungen zur Beurteilung der Funktionsfähigkeit der Leber bei der Proteinsynthese herangezogen werden.
Thromboplastin L wird aus Kaninchenhirn gewonnen, ähnelt aber mit seinem niedrigen „International Sensitivity Index" (ISI) humaner Blutgerinnungszeit. Der ISI von Thromboplastin L liegt bei ca. 1,1 und ist gegen WHO „International Reference Preparation" kalibriert[5]. Thromboplastin L ist besonders für die Überwachung oraler Antikoagulanztherapien geeignet und, in Verbindung mit dem entsprechenden Faktor-Mangelplasma, bei der Messung von Faktoraktivitäten im extrinsischen System. Gewebethromboplastin ist in Anwesenheit von Calcium-Ionen ein Aktivator, der das extrinsische Gerinnungssystem auslöst. Gibt man eine Mischung von Gewebethromboplastin und Calcium-Ionen zu normalem Citratplasma, wird die Gerinnungskaskade aktiviert und es bildet sich ein Fibringerinnsel. Besteht innerhalb des extrinsischen Systems ein Mangel, verlängert sich, je nach Schwere dieses Mangels, die Zeit bis zur Ausbildung eines Gerinnsels.

WARNHINWEISE UND VORSICHTSMASSNAHMEN

Die in diesem Kit enthaltenen Reagenzien sind ausschließlich für die Verwendung von *in-vitro*-Diagnosen vorgesehen. NICHT VERSCHLUCKEN. Tragen Sie beim Umgang mit sämtlichen Komponenten des Kits geeignete Schutzausrüstung. Beachten Sie gegebenenfalls die Verweise auf entsprechende Gefahren- und Vorbeugeerklärungen in der Produktsicherheitserklärung. Entsorgen Sie die Komponenten gemäß den örtlichen Vorschriften.

ZUSAMMENSETZUNG

Komponente	Inhalt	Beschreibung	Vorbereitung
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Flüssiges Thromboplastin aus Hasenhirn mit Calciumchlorid, Stabilisatoren und Konservierungsstoffen.	Das flüssige, kalzifizierte Thromboplastin ist einsatzbereit. Für die Durchführung von standardmäßigen PT-Analysen ist kein zusätzliches Calcium erforderlich. Der Inhalt der Ampulle muss vor der Verwendung gut gemischt werden (5 Minuten auf dem Walzenmischer).
Jedes Kit enthält eine Gebrauchsanweisung			
Jedes Kit enthält chargenspezifischen Referenzwerten			

ERFORDERLICHE, ABER NICHT MITGELIEFERTE ARTIKEL

Die folgenden Produkte können in Kombination mit Thromboplastin L verwendet werden:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

LAGERUNG, HALTBARKEIT UND STABILITÄT

Ungeöffnete Reagenzien sind unter den auf Verpackung oder Fläschchen angegebenen Lagerbedingungen bis zum aufgedruckten Verfallsdatum stabil.

Thromboplastin L	Offene Ampullen sind 2 Monate bei $^{+}$2 –$^{+}$8°C, 5 Tage bei $^{+}$15°C (im Sysmex CA-1500) und 6 Stunden bei $^{+}$37°C (im AC-4 mit Reagenzbehälter und Deckel) stabil. Eine Stabilität von 7 Tagen im Schichteinsatz (Sysmex CA-1500) kann erreicht werden. NICHT EINFRIEREN. Große Verklumpungen oder Veränderungen in den Normalwerten können auf eine Verfall des Produkts hinweisen.

PROBENENTNAHME UND VORBEREITUNG

Nur Plastik oder Silikonglas verwenden. Blut (9 Teile) sollte in 3,2% oder 3,8% Natriumcitrat als Antikoagulanz (1 Teil) entnommen werden. 15 Minuten bei 1500 g zentrifugieren und Plasma abpipettieren. Plasma bei $^{+}$18 –$^{+}$24°C lagern. Plasma sollte innerhalb von 4 Stunden verarbeitet oder tief gefroren bei -20°C für 2 Wochen oder -70°C für 6 Monat gelagert werden. Vor dem Testen schnell bei $^{+}$37°C auftauen. Nicht länger als 5 Minuten bei $^{+}$37°C belassen[6].

VORGEHENSWEISE

Um einen korrekten INR zu erhalten wird empfohlen, den laborspezifischen ISI für das Reagenz mit dem verwendeten Testsystem zu bestimmen. Helena Biosciences Europe empfiehlt zu diesem Zweck das Plasma-Kalibrator-Set REF 5519[7,8]. Das sollte mit jeder neuen Reagenzien-Charge durchgeführt werden. Das Helena Biosciences Europe INR Reference Set (REF 5490) dient zur Überprüfung von Verschiebungen im ISI vor Ort, die unter anderem durch Veränderungen der Labortemperatur und nach Wartungsarbeiten an den Geräten festgestellt worden sind.

Manuelle Methode

1. Mischen Sie eine ausreichende Menge von Thromboplastin L an, um die für den Tag geplanten Tests durchzuführen und inkubieren Sie es nicht länger als 4 Stunden bei $^{+}$37°C.
2. 0,1 mL des zu testenden Plasmas bei $^{+}$37°C 2 Minuten vorwärmen.
3. 0,2 mL des frisch zubereiteten Thromboplastin-Reagenz zum Plasma pipettieren, dabei gleichzeitig Stoppuhr drücken.
4. Die Zeit bis zur Gerinnselbildung bis auf 0,1 Sekunden genau stoppen.

Automatisierte Methoden

Siehe die Bedienungsanleitung des entsprechenden Geräts für genaue Anweisungen oder wenden Sie sich an Helena Biosciences Europe für spezielle anwendungstechnische Hinweise.

INTERPRETATION DER ERGEBNISSE

Ergebnisse sollten bis auf 0,1 Sekunden genau gemessen werden und Doppelbestimmungen nicht mehr als 5% abweichen. % TPZ-Werte können ausgehend von der Kalibratorkurve interpoliert werden (% TPZ des TP-Kalibrationsplasmas zu gemessener Gerinnungszeit) und sollten auf doppeltlogarithmischem Millimeterpapier eine gerade Linie ergeben.

INR-Werte können anhand der folgenden Formel berechnet werden: INR = (PT Zeit Patient / Mittelwert normale TPZ)^{ISI}

Für klare Leitlinien zu den Indikationen für und der Versorgung von Patienten unter Warfarin siehe die aktuelle Ausgabe der "Guidelines on oral anticoagulation with warfarin" der British Society for Haematology. Zum Zeitpunkt der Drucklegung ist das die 4. Ausgabe, 2011[9].

EINSCHRÄNKUNGEN

Die Verwendung einer Serienverdünnung von Referenzplasma ist für die %PT-Kurve nicht zu empfehlen, da das zu Diskrepanzen aufgrund von niedrigem Fibrinogen in den Referenzplasma-Verdünnungen führen kann, das nicht den Patientenproben entspricht, die in der Regel normale Fibrinogen-Werte haben. Helena Biosciences Europe empfiehlt zu diesem Zweck das Set 5504R %PT/Direct INR einzusetzen.

QUALITÄTSKONTROLLE

Jedes Labor muss für eine eigene Qualitätskontrolle sorgen. Vor jeder Testreihe mit Patientenproben müssen normale und pathologische Kontrollplasmen getestet werden, um eine zufrieden stellende Geräteleistung und Bedienung zu gewährleisten. Liegen die Kontrollen außerhalb des Normbereichs, sind die Patientenergebnisse nicht zu verwenden.
In Verbindung mit diesem Produkt bietet Helena Biosciences Europe die folgenden Kontrollen an:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

REFERENZWERTE

Referenzwerte können je nach Technik und verwendetem System von Labor zu Labor unterschiedlich sein. Aus diesem Grund sollte jedes Labor seine eigenen Referenzwertbereiche erstellen. Dieses ist besonders für die ISI-Kalibration vor Ort wichtig. Mit der Instrumentenreihe Sysmex liegen die typischen Normwerte zwischen 11,50 - 14,60 Sekunden; 0.930 - 1.160 INR; 79.10 - 112.80 %PT .

LEISTUNGSMERKMALE

Die folgenden Leistungseigenschaften wurden von Helena Biosciences Europe oder in ihrem Auftrag mit einem Sysmex CA-1500 Gerinnungsgerät ermittelt. Jedes Labor muss seine eigenen Werte ermitteln.

Reproduzierbarkeit

Probe	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Wiederholbarkeit	0,07	0,59	0,24	1,09	0,45	1,11
Bei verschiedenen Analysen	0,10	0,83	0,16	0,75	0,49	1,20
An verschiedenen Tagen	0,04	0,32	0,06	0,27	0,25	0,62
Selbes Gerät/Labor	0,12	1,07	0,29	1,35	0,72	1,75

Störungen

Helena Thromboplastin L ist unempfindlich gegenüber Heparinwerten bis zu 2 Einheiten/mL. Mit einer Störschwelle von 5 % gibt es keine besondere Interferenz durch Hämoglobin bei Konzentrationen von bis zu 10 g/l. Mit einer Störschwelle von 5 % gibt es keine besondere Interferenz durch Bilirubin bei Konzentrationen von bis zu 0,5 g/l bei Thromboplastin L. Lipidinterferenztests zeigen, dass die Lipidmenge die Gerinnungszeit des Reagenz bis 3,7 g/l nicht direkt beeinflusst. Höhere Lipidkonzentrationen verhindern die Gerinnungserkennung.

