АО "ЭКОлаб"

142530 Московская обл., г.Электрогорск, ул.Буденного, д.1, 1А Тел. . 8(800)333-33-47

ПАСПОРТ № 532

Набор реагентов
Сыворотки диагностические сальмонеллёзные адсорбированные
О-моновалентные-плюс для реакции агглютинации
Комплект № 2
Комплект № 2/1 Сальмонеллезная моновалентная сыворотка О-1, сухая

ТУ 21.20.23.110-253-70423725-2017 **Дата изготовления 2024.03.13**

РУ № РЗН 2018/7452 от 07.08.2018 **Годен до 2029.03.13**

№ серии 86/24

№	Наименование показателя	Характеристика и нормы	Результаты контроля
1	Внешний вид	Аморфная масса белого или кремового цвета	*Соответствует*
2	*Технические характеристики*		
2.1	Растворимость	Сухие сыворотки должны растворяться, в 2 мл 0,9 % водного раствора хлористого натрия при встряхивании в течение 1-2 мин. Полученные растворы должны быть прозрачными или слегка опалесцирующими.	*Соответствует,* *1 мин* *Прозрачный раствор*
2.2	Потеря в массе при высушивании, %, не более	Не более 3,0%	*2,0 %*
2.3	Микробиологическая чистота	При посеве 0,1 мл растворенного препарата на чашку Петри допускается рост не более 20 колоний	*Роста нет*
2.4	Герметичность	Флаконы с препаратом должны быть герметично укупорены	*Флаконы герметичны*
2.5	Аналитическая чувствительность	Определяется со стандартными образцами предприятия, содержащими гомологичный О-антиген и составляет 100%	*100%*
2.6	Аналитическая специфичность	Определяется со стандартными образцами предприятия, содержащими гетерологичный О-антиген и составляет 100%	*100%*
2.7	Специфическая активность	определяется со стандартными образцами предприятия, содержащими гомологичный О-антиген и составляет 100%	*100%*

Хранить: При температуре от 2 до 8 °С. Замораживание не допускается. Допускается транспортирование при температуре от 9 до 25 °С в течение 14 сут.
Заключение: Препарат удовлетворяет требованиям ТУ 21.20.23.110-253-70423725-2017

Дата выдачи: 13.03.2024 г.

Начальник ОБТК Морозова.Т.В.

Digitally signed by Ceaicovschi Tudor
Date: 2024.08.01 14:37:36 EEST
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Location: Moldova

УТВЕРЖДЕНА

Приказом Росздравнадзора

от 25.02 2013 г.№ 387-пр/13

«УТВЕРЖДАЮ»

Генеральный директор
ФГУП «НПО «Микроген»
Минздрава России
_____В.Ф. Руденко
«22» 02 2013 г.

ИНСТРУКЦИЯ

по применению набора реагентов **Сыворотки диагностические ботулинические типов А, В, С, Е, F нативные лошадиные сухие для реакции биологической нейтрализации**

1. НАЗНАЧЕНИЕ

Набор реагентов **Сыворотки диагностические ботулинические типов А, В, С, Е, F нативные лошадиные сухие для реакции биологической нейтрализации** предназначен для диагностики и идентификации типа возбудителя ботулизма в реакции нейтрализации токсина.

2. ХАРАКТЕРИСТИКА НАБОРА

2.1. Принцип действия.

Набор реагентов выявляет специфические антитоксины, нейтрализующие ботулинические токсины одноименного типа возбудителя ботулизма в реакции нейтрализации токсина.

Набор реагентов представляет собой сыворотки, полученные из крови лошадей, гипериммунизированных ботулиническими моноанатоксинами и токсинами соответствующих типов. В 1 мл ботулинической сыворотки типа А содержится не менее 200 МЕ (международные единицы активности), сыворотки типа В – не менее 100 МЕ, типа С – не менее 150 МЕ, типа Е – не менее 200 МЕ, типа F – не менее 50 МЕ.