Methodenvergleich

Thromboplastin L und Thromboplastin LI wurden an 268 Proben angewandt. Dabei wurden die Gerinnungszeit in Sekunden verglichen und die INR-Werte bestimmt. Es ergaben sich folgende Korrelationen:

Thromboplastin L (sekunden) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

LITERATURVERZEICHNIS

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9. Keeling D (2011) Guidelines on Oral Anticoagulation with warfarin: Forth Edition, *British Journal of Haematology,* **154(3):** 311-324.

Thromboplastin L
Istruzioni per l'uso

it

SCOPO PREVISTO

III kit Thromboplastin L è concepito per l'esecuzione di dosaggi di emostasi basati sulla presenza di coaguli.

I primo test del tempo di protrombina standardizzato venne messo a punto dal Dr. Armand Quick nel 1935. Attualmente, questo test è diventato il metodo basilare di screening della coagulazione per la diagnosi di deficienze congenite ed acquisite dei fattori di coagulazione dal percorso estrinseco (fattori II, V, VII e X)[1,2]. Questo test viene utilizzato anche per l'induzione e il monitoraggio della terapia anticoagulante orale[3,4] e può essere impiegato per valutare la capacità di sintesi proteica del fegato in disordini epatici cronici o acuti.
Il kit Thromboplastin L è realizzato a partire da cervello di coniglio, ma rassomiglia a BCT umano in termini di basso indice di sensibilità internazionale (ISI). L'ISI del kit Thromboplastin L è approssimativamente pari a 1,1 ed è calibrato rispetto alla preparazione di riferimento internazionale dell'OMS[5]. Il kit Thromboplastin L è particolarmente indicato per il monitoraggio della terapia anticoagulante orale e, in combinazione con plasma carente del fattore appropriato, per la misurazione dell'attività del fattore nel percorso estrinseco. In presenza di ioni di calcio, la tromboplastina tissutale è un attivatore che dà inizio al percorso di coagulazione estrinseco. Quando una miscela di tromboplastina tissutale e di ioni di calcio viene aggiunta a normale plasma citrato, si attiva il meccanismo di coagulazione che porta alla formazione di un coagulo di fibrina. Qualora sussista una deficienza all'interno del percorso estrinseco, il tempo richiesto per la formazione del coagulo risulterà prolungato in funzione della gravità della deficienza.

AVVERTENZE E PRECAUZIONI

I reagenti contenuti in questo kit sono destinati esclusivamente alla diagnostica *in vitro* - NON INGERIRE. Indossare un'adeguata attrezzatura protettiva personale durante la manipolazione di tutti i componenti del kit. Per conoscere i relativi simboli precauzionali e di pericolo, laddove pertinente, fare riferimento alla dichiarazione di sicurezza del prodotto. Smaltire i componenti conformemente alle normative locali vigenti.

COMPOSIZIONE

Componente	Contiene	Descrizione	Preparazione
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Tromboplastina liquida di cervello di coniglio contenente cloruro di calcio, stabilizzatori e conservanti.	La tromboplastina calcica liquida è pronta all'uso. Per eseguire dosaggi PT standard non è necessario altro calcio. Il contenuto della fiala deve essere miscelato accuratamente prima dell'uso (5 minuti su un rullo).

Ogni kit contiene un Istruzioni per l'uso.

Ogni kit contiene un inserto recante i valori di riferimento specifici per il lotto.

MATERIALI NECESSARI, MA NON IN DOTAZIONE

In combinazione con la Thromboplastin L è possibile utilizzare i seguenti prodotti:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

CONSERVAZIONE, VITA UTILE E STABILITÀ

I reagenti non aperti sono stabili fino alla data di scadenza indicata se conservati nelle condizioni riportate sul flacone o sull'etichetta del kit

Thromboplastin L — Le fiale aperte sono stabili per 2 mesi ad una temperatura compresa tra $^{+}$2 e $^{+}$8°C, per 5 giorni a $^{+}$15°C (Sysmex CA-1500 on-board) e per 6 ore a $^{+}$37°C (AC-4 on-board compresi il contenitore del reagente e il tappo). È possibile ottenere una stabilità d'uso di 7 giorni (Sysmex CA-1500).
NON CONGELARE. Ammassi consistenti di particelle o variazioni nei valori previsti possono essere indice di deterioramento del prodotto.

RACCOLTA E PREPARAZIONE DEI CAMPIONI

Nel corso dell'intera procedura è necessario utilizzare plastica o vetro siliconizzato. Il sangue (9 parti) deve essere raccolto in sodio citrato al 3,2% o al 3,8% come anticoagulante (1 parte). Separare il plasma in seguito a centrifugazione a 1500 x g per 15 minuti. Il plasma deve essere conservato a $^{+}$18 –$^{+}$24°C. I test devono essere completati entro 4 ore dalla raccolta dei campioni; in alternativa, il plasma può essere conservato congelato a -20°C per 2 settimane o a -70°C per 6 mese. Decongelare rapidamente a $^{+}$37°C prima di eseguire i test. Non conservare a $^{+}$37°C per oltre 5 minuti[6].

PROCEDURA

Per un rilevamento accurato dell'INR si raccomanda di determinare l'ISI specifico del laboratorio per il reagente con il sistema di test in uso. A tale scopo si raccomanda il ISI Calibrant Plasma Set (REF 5519) di Helena Biosciences Europe[7,8]. Questa procedura deve essere eseguita per ogni nuovo lotto di reagente. L'INR Reference Set (REF 5490) di Helena Biosciences Europe deve invece essere utilizzato per rilevare eventuali spostamenti dell'ISI del sistema locale osservati in concomitanza con cambiamenti della temperatura del laboratorio e in seguito a manutenzione dello strumento, tra le altre variazioni locali.

Metodo Manuale

1. Miscelare un quantitativo di Thromboplastin L sufficiente a completare i test previsti per la giornata e incubare a +37°C per un massimo di 4 ore.
2. Preriscaldare 0,1 mL di plasma di prova a $^{+}$37°C per 2 minuti.
3. Aggiungere al plasma 0,2 mL di reagente a base di tromboplastina appena miscelato, azionando contemporaneamente un cronometro.
4. Annotare il tempo di formazione del coagulo con un'approssimazione a 0,1 secondi.

Metodo Automatico

Fare riferimento al manuale utente dello strumento appropriato per istruzioni dettagliate oppure contattare Helena Biosciences Europe per le note applicative specifiche dello strumento.

INTERPRETAZIONE DEI RISULTATI

I risultati devono essere indicati con un'approssimazione a 0,1 secondi e le ripetizioni devono corrispondere con una tolleranza del 5%. I valori di %PT possono essere interpolati dal grafico di calibrazione (%PT dei plasmi di calibrazione PT vs. tempo di coagulazione rilevato), che, se tracciato su carta a doppia scala logaritmica, deve apparire sotto forma di linea retta.

I valori di INR possono essere calcolati utilizzando la seguente formula: INR = (Tempo di PT Paziente / Tempo di PT normale medio)^{ISI}

Per una guida chiara sulle indicazioni per la gestione dei pazienti con warfarina fare riferimento a The British Society for Haematology per la loro edizione più aggiornata delle 'Linee guida sull'anticoagulazione orale con warfarina'. Al momento della stampa questa è la quarta edizione del 2011[9].

LIMITAZIONI

Si sconsiglia l'impiego di diluizioni seriali di un plasma di riferimento per la curva %PT, che infatti possono dare luogo a discrepanze dovute al basso livello di fibrinogeno nelle diluizioni del plasma di riferimento, che non compaiono invece nei campioni dei pazienti con livelli di fibrinogeno prevalentemente normali. Helena Biosciences Europe consiglia di utilizzare a questo scopo il kit 5504R %PT/Direct INR.

CONTROLLO QUALITÀ

Ogni laboratorio deve definire un programma di controllo qualità. I plasmi di controllo normali e anormali devono essere testati prima di ogni lotto di campioni di pazienti, per garantire un livello prestazionale soddisfacente sia per quanto riguarda lo strumento che per l'operatore. Qualora i controlli non funzionassero come previsto, i risultati relativi ai pazienti dovranno essere considerati non validi.
Helena Biosciences Europe mette a disposizione i seguenti controlli utilizzabili con questo prodotto:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

VALORI DI RIFERIMENTO

Per la sicurezza del paziente, è necessario che il sistema sia monitorato continuamente da un operatore qualificato. Per tale motivo ciascun laboratorio dovrà elaborare i propri range di riferimento. Ciò è particolarmente importante per la calibrazione dell'ISI locale. Con l'impiego della gamma di strumenti Symex, i valori normali che variano tra 11,50 - 14,60 secondi; 0.930 - 1.160 INR; 79.10 - 112.80 %PT sono ritenuti tipici.

CARATTERISTICHE PRESTAZIONALI

Le seguenti caratteristiche prestazionali sono state determinate da Helena Biosciences Europe o dai propri rappresentanti con l'utilizzo di uno strumento di coagulazione Sysmex CA-1500. Ciascun laboratorio dovrà pertanto elaborare i propri dati prestazionali.

Riproducibilità

Campione	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Ripetibilità	0,07	0,59	0,24	1,09	0,45	1,11
Tra le serie	0,10	0,83	0,16	0,75	0,49	1,20
Tra giorni	0,04	0,32	0,06	0,27	0,25	0,62
All'interno del dispositivo/laboratorio	0,12	1,07	0,29	1,35	0,72	1,75

Interferenze

La Thromboplastin L Helena non è sensibile ai livelli di eparina di oltre 2 U/mL. Utilizzando una soglia di interferenza del 5%, non risulta esserci alcuna significativa interferenza da parte dell'emoglobina a concentrazioni fino a 10 g/l. Utilizzando una soglia di interferenza del 5%, non risulta esserci alcuna significativa interferenza da parte della bilirubina a concentrazioni fino a 0,5 g/l per la Thromboplastin L. I test per le interferenze dei lipidi dimostrano che i livelli dei lipidi non influenzano direttamente il tempo di coagulazione del reagente fino a 3,75 g/l. Concentrazioni lipidiche superiori a questo valore impediscono il rilevamento del coagulo.

Confronto dei metodi

Si è eseguito un confronto su 268 campioni tra il tempo di coagulazione in secondi e i valori INR utilizzando la tromboplastina L e la tromboplastina LI. Si sono ottenute le seguenti correlazioni:

Thromboplastin L (secondi) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

BIBLIOGRAFIA

1. Quick AJ (1935) A Study of the Coagulation Defect in Hemophilia and Jaundice, *Am. J. Med. Sci,* **190:** 501.
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Thromboplastin L
Instrucciones de uso

es

USO PREVISTO

El uso previsto del kit Thromboplastin L es realizar ensayos de hemostasia basados en la coagulación.

La primera prueba estandarizada de la protrombina en una sola etapa fue desarrollada por el Dr. Armand Quick en 1935. Ahora se ha convertido en la prueba de cribado básico de la coagulación para el diagnóstico de deficiencias congénitas y adquiridas de factores de coagulación de la vía extrínseca (factores II, V, VII y X)[1,2]. Se usa también para la inducción y monitorización del tratamiento anticoagulante oral[3,4] y puede usarse para valorar la capacidad de síntesis de proteínas del hígado en trastornos hepáticos crónicos o agudos.
La Thromboplastin L tiene su origen en cerebro de conejo, pero se parece a la BCT humana en su bajo Índice de Sensibilidad Internacional (ISI). El ISI de Thromboplastin L es de aproximadamente 1,1 y se calibra contra el preparado de referencia internacional de la OMS[5]. La prueba de Thromboplastin L está especialmente adaptada a la monitorización del tratamiento anticoagulante oral y, conjuntamente con el plasma deficiente en el factor oportuno, la medición de la actividad de los factores en la vía extrínseca. La tromboplastina tisular, en presencia de iones calcio, es un activador que inicia la vía extrínseca de la coagulación. Cuando se añade una mezcla de tromboplastina tisular e iones calcio al plasma normal citratado, se activa el mecanismo de coagulación, conduciendo a un coágulo de fibrina. Si se produce una deficiencia dentro de la vía extrínseca, el tiempo necesario para la formación de coágulos se prolongará dependiendo de la intensidad de la deficiencia.

ADVERTENCIAS Y PRECAUCIONES

Los reactivos que contiene este kit son sólo para uso de diagnóstico *in vitro*: NO INGERIR. Lleve el equipo de protección personal adecuado cuando utilice todos los componentes del kit. Consulte la declaración de seguridad del producto para saber más sobre las indicaciones adecuadas de advertencia y riesgo. Desechar los componentes de conformidad con las normativas locales.

COMPOSICIÓN

Componente	Contiene	Descripción	Preparación
Thromboplastin L	2 x 5 mL (REF 5265HL) 8 x 5 mL (REF 5265L) 10 x 10 mL (REF 5267L)	Tromboplastina líquida de cerebro de conejo que contiene cloruro de calcio, estabilizadores y conservantes.	La tromboplastina líquida calcificada está lista para su uso. No es necesario más calcio para realizar pruebas estándar de PT. Los contenidos del vial se deben mezclar bien antes de utilizarlo (5 minutos en el rodillo).

Cada kit contiene instrucciones de uso.

Cada kit contiene valores de referencia específicos insertados del lote.

ARTÍCULOS NECESARIOS NO SUMINISTRADOS

Los siguientes productos se puede utilizar junto con la Thromboplastin L:

REF 5519	ISI Calibrant Plasma Set
REF 5490	INR Reference Set

ALMACENAMIENTO, CADUCIDAD Y ESTABILIDAD

Los reactivos no abiertos son estables hasta la fecha de caducidad indicada cuando se conservan en las condiciones indicadas en el vial o en la etiqueta del kit.

Thromboplastin L — Los viales abiertos permanecen estables durante 2 meses a una temperatura de entre $^{+}$2 – $^{+}$8°C, 5 días a una temperatura mayor a $^{+}$15°C (en el Sysmex CA1500), y 6 horas a una temperatura mayor a $^{+}$37°C (en el AC-4, incluido el contenedor del reactivo y el tapón). Se puede conseguir estabilidad multiuso de 7 días (Sysmex CA-1500).
NO CONGELAR. Los grumos grandes de partículas o los cambios en los valores esperados pueden indicar deterioro del producto.

RECOGIDA Y PREPARACIÓN DE LAS MUESTRAS

Debe usarse siempre plástico o vidrio siliconizado. Debe recogerse sangre (9 partes) en el anticoagulante citrato sódico al 3,2% o al 3,8% (1 parte). Separar el plasma después de la centrifugación a 1500 x g durante 15 minutos. El plasma debe conservarse a $^{+}$18 –$^{+}$24°C. Las pruebas deberían terminarse en 4 horas desde la recogida de las muestras o el plasma puede conservarse congelado a -20°C durante 2 semanas o -70°C durante 6 mes. Descongelar rápidamente a $^{+}$37°C antes de realizar la prueba. No conservar a $^{+}$37°C durante más de 5 minutos[6].

PROCEDIMIENTO

Para la comunicación exacta del INR, se recomienda determinar la ISI específica del laboratorio del reactivo con el sistema de prueba en uso. Se recomienda el ISI Calibrant Plasma Set de Helena Biosciences Europe (REF 5519) para este fin[7,8]. Esto debe realizarse para cada nuevo lote de reactivos. Debe usarse el Set de Referencia de INR de Helena Biosciences Europe (REF 5490) para comprobar las desviaciones en el ISI del sistema local que se han observado con cambios en la temperatura del laboratorio y el mantenimiento posinstrumental, entre otras variaciones locales.

Método Manual

1. Mezclar la cantidad suficiente de Thromboplastin L para completar la prueba anticipada para el día e incubar a +37°C durante un período de tiempo no superior a 4 horas.
2. Precaliente 0,1 mL del plasma de prueba a $^{+}$37°C durante 2 minutos.
3. Añada 0,2 mL de reactivo de tromboplastina recién mezclado al plasma mientras pone en marcha simultáneamente un cronómetro.
4. observa el tiempo hasta la formación del coágulo procurando afinar en la décima 0,1 de segundo más próxima.

Método Automatizado

Consulte el manual del usuario del instrumento adecuado para instrucciones detalladas o póngase en contacto con Helena Biosciences Europe para notas de aplicación específicas del instrumento.

INTERPRETACIÓN DE LOS RESULTADOS

Los resultados deben comunicarse en los 0,1 segundos más próximos y las pruebas duplicadas deben estar de acuerdo entre sí dentro del 5%. Los valores de %TP pueden interpolarse a partir del gráfico de calibración (%TP de los plasmas de calibración del TP frente al tiempo de coágulo medido) que debe ser una línea recta cuando se representa en un papel de gráficos log-log.

Los valores de INR pueden calcularse usando la siguiente fórmula: INR = (Tiempo de TP Paciente / Tiempo de TP normal medio)^{ISI}

Si necesita una guía clara de indicaciones y tratamiento de pacientes con warfarina, consulte The British Society for Haematology y su última edición de "Guidelines on oral anticoagulation with warfarin" que, en el momento de impresión de este documento, se encuentra en su cuarta edición de 2011[9].

LIMITACIONES

El uso de diluciones seriadas de un plasma de referencia para la curva de %TP no se recomienda, porque puede llevar a discrepancias producidas por el bajo fibrinógeno en las diluciones del plasma de referencia, que no se reflejan en las muestras de pacientes que tienen fundamentalmente niveles normales de fibrinógeno. Helena Biosciences Europe recomienda utilizar el kit 5504R %PT/INR directa a tal fin.

CONTROL DE CALIDAD

Cada laboratorio debe establecer un programa de control de calidad. Los controles normales y anormales deben estudiarse antes de cada lote de muestras del paciente, para asegurar un funcionamiento adecuado del instrumento y el operador. Si los controles no se realizan como se esperaba, los resultados del paciente deben considerarse inválidos.
Helena Biosciences Europe suministra los siguientes controles disponibles para usar con este producto:

REF 5186	Routine Control N
REF 5187	Routine Control A
REF 5183	Routine Control SA
REF 5490	INR Reference Set

VALORES DE REFERENCIA

Los valores de referencia pueden variar entre los laboratorios dependiendo de las técnicas y sistemas usados. Por esta razón, cada laboratorio debe establecer su propio intervalo normal. Esto es especialmente importante para la calibración local del ISI. Con la serie de instrumentos Sysmex, es frecuente que los valores normales varíen entre 11,50 - 14,60 segundos; 0.930 - 1.160 INR; 79.10 - 112.80 %PT .

CARACTERÍSTICAS FUNCIONALES

Las siguientes características de rendimiento han sido determinadas por Helena Biosciences Europe o sus representantes usando un instrumento de coagulación Sysmex CA-1500. Cada laboratorio debe establecer sus propios datos de rendimiento.

Reproductibilidad

Muestra	Routine Control N		Routine Control A		Routine Control SA	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Repetibilidad	0,07	0,59	0,24	1,09	0,45	1,11
Entre series	0,10	0,83	0,16	0,75	0,49	1,20
Entre días	0,04	0,32	0,06	0,27	0,25	0,62
En el dispositivo/laboratorio	0,12	1,07	0,29	1,35	0,72	1,75

Interferencias

Helena Thromboplastin L no detecta niveles de heparina inferiores a 2 U/mL.Con un umbral de interferencia del 5%, no hay interferencias significativas de hemoglobina en concentraciones de hasta 10 g/L. Con un umbral de interferencia del 5%, no hay interferencias significativas de bilirrubina en concentraciones de hasta 0,5 g/L para Thromboplastin L. La interferencia de lípidos demuestra que los niveles de lípidos no afectan directamente al tiempo de coagulación del reactivo hasta 3,75 g/L. Las concentraciones de lípidos superiores evitan detectar la coagulación.

Comparación del método

La comparación del tiempo de coagulación y los valores INR se determinó con tromboplastina L y tromboplastina LI en 268 muestras. Se obtuvieron las siguientes correlaciones:

Thromboplastin L (segundo) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Thromboplastin L (INR) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

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Тест-система "Жидкий тромбопластин"
инструкция

ru

НАЗНАЧЕНИЕ

Комплект Тест-система "Жидкий тромбопластин" предназначен для выполнения анализов гемостаза на основе кровяного сгустка.

Впервые стандартизированный одностадийный тест для определения протромбинового времени был предложен д-ром Армандом Квиком в 1935г. Сейчас он стал основным скрининговым тестом для диагностики врожденного и приобретенного дефицитов факторов свертывания крови по внешнему пути (факторы II, V, VII и X)[1,2]. Он также используется для мониторинга терапии оральными антикоагулянтами[3,4], а также может применяться и для оценки белок синтетической функции печени при ее острых либо хронических заболеваниях.
Реагент приготовлен из экстракта ткани мозга кролика и по значению своего МИЧ (Международного Индекса Чувствительности) сопоставим со Стандартом Тромбопластина Британии (BCT – British Comparative Thromboplastin). МИЧ Жидкого тромбопластина примерно равен 1.1 и откалиброван относительно международного референса BO3[5]. Жидкий тромбопластин особенно подходит для мониторинга терапии оральными антикоагулянтами и для измерения активности факторов внешнего пути свертывания(вместе с соответствующей фактор-дефицитной плазмой). Тканевый тромбопластин в присутствии йонов кальция является активатором внешнего пути свертывания крови. При добавлении смеси тканевого тромбопластина с кальцием к нормальной цитратной плазме активируется механизм её свертывания, приводящий к образованию фибринового сгустка. Если у пациента имеет место дефицит факторов внешнего пути, то время, необходимое для образования сгустка будет удлиняться прямо пропорционально степени дефицита факторов.

ПРЕДУПРЕЖДЕНИЯ И МЕРЫ ПРЕДОСТОРОЖНОСТИ

Содержащиеся в данном наборе реагенты предназначены только для *in vitro* диагностики– НЕ ПРИНИМАТЬ ВНУТРЬ! При работе со всеми компонентами набора использовать соответствующие средства индивидуальной защиты. В случае необходимости см. свидетельство о безопасности изделия для ознакомления с соответствующими описаниями опасного воздействия и сведениями о мерах предосторожности. Удаление компонентов в отходы производите в соответствии с местными правилами.

СОСТАВ

Компоненты	Состав набора	Описание	Приготовление реагентов
Жидкий тромбопластин	2 x 5 мл (Кат.№ 5265HL) 8 x 5 мл (Кат.№ 5265L) 10 x 10 мл (Кат.№ 5267L)	Тромбопластин-кальциевая суспензию реагента из экстракта ткани мозга кролика, раствора хлорида кальция и стабилизаторов	Жидкий кальцинированный тромбопластин, готовый для использования. Для проведения теста ПВ дополнительный кальций не требуется. Содержимое флакона перемешать до использования (5 мин. на роллере)

Каждый набор содержит инструкцию по применению.

Вкладыш с указанием референсных значений к различным анализаторам и методам исследования, характерным для данного лота.

НЕОБХОДИМЫЕ КОМПОНЕНТЫ, НЕ ВКЛЮЧЕННЫЕ В КОМПЛЕКТ ПОСТАВКИ

Продукция ниже, которая может использоваться вместе с Тест-системой «Тромбопластин»:

Кат.№ 5519	Калибратор МИЧ
Кат.№ 5490	Контроль на МНО

ХРАНЕНИЕ, СРОК ГОДНОСТИ И УСТОЙЧИВОСТЬ

Невскрытые флаконы с реагентами хранятся до истечения срока годности в условиях, указанных на этикетке.

Жидкий тромбопластин — Вскрытые флаконы годны к применению в течение 2 месяцев при температуре хранения 2-8°C, 5 дней при 15°C (на борту Sysmex CA-1500) и 6 часов при 37°C (на борту AC-4, используя контейнер для реагентов с крышкой). Стабильность реагента на борту Sysmex CA-1500 - 7 дней.
НЕ ЗАМОРАЖИВАТЬ! Признаки ухудшения качества реагента: большое скопление частиц или отличия от ожидаемых значений могут означать ухудшение свойств реактива.

ОТБОР И ПОДГОТОВКА ОБРАЗЦОВ

Для работы следует использовать только пластиковые или силиконированные стеклянные пробирки. Кровь забирается в пробирку с цитратным антикоагулянтом (3,2% или 3,8% цитрат натрия) в соотношении 9 + 1. После центрифугирования при 1500 g, в течение 15 минут (использование других параметров должно проверяться лабораторией), полученную плазму необходимо отделить от форменных элементов крови. Плазму следует хранить при температуре $^{+}$18 –$^{+}$24°C. Тестирование должно быть проведено в течение 4 часов после забора образцов, либо плазму можно однократно заморозить и хранить при температуре -20°C в течение 2 недель или при -70°C в течение 6 месяцев. Перед проведением исследования плазму следует быстро разморозить при $^{+}$37°C. Не держать плазму при $^{+}$37°C более 5 минут[6].

ПРОЦЕДУРА

Для установления более точного МНО рекомендуется определить специфическое для лаборатории значение МИЧ (так называемый «локальный» МИЧ) для жидкого тромбопластина. Helena Biosciences Europe рекомендует для этих целей применять Калибратор МИЧ (Кат.№ REF 5519)[7,8]. Подобная процедура должна быть проведена для каждой новой партии реагентов. Контроль на МНО (Кат.№ REF 5490) используется для контроля изменения в «локальном» МИЧ, так как его значение может незначительно варьировать в зависимости от используемых приборов, а также изменений температуры в лаборатории и других локальных факторов.

Ручной Метод

1. Взять необходимое количество жидкого тромбопластина, необходимое для проведения тестирования в течение дня и инкубировать при 370С (но не более 4 часов).
2. Прогреть 0,1 мл тестируемой плазмы при $^{+}$37°C в течение 2 минут.
3. Добавить 0,2 мл свежеприготовленной рабочей смеси реагентов к плазме и немедленно включить таймер.
4. Заметить время, необходимое для образования сгустка с точностью до 0,1сек.

Автоматизированный Метод

Для проведения тестирования на автоматических коагулометрах, необходимо обратиться к руководству пользователя и к соответствующей адаптации, которые доступны у официальных дистрибьюторов и компании Хелена.

ИНТЕРПРЕТАЦИЯ РЕЗУЛЬТАТОВ

Результаты должны быть представлены с точностью до 0,1 сек и разница в повторах не должна превышать 5%. Значение %ПВ можно определить по калибровочному графику (график зависимости %ПВ от измеренного времени), который должен быть строго линейным в билогарифмических координатах при построении графика на миллиметровке с логарифмическим масштабом на обеих осях.

МНО может быть вычислено по формуле: МНО= {ПВ (пациента)/среднее ПВ (норма)}^{МИЧ}

Для более подробной информации по мониторингу пациентов на Варфарине обратитесь к рекомендациям Британского Общества по Гематологии - «Рекомендации по антикоагулянтной терапии варфарином», 4-е издание 2011г. на время печати этого документа[9].

ОГРАНИЧЕНИЯ

Для получения графика зависимости (%ПТ) от времени свертывания не рекомендуется использовать серии разведений референсной плазмы, поскольку это может привести к неточности, вызванной низким содержанием фибриногена в больших разведениях референсной плазмы, что не соответствует образцам пациентов, имеющих, в основном, нормальный уровень фибриногена. Компания Хелена рекомендует использовать калибратор кат. номер 5504R для %ПВ, и прямого определения МНО.

КОНТРОЛЬ КАЧЕСТВА

Каждая лаборатория должна установить программу контроля качества. Перед измерением каждой партии образцов пациентов необходимо протестировать нормальную и патологическую плазму, чтобы удостовериться в удовлетворительной работе оборудования и оператора. Если контрольные измерения не совпадают с ожидаемыми значениями, то измеренные данные пациентов следует считать недостоверными.
Компания Хелена рекомендует следующие контрольные материалы:

Кат.№ 5186	Контроль качества, норма
Кат.№ 5187	Контроль качества, умеренно выраженная патология
Кат.№ 5183	Контроль качества, высокая патология
Кат.№ 5490	Контроль на МНО

НОРМАЛЬНЫЕ ПОКАЗАТЕЛИ

Референсные значения могут варьировать между лабораториями в зависимости от используемых методов и анализаторов. В связи с этим каждая лаборатория должна определить свою собственную область нормальных значений. Это крайне важно для установки локального МИЧ тромбопластина. Диапазон нормальных значений пациентов 11,50 - 14,60 сек.; 0.930 - 1.160 INR; 79.10 - 112.80 %PT с использованием коагулометров Sysmex.

ЭКСПЛУАТАЦИОННЫЕ ХАРАКТЕРИСТИКИ

Компания Хелена или её дистрибьюторы определили следующие ориентировочные аналитические характеристики. Каждая лаборатория должна определить свои собственные аналитические характеристики. При использовании оптико-механического коагулометра и реагентов Хелена были определены следующие коэффициенты вариации (CV):

Воспроизводимость

Образец	Контроль качества, норма		Контроль качества, умеренно выраженная патология		Контроль качества, высокая патология	
	SD	*CV (%)*	*SD*	*CV (%)*	*SD*	*CV (%)*
Воспроизводимость	0,07	0,59	0,24	1,09	0,45	1,11
в пределах аналитической серии	0,10	0,83	0,16	0,75	0,49	1,20
между разными аналитическими сериями	0,04	0,32	0,06	0,27	0,25	0,62
между партиями/лабораториями	0,12	1,07	0,29	1,35	0,72	1,75

Тест-система "Жидкий тромбопластин" не чувствителен к гепарину в концентрации до 2 Ед/мл. Используя 5% допустимое отклонение, реагент не чувствителен к гемоглобину в концентрации до 10 г/Л. Используя 5% допустимое отклонение, реагент не чувствителен к билирубину в концентрации до 0.5 г/Л. Не обнаружено чувствительности к уровню липидов до 3.75 г/Л оказывающих воздействие на время свёртываемости. Концентрации липидов выше этого уровня предотвратит обнаружение сгустка.

Сравнение со стандартами:
Сравнение значений МНО 268 образцов, определённых с помощью Тест-системы "Тромбопластин" и Тест-системы "Жидкий тромбопластин" дало следующие корреляционные соотношения:

Жидкий Тромбопластин (сек) = 0,9911x + 0,1038	r^2 = 0,9941	n = 268
Жидкий Тромбопластин (МНО) = 0,9853x + 0,0261	r^2 = 0,9500	n = 268

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14
Expiry Date: 2024-04-13

...making excellence a habit.™

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25

Effective Date: 2021-04-14

Latest Revision Date: 2021-04-13

Expiry Date: 2024-04-13

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 10462 rev. 7

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

ELITECH CLINICAL SYSTEMS SAS

Zone Industrielle

61500 SEES FRANCE

pour les activités

for the activities

Conception, production, contrôle et commercialisation de produits de chimie cliniques pour le diagnostic in vitro. Validation de la combinaison réactifs et automates. Distribution d'automates et de produits de chimie cliniques pour le diagnostic in vitro.

Design, production, control and sales of clinical chemistry products intended to be used for in vitro diagnostics. Validation of the combination reagents and analyzers. Distribution of clinical chemistry analyzers and products for in vitro diagnostics.

réalisées sur le(s) site(s) de

performed on the location(s) of

ELITech Clinical Systems SAS
Zone industrielle - 61500 SEES - FRA

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité / *Effective date :* **July 28th, 2020 (included)**

Valable jusqu'au / *Expiry date :* **July 27th, 2023 (included)**

Etabli le / *Issued on :* **July 17th, 2020**

DocuSigned by:
Lionel DREUX
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GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Lionel DREUX
Certification Director

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GMED N° 10462–7
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Renouvelle le certificat 10462-6

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ELITechGroup
EMPOWERING IVD

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs référencés dans la liste ci-jointe (2 pages), sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Ces dispositifs sont classés dans la catégorie « autre dispositif » puisqu'ils n'appartiennent ni à la liste A et liste B de l'annexe II et ni à la classe des autotests.

Cette déclaration est basée sur le contenu de chaque dossier technique et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2023).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents such as listed attached (2 pages) , conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

These devices are classified in the "other device" category since they do not belong neither to list A or list B of annex II nor to self-testing class.

This declaration is based on the contents of each technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2023).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos referenciados en la lista adjunta (2 páginas), son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Estos dispositivos se clasifican en la categoría "otro dispositivo", ya que no pertenecen a la lista A ni a la lista B del anexo II, tampoco a la clase de autodiagnóstico.

Esta declaración se basa en el contenido de cada expediente técnico y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2023).

Sées, le 12 Mai 2021

Valérie LAMBERT,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

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SIRET 318 365 228 00036

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Metabolites divers / Miscellaneous metabolites		
ALBUMIN	ALBU-0600/0700/0250/M830	53597
ALBUMIN ENVOY	ALBU-0850	
BILIRUBIN DIRECT 4+1	BIDI-0600/0250	53233
BILIRUBIN TOTAL 4+1	BITO-0600/0250	53229
BILIRUBIN TOTAL & DIRECT 4+1	BITD-0600	53229/53233
CREATININE ENVOY	CRSL-0850	53250
CREATININE JAFFE	CRCO-0600/0700	53251
CREATININE PAP	CRSL-M490	53250
CREATININE PAP SL	CRSL-0630/0250	
DIRECT BILIRUBIN	BIDI-M430	53233
DIRECT BILIRUBIN ENVOY	BIDV-0850	53233
GLUCOSE ENVOY	GPSL-0850	53301
GLUCOSE HK	GHSL-M490	
GLUCOSE HK SL	GHSL-0600/0250	
GLUCOSE PAP	GPSL-M690	
GLUCOSE PAP SL	GPSL-0507/0500/0707/0700/0250/0455/0497	
LACTATE	LACT-0100	53342
MICROPROTEIN PLUS	PRTU-0600/0250	53481
PHOSPHORUS	PHOS-0600/0230/M430	59123
PHOSPHORUS ENVOY	PHOS-0850	
TOTAL BILIRUBIN	BITO-M430	53229
TOTAL BILIRUBIN ENVOY	BITV-0850	53229
TOTAL PROTEIN	PROB-M830	53985
TOTAL PROTEIN ENVOY	PROB-0850	
TOTAL PROTEIN PLUS	PROB-0600/0700/0250	
UREA	URSL-M830	53587
UREA ENVOY	URSL-0850	
UREA UV SL	URSL-0427/0420/0500/0507/0250/0455	
URIC ACID	AUML-M830	53583
URIC ACID ENVOY	AUVD-0850	
URIC ACID MONO SL	AUML-0497/0427/0420/0500/0507/0707/0250	
URIC ACID SL	AUSL-0250	
URINE PROTEIN	PRTU-M230	53481
Enzymes / Enzymes		
ALP (DEA) SL	PASL-0400/0420/0230	52928
ALP ENVOY	PIVD-0850	
ALP IFCC	ALPI-0230	
ALT ENVOY	ALSL-0850	52923
ALT/GPT	ALSL-M490	
ALT/GPT 4+1 SL	ALSL-0410/0430/0510/0250/0455	
AMYLASE	AMSL-M430	52940
AMYLASE ENVOY	AMSL-0850	
AMYLASE SL	AMSL-0390/0400/0230	
AST/GOT	ASSL-M490	52954
AST ENVOY	ASVD-0850	
AST/GOT 4+1 SL	ASSL-0410/0430/0510/0250/0455	
CHOLINESTERASE	CHES-0053	52971
CK ENVOY	CKSL-0850	53003
CK-MB ENVOY	CMSL-0850	52994
CK-MB SL / CKMB	CMSL-0410/0430/0230	
CK NAC	CKSL-M230	53003
CK NAC SL	CKSL-0410/0430/0230	
GAMMA-GT	GISL-M230	53027
GAMMA-GT PLUS SL	GISL-0400/0420/0250	
GGT ENVOY	GISL-0850	
LDH ENVOY	LLSL-0850	53072
LDH IFCC	LLSL-M230	
LDH-L SL	LLSL-0400/0420/0230	
LIPASE	LPSL-0250	53108
LIPASE ENVOY	LPSL-0850	
LIPASE SL	LPSL-0230	
Electrolytes / Oligo-élements / Electrolytes / Trace-elements		
CALCIUM ARSENAZO	CALA-0600/0250/M430	45789
CALCIUM ENVOY	CALA-0850	
CHLORIDE	CHLO-0600/0250	60037
IRON ENVOY	FEFE-0850	54758
IRON FERENE	FEFE-0230/0600/M230	
MAGNESIUM ENVOY	MAGX-0850	46795
MAGNESIUM XB	MGXB-0250/0600/M430	
MAGNESIUM XYLIDYL	MAGX-0230/0600	
Lipides / Lipids		
CHOLESTEROL	CHSL-M690	53359
CHOLESTEROL ENVOY	CHSL-0850	
CHOLESTEROL HDL SL 2G	HDLL-0230/0380/0390	53391
CHOLESTEROL LDL SL 2G	LDLL-0230/0380/0390	53395
CHOLESTEROL SL	CHSL-0507/0500/0700/0707/0250/0455/0497	53359
HDL CHOLESTEROL	CHDL-0250/0600/M330	53391
HDL CHOLESTEROL ENVOY	HDLL-0850	
LDL CHOLESTEROL	CLDL-0250/M330	53395
LDL CHOLESTEROL ENVOY	LDLL-0850	
TRIGLYCERIDES	TGML-M690	53460
TRIGLYCERIDES ENVOY	TGML-0850	
TRIGLYCERIDES MONO SL NEW	TGML-0427/0425/0515/0700/0517/0707/0497	
TRIGLYCERIDES SL	TGML-0250/0455	

Vla

REACTIFS - REAGENTS - REACTIVOS	RÉFÉRENCES - REFERENCES - REFERENCIAS	Code GMDN
Contrôles-Calibrants-Standards / Controls-Calibrators-Standards		
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	44698
CK-MB CONTROL	CKMB-0900	44693
ELICAL 2	CALI-0550	47868
ELITROL I	CONT-0060	47869
ELITROL II	CONT-0160	
GLUCOSE Standard 100 mg/dL	GLUP-0055	41818
HDL LDL CALIBRATOR	HLCA-0041	47868
ISE CONTROL I	ISCT-0046	47869
ISE CONTROL II	ISCT-0047	
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	44702
UREA Standard 50 mg/dL	URUV-0055	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	44704
Protéines spécifiques / Specific proteins		
ANTI-STREPTOLYSIN O	ASLO-0250	59055
CRP IP	ICRP-0400/M230	53705
CRP IP CALIBRATOR SET	ICRP-0043	41838
CRP IP CONTROL I	ICRP-0046	41839
CRP IP CONTROL II	ICRP-0047	
CRP WR	CRPW-0230	53705
CRP WR CALIBRATOR SET	CRPW-0043	41838
CRP WR CONTROL	CRPW-0045	41839
CRP WR ENVOY	CRPW-0850	53705
FERRITIN	IFRT-0230	53718
FERRITIN CALIBRATOR	IFRT-0042	41927
HAPTOGLOBIN IP	IHAP-0400	53737
HbA1c	HBAC-0240	59090
HbA1c CALIBRATOR SET	HBAC-0043	53315
HbA1c CONTROL L + H	HBAC-0049	44435
IgA IP	IIGA-0400	53760
IgG IP	IIGG-0400	53787
IgM IP	IIGM-0400	53795
µALBUMIN IP	IMAL-0400	53475
µALBUMIN IP CALIBRATOR SET	IMAL-0043	53477
µALBUMIN IP CONTROL I	IMAL-0046	53478
µALBUMIN IP CONTROL II	IMAL-0047	
OROSOMUCOID IP	IORO-0400	53606
PREALBUMIN IP	IPAL-0400	53957
PROTEIN IP CALIBRATOR SET	IPRO-0043	53593
RF CALIBRATOR	IRFA-0042	42230
RHEUMATOID FACTOR	IRFA-0230	55111
RHEUMATOLOGY CONTROL I	IRCT-0046	47869
RHEUMATOLOGY CONTROL II	IRCT-0047	
TRANSFERRIN IP	ITRF-0400	59041
Vitamines/Vitamins		
VITAMIN D	VITD-0250	54476
VITAMIN D CALIBRATOR SET	VITD-0043	54474
VITAMIN D CONTROL SET	VITD-0049	54475
ISE Solutions pour électrodes selectives d'ions / ISE Solutions for ion-selective electrodes		
ISE BASELINE SOLUTION ENVOY	ISBA-0850	59238
ISE CALIBRATORS	ISCA-0250	52867
ISE CALIBRATOR ENVOY	ISCV-0850	
ISE CLEANER/CONDITIONER	ISCC-0280	59058
ISE DILUENT	ISDI-0250	58237
ISE DILUENT ENVOY	ISDV-0850	
ISE REFERENCE SOLUTION	ISRS-0800	59238
ISE REFERENCE SOLUTION ENVOY	ISRS-0850	
Solutions de lavage pour les équipements ELITech Clinical Systems / Cleaning solutions for ELITech Clinical Systems Equipments		
ACID SOLUTION for ELITech Clinical Systems Analyzers	SLHC-5900	59058
SYSTEM CLEANING SOLUTION for ELITech Clinical Systems Analyzers	SLNA-5900	59058
SYSTEM SOLUTION	SLSY-5905	58236
SYSTEM SOLUTION for ELITech Clinical Systems Analyzers	SLSY-5900	
WASH SOLUTION A	SOLA-M163	59058
WASH SOLUTION B	WASH SOLUTION B	59058
Tests d'agglutination / Agglutination tests		
CRP LATEX	LXCR-0112	53707

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Medica Corporation

(FIN F002402)

Main Site: 5 Oak Park Drive, Bedford, Massachusetts, 01730, United States

Additional Site: 3 Oak Park Drive, Bedford, Massachusetts, 01730, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

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

The management system is applicable to:

Design, Development, Manufacture, Service, Installation and Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:
0089217

Initial Certification Date:
2019-04-19

Certification Effective Date:
2019-04-19

Certification Expiry Date:
2022-04-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

The design, engineering, manufacturing and distribution of Single Use Systems and supporting hardware, including installation-, service- and maintenance activities for the pharmaceutical and biotech industry.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

Certificate Number:	16880
EAC Code:	34
Certified Since:	March 22, 2012
Valid Until:	March 19, 2024
Reissued:	March 20, 2021
Cycle Issued:	March 20, 2021

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

Declaration of CE conformity

Avantor Performance Materials B.V. reg. no. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20
7418 AM Deventer
The Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T.Baker® label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III. The BeneSphera™ 3 Part Diff Analyzer H32 is in compliance with IEC 61010, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self-registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

January 6, 2015

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker® product list for CE marked products

Product no.	Product	Pack size
Hematology Analyzer		
2983	BeneSphera™ 3-part Diff Hematology Analyzer H32	1 unit
Clinical Chemistry Analyzer		
2946	BeneSphera™ Clinical Chemistry Analyzer C72	1 unit
Diluents		
3961	Diluid 100 Plus	20 liter
2990.9010PC	Diluid™ 22	10 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9020	Diluid Abacus	20 liter
3430.9010	Diluid Abacus	10 liter
3996	Diluid AC 900	20 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
2901.9010PC	Diluid BS34	10 liter
3963	Diluid III Diff	20 liter
3963.9010	Diluid III Diff	10 liter
3459.9020	Diluid Erma	20 liter
3419.9020PC	Diluid M5	20 liter
3439.9020PC	Diluid Mindray	20 liter
3483.9020PC	Diluid NR	20 liter
2987.9020PC	Diluid Ruby	20 liter
3832.9020	Diluid/Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3495.9010PC	Sheath D	10 liter
3471.9020PC	Sheath Fluid 3000/3500	20 liter
Lyses		
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet 1000 CN free	5 liter
2986.0500PE	CyMet™ 22	500 ml
3469.9010PC	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3839.5000PC	CyMet 3500	5 liter
3825	CyMet 3500 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3417.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
2950.2500PE	CyMet ASA	2.5 liter
2951.0500PE	CyMet ASB	500 ml
2952.9010PC	CyMet AS CN Free	10 liter
3755	CyMet Automated	5 liter
2982.0500PE	CyMet BS3 CN free	500 ml
2902.1000PE	CyMet BS34 CN Free	1 liter
3968.0500	CyMet III Diff	500 ml
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3511.1000	CyMet III Diff CN free	1 liter
3511.5000	CyMet III Diff CN free	5 liter
3416.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3853.1000	CyMet H20	1 liter
3425.0500	CyMet KX CN Free	500 ml
2985.1000PE	CyMet LH 53	1 liter
3489.1000PE	CyMet MBA	1 liter
3418.1000PE	CyMet MD(I)	1 liter
2984.1000PE	CyMet MD(I) 53	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3497.0500PE	CyMet MH CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3863.1000	CyMet Micro CN free	1L micros
3441.0500PE	CyMet Mindray	500 ml
3440.0500PE	CyMet Mindray CN Free	500 ml
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
2988.5000PC	CyMet Ruby CN Free	5 liter
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3788	CyMet STX/STL	1 liter
3475.5000PC	LeucoLyse	5 liter
2989.5000PC	LeucoLyse Ruby	5 liter
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3513.1000PE	RBCLyse™	1 liter
3518G.1000PE	RBCLyse G	1 liter
3514.0500PE	WBCStabilise™	500 ml
Reticulocyte Reagents		
3493.1000PE	RetiClear™ MHG	1 liter
3774	RetiCount™	30 ml
2953.0210PE	RetiCount AS	210 ml
3777	RetiCount CD	15 x 3.5 ml
3494.0200PE	RetiCount G	200 ml
Cleaners		
3507.9020	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3763	DetectoTerge™	5 liter
3766	DetectoTerge	1 liter
2970.0900PE	DetectoTerge BS	900 ml
3917	HypoChlorite	5 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3432.1000PE	ProClean Abacus	1 liter
3432.5000	ProClean Abacus	5 liter
3902.0100PE	ProClean CD	100 ml
3862.9020PC	ProClean Extra	20 liter
3862.5000	ProClean Extra	5 liter
3862.1000	ProClean Extra	1 liter
3867.1000PE	ProClean Extra	1L micros
3498.1000PE	ProClean MX5	1 liter
3901	ProClean Plus	100 ml
3442.5000PE	Rinse Mindray	5 liter

Product no.	Product	Pack size
Reagent Packs		
2910	Reagent Pack BS34	1 pack
Hematology Controls and Calibrators		
3427/3428/3429	8-Parameter Control L/N/H	2.5 ml
3463/3464/3465	8-Parameter Control L/N/H	2.5 ml
3701/3702/3703	8-Parameter Control L/N/H	4.5 ml
3746	8-Parameter Control L+N+H	3 x 2.5 ml
3747	8-Parameter Control 4xN	4 x 2.5 ml
3751	8-Parameter Control 1xL+4xN+1xH	6 x 2.5 ml
3633/3634/3635	8-Parameter Control ext L/N/H	2.5 ml
3433/3434/3435	3-Diff Control L/N/H	2.5 ml
3502/3503/3504	3-Diff Control L/N/H	4.5 ml
3466	3-Diff Control 4xL	4 x 2.5 ml
3467	3-Diff Control 4xN	4 x 2.5 ml
3468	3-Diff Control 4xH	4 x 2.5 ml
3421/3422/3423	3-Diff Control ext L/N/H	2.5 ml
3681/3682/3683	5D Control L/N/H	5.0 ml
3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3613/3614/3615	BC-Diff 5 Control L/N/H	4.5 ml
3940	Cal Set 1	2 x 2.5 ml
3452/3453/3454	CD-Diff Control L/N/H	3.0 ml
3838	CD-Diff Control 2xL+2xN+2xH	6 x 3.0 ml
3455/3456/3457	K-Diff Control L/N/H	2.5 ml
3424	Platelet Control Ext. value	5 x 3 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3652/3653/3654	XE-RET Control L/N/H	3.0 ml

Product no.	Product	Pack size
Stains and Dyes		
3800.1000PE	Eosin-Y Alcoholic	1 liter
3800.2500PE	Eosin-Y Alcoholic	2.5 liter
3800.9200	Eosin-Y Alcoholic	200 liter
3446.1000PE	Eosin Y 0.5% Aqueous	1 liter
3446.9200	Eosin Y 0.5% Aqueous	200 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3856.9180ST	Giemsa	180 liter
3870.1000	Hematoxyline (Mayer)	1 liter
3870.2500	Hematoxyline (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3873.9200	Hematoxyline (Harris, Gill II)	200 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	500 ml
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
Clearing agent		
3905.2500PE	UltraClear™	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
Mounting media		
3921.0500	UltraKitt™	500 ml
3921.0600	UltraKitt	6 x 100 ml
3921.9025ST	UltraKit	25 liter
3882.0500	Mounting Medium High	500 ml
3883.0500	Mounting Medium Low	500 ml
Fixatives		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010PE	10% v/v Buffered Formaldehyde	10 liter
3933.9020	10% v/v Buffered Formaldehyde	20 liter
3933.9200	10% v/v Buffered Formaldehyde	200 liter
3880.1000	Bouin's Fixative	1 liter
3869.1200	Cervix Fixative	12 x 125 ml
3884.9010PC	Cytology Fixative LBCM	10 liter
3409.9010	Immuno PBS 20x concentrated	10 liter
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

CERTIFICATE

This is to certify that

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

with the organizational units/sites as listed in the annex
has implemented and maintains a **Quality Management System**.

Scope:
Sales and supply of branded and private label chemicals, consumables, laboratory equipment, furniture, and medical devices from global leading developers and manufacturers of those products to customers in biopharma, healthcare, advanced technology and applied materials, education and government; manufacture of private label products, primarily laboratory and production chemicals including custom manufacturing solutions used in biopharmaceutical and industrial applications and production processes; provide value-added service offerings such as client outsourced activities: including sourcing and procurement, logistics, chemical and equipment tracking, lab and production services, scientific services and sample management; technical services in-house and at customer sites including installation, maintenance, qualification, calibration and repair of laboratory equipment

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	530840 QM15
Valid from	2021-08-04
Valid until	2024-06-28
Date of certification	2021-08-04

DAkkS Deutsche Akkreditierungsstelle D-ZM-16074-01-00

DQS GmbH

Markus Bleher
Managing Director

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530842 **VWR International GmbH** **Graumanngasse 7** **1150 Wien** **Austria**	Sales and supply; Lab and Production Services
530843 **VWR International GmbH** **Zimbagasse 5** **1210 Wien** **Austria**	Distribution; Technical Services
530841 **VWR International bv** **Researchpark Haasrode 2020** **Geldenaaksebaan 464** **3001 Leuven** **Belgium**	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531223 **VWR International GmbH** **Rue de Rive 18** **1260 Nyon** **Switzerland**	Sales and supply
531224 **VWR International GmbH** **Grabenstraße 1** **8952 Schlieren** **Switzerland**	Sales and supply; Distribution; Lab and Production Services; Technical services
531221 **VWR International GmbH** **Lerzenstraße 16 / 18** **8953 Dietikon** **Switzerland**	Sales and supply

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530844 **VWR International s.r.o.** **Praská 442** **281 67 Stribrná Skalice** **Czech Republic**	Sales and supply; Distribution; Kitting Services; Technical services
530847 **VWR International s.r.o.** **Pivovarská 30** **75661 Rožnov prod Radhoštêm** **Czech Republic**	Sales and supply
530868 **VWR International GmbH** **Großenhainer Straße 99** **01127 Dresden** **Germany**	Sales and supply
530869 **VWR International GmbH** **Wöhlerstraße 42** **30163 Hannover** **Germany**	Sales and supply
530867 **VWR International GmbH** **Hilpertstraße 20A** **64295 Darmstadt** **Germany**	Sales and supply; Lab and Production Services; Technical services
539946 **VWR International GmbH** **Heinrich-Blanc-Straße 40** **76646 Bruchsal** **Germany**	Distribution

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530865 **VWR International GmbH** **John-Deere-Straße 5** **76646 Bruchsal** **Germany**	Sales and supply; Distribution
530866 **VWR International GmbH** **Vichystraße 2** **76646 Bruchsal** **Germany**	Distribution
530870 **VWR International GmbH** **Fraunhoferstr.11** **85737 Ismaning** **Germany**	Sales and supply
530871 **VWR International GmbH** **James-Franck-Ring 9** **89081 Ulm** **Germany**	Sales and supply
530859 **VWR International A/S** **Tobaksvejen 21** **2860 Søborg** **Denmark**	Sales and supply; Distribution; Lab and Production Services; Technical services
531213 **VWR International Eurolab, S.L.** **C/ De la Technología, 5-17A7 - Llinars Park** **08450 Llinars Del Vallès Barcelona** **Spain**	Sales and supply; Distribution; Lab and Production Services; Technical services

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
530860 **VWR International Oy** **Valimotie 9** **00380 Helsinki** **Finland**	Sales and supply; Distribution; Lab and Production Services; Technical services
530863 **VWR International S.A.S.** **Europarc** **26 Avenue Leonard de Vinci** **33608 Pessac Cedex** **France**	Sales and supply
530861 **VWR International S.A.S** **Chemin de la Croix Saint-Marc** **Z.I. de Vaugereeau** **45250 Briare-le-Canal** **France**	Distribution; Manufacture
530862 **VWR International S.A.S** **Immeuble Estréo,** **1-3 Rue d'Aurion** **93110 Rosny-sous-Bois** **France**	Sales and supply; Lab and Production Services; Technical services
531226 **VWR International Ltd** **VWR House** **Warren Court** **Feldspar Close** **Enderby** **LE19 4SD** **Leicester** **United Kingdom**	Sales and supply

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531228 **LAB3 Service** **1 Dragon Court** **Crofts End Road** **St George** **Bristol** **BS5 7XX** **United Kingdom**	Lab and Production Services; Technical services
531225 **VWR International Ltd.** **Customer Service Centre** **Hunter Boulevard** **Magna Park** **Lutterworth, Leicestershire** **LE17 4 XN** **United Kingdom**	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531227 **VWR International Ltd.** **14 Media Village** **Liscombe Park** **Soulbury** **Leighton Buzzard** **LU7 0GA** **United Kingdom**	Sales and supply
540366 **VWR International** **Medical Equipment Supplies and Management** **The Solutions Buckshaw Village, Chorley** **Chorley** **PR7 7EL** **United Kingdom**	Sales and supply; Distribution; Technical Services

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531229 **Basan - the cleanroom division of VWR** **Units 2 & 3 Newton Court** **Basingstoke** **RG24 8GF** **United Kingdom**	Sales and supply; Distribution; Manufacture
546015 **Hichrom Ltd** **1-3 The Markham Centre, Station Road,** **Theale,** **Reading, Berkshire** **RG7 4AB** **United Kingdom**	Manufacture of UHPLC and HPLC columns with lot traceability. Procurement and distributor for UHPLC and HPLC columns and associated solvents, packing materials and accessories with lot traceability
531198 **VWR International Kft.** **Simon László utca 4** **4034 Debrecen** **Hungary**	Sales and supply; Distribution; Lab and Production Services; Technical services
531199 **VWR International Ltd** **Orion Business Campus** **Northwest Business Park** **Ballycoolin, Blanchardstown** **Dublin 15** **Ireland**	Sales and supply; Distribution; Lab and Production Services; Technical services
531200 **VWR International (Northern Ireland) Ltd** **19 Clarendon Street** **Derry BT4 87EP** **Ireland**	Sales and supply

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531201 **VWR International s.r.l.** **Via San Giusto 85** **20153 Milano** **Italy**	Sales and supply; Lab and Production Services; Technical Services; Manufacture
531203 **VWR International B.V.** **Orlyplein 85** **1043 AP Amsterdam** **Netherlands**	Sales and supply; Lab and Production Services; Technical services
531205 **VWR International AS** **Brynsalleen 4** **0667 Oslo** **Norway**	Sales and supply; Lab and Production Services; Technical services
531206 **VWR International AS** **Kokstadtflaten 35** **5152 Bønes (Bergen)** **Norway**	Sales and supply
531207 **VWR International AS** **Leirfossvegen 27** **7038 Trondheim** **Norway**	Sales and supply
531211 **VWR International Sp. z. o.o.** **Limbowa 5** **80-175 Gdańsk** **Poland**	Sales and supply; Lab and Production Services; Technical services

Annex to certificate
Registration No. 530840 QM15

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location	Scope
531212 **VWR International Sp. z. o.o.** **Aleja Niepodległości 606/610** **81-879 Sopot** **Poland**	Distribution
531208 **VWR International** **Material De Laboratorio, LDA** **Centro Empresarial de Alfragide** **Rua da Industria, nº 6** **2610-088 Alfragide** **Portugal**	Sales and supply; Distribution; Lab and Production Services; Technical services
531217 **VWR International AB** **Fagerstagatan 18A** **163 94 Stockholm** **Sweden**	Sales and supply; Lab and Production Services; Technical services
531220 **VWR International AB** **Skiffervägen 12** **224 78 Lund** **Sweden**	Sales and supply
531218 **VWR International AB** **Varbergsgatan 2** **412 65 Göteborg** **Sweden**	Sales and supply
531219 **VWR International AB** **Nordiskt Centrallager** **Gjuterigatan 3 (Bofors Industriområde)** **691 50 Karlskoga** **Sweden**	Distribution

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.

Lloyd's Register

Current issue date: 22 June 2021
Expiry date: 21 June 2024
Certificate identity number: 10361225

Original approval(s):
ISO 13485 - 9 June 2019

Certificate of Approval

This is to certify that the Management System of:

ELITechGroup B.V.

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00020722

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register

Certificate identity number: 10361225

Certificate Schedule

Location	Activities
ELITechGroup B.V. Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.
ELITechGroup B.V. Kanaaldijk 90, 6956 AX Spankeren, The Netherlands	**ISO 13485:2016** Design, development and manufacturing of clinical chemistry analyzers, contract manufacturing of erythrocyte sedimentation rate analyzers and warehousing of erythrocyte sedimentation rate tubes for the in vitro diagnostic investigation of samples of human origin.

UKAS MANAGEMENT SYSTEMS
001

ELITechGroup B.V.
P.O.Box 100
6950 AC Dieren
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands
T: +31 313 430 500
F: +31 313 427 807
info.ecsnl@elitechgroup.com
www.elitechgroup.com
Chamber of Commerce 09175642

To: Whom it May Concern

Regulatory status of parts & accessories

As mentioned on the current Declarations of Conformity of our Clinical Chemistry Analyzers also the accessories conform to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC). This applies to the parts and accessories as mentioned in the attached list.

'IVD accessory' means an article which, whilst not being an IVD medical device, is intended specifically by its manufacturer to be used together with an IVD device to enable that IVD device to be used in accordance with its intended purpose.

ELITechGroup B.V.

Adriaan P. Intveld
Manager Quality Assurance & Regulatory Affairs

ELITechGroup
CLINICAL SYSTEMS

Part number	Description	IVD medical device	IVD accessory	general laboratory use	spare part	supporting part
1540-001	Anti-Slip sheet					✓
2206-007	Cooling Liquid (1 L)					✓
3062-021	Sample cup (1000 pcs)		✓			
3062-033	Sample tube 6 ml (500 pcs)					✓
3062-040	Water container 10 L					✓
3062-041	Water container 5 L					✓
3066-155	Syringe 100 µl		✓			
3066-156	Syringe 1 ml		✓			
3069-040	Keyboard Dust cover					✓
3069-047	Keyboard Dust cover					✓
3070-518	Cap holder					✓
3070-538	Cap rotor Left					✓
3070-539	Cap rotor right					✓
3201-002	Dichromate 8 Abs (25ml)		✓			
3365-192	USB Stick					✓
3374-003	Mains cable (USA)					✓
3374-059	Pumpunit cable		✓			
3374-066	Mains cable					✓
3374-097	Serial Null-modem cable					✓
3374-286	USB Extension cable					✓
4804-038	Reagent identification Disc					✓
6001-826	Diluted Waste container		✓			
6001-827	Concentrated Waste container		✓			
6001-860	Water container		✓			
6001-861	Tube assy (analyser)		✓			
6001-872	Tube assy (cooling unit)		✓			
6002-102	Assorter unit				✓	
6002-386	System software on CD		✓			
6002-706	Reaction Rotor set (3 pcs)		✓			
6002-726	System Disc		✓			
6002-817	Bottle 30 ml (20 pcs)		✓			
6002-818	Bottle 15 ml (20 pcs)		✓			
6002-904	Water container 5 L		✓			
6002-910	Assorter unit				✓	
6002-913	External tubing		✓			
6003-074	System software on USB stick		✓			
6003-444	Diluted Waste Container 5 L		✓			
6003-466	Keyboard Support option					✓
6003-797	CW Waste Container 2 L		✓			
6003-808	Assorter unit				✓	

Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity CE

Product Name:	Model/Type:
EasyLyte and accessories per attachment	EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH, Na/K/Cl/Ca/Li
EasyElectrolytes and accessories per attachment	EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:

Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenace Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02

Awareness Technology, Inc..

Certificate of Training

Eng. Sergiu Sorocovici

Global Biomarketing Group

Chisnau, Moldova

has succesfully completed a comprehensive course of training for the applications, operation, technical service and repairs of the

ChemWell ® Automated EIA/Chemistry Analyzer

Awareness Technology manufactured instrument.

On this 20th day of November, 2007

Greg Vandegrift — November 20, 2007

Signature — Date

ELITechGroup
VITAL
SCIENTIFIC

Instrument Training

Vital Scientific BV hereby declares that the participant has attended a four days seminar for service engineers and the participant is now a certified engineer for the declared instruments.

Participant: Mr. S. Sorocovici

Company: Global Biomarketing Group-Moldova SRL
Moldova

Instrument: Vitalab: XL Series
E Series
Junior Series
Dry ISE
Micro Series
ProXS

Date of training: April 20th – April 23rd, 2010

System Support Manager:

Jan Oostendorp

System Support Engineer:

Frank v.d. Korput

Coagulation

Behnk Elektronik

CERTIFICATE

Mr. Sergey Sorokovitsch

actively and successfully participated

in

SERVICE AND APPLICATION TRAINING

for

Thrombolyzer Systems

from 26th November to 30th November 2012

location

Kommanditgesellschaft
Behnk Elektronik GmbH & Co.
Hans-Böckler-Ring 27
22851 Norderstedt
Germany

Holger Behnk, Director

EasyBloodGas™ analyzer
EasyLyte® analyzer

EasyElectrolytes® analyzer
EasyStat® analyzer

Training Certificate

This is to certify that

Mr. Sergiu Sorocovici

of ***GBG-MLD S.R.L.***

has completed training for the operation and service of the

EasyBloodGas™ analyzer, **EasyElectrolytes®** analyzer, **EasyLyte®** analyzer and **EasyStat®** analyzer

04/22/2016
DATE

Medica Corporation

David Hagopian
Director of Technical Support

Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

Hiroshi Shimosaka
President
ERMA INC.