2. 2. Состав набора.

По 5 ампул сыворотки одного типа в объеме, зависящем от специфической активности набора реагентов (не менее 200 МЕ для типов А и Е, 100 для типа В, 150 для типа С, 50 для типа F) в пачке с инструкцией по применению.

3. АНАЛИТИЧЕСКИЕ И ДИАГНОСТИЧЕСКИЕ ХАРАКТЕРИСТИКИ

Набор реагентов должен содержать специфические антитоксины, нейтрализующие ботулинические токсины одноименного типа в реакции нейтрализации токсина.

4. МЕРЫ ПРЕДОСТОРОЖНОСТИ

Набор реагентов безопасен. Все сточные растворы, пробы, реагенты биологического происхождения и оборудование, находившееся в контакте с сыворотками, следует обрабатывать в соответствии с СП 1.3.2322-08 «Безопасность работы с микроорганизмами III-IV групп патогенности (опасности) и возбудителями паразитарных болезней».

5. ОБОРУДОВАНИЕ И МАТЕРИАЛЫ

- пипетки стеклянные градуированные (1, 2 ,5 мл);
- пробирки стеклянные вместимостью 5 мл;
- стаканы стеклянные химические, объем 100 мл:
- шприц медицинский, объем 5 мл;
- центрифуга лабораторная (2500-3000 об/мин.)
- термостат, температура (37±0,2) °С;
- 0,9% раствор натрия хлорида изотонический;
- 1 % раствора трипсина или панкреатина

6. АНАЛИЗИРУЕМЫЕ ОБРАЗЦЫ

Промывные воды желудка, остатки пищи из желудка, моча и испражнения больного, различные органы трупов (2-3 кусочка по 5-10 г из сердца, печени, селезенки, почек, головного мозга, стенки желудка, толстого и тонкого кишечника), кровь, пищевые продукты, фураж, силос и другие объекты.

7. ПРОВЕДЕНИЕ АНАЛИЗА

7. 1. Приготовление экстрактов для реакции.

Исследованию на присутствие ботулинического токсина могут быть подвергнуты промывные воды желудка, остатки пищи из желудка, моча и испражнения больного, различные органы трупов (2-3 кусочка по 5-10 г из сердца, печени, селезенки, почек, головного мозга, стенки желудка, толстого и тонкого кишечника), кровь, пищевые продукты, фураж, силос и другие объекты.

Из органов трупов (наиболее часто токсин обнаруживается в печени), из сгустков крови, содержимого желудка, кишечника и испражнений делают экстракты. Экстрагирование токсинов из продуктов, содержащих поваренную соль, проводят дистиллированной водой. Настаивание исследуемого материала проводят 1-2 часа, после чего фильтруют через вату. Полученная после фильтрации жидкость, а также сыворотка крови и моча могут быть использованы для постановки реакции биологической нейтрализации.

Для обнаружения токсина в пищевых продуктах, учитывая возможность гнездового расположения токсина, пробы материалов берут в количестве 20-25 г из мест, наиболее подозрительных по органолептическим свойствам, растирают в ступке и заливают двойным объемом физиологического раствора. После двухчасового выдерживания экстракт центрифугируют, а затем с ним ставят реакцию нейтрализации.

Примечание. Учитывая, что значительная часть токсина типа Е продуцируется в виде протоксина, активирующегося под действием пищеварительных ферментов, для выявления токсина типа Е экстракт из продуктов перед постановкой реакции нейтрализации рекомендуется подвергнуть активации панкреатином или трипсином (1 мл 1 % раствора фермента на 10 мл экстракта). Смесь экстракта с ферментом выдерживают при температуре 37 °С в течение 2 ч.

Для постановки реакции нейтрализации может быть использована жидкость из овощных, рыбных, мясных консервов после центрифугирования.

Присутствие ботулинических токсинов в полученных экстрактах или в жидких исследуемых материалах определяют путем постановки реакции биологической нейтрализации с типоспецифическими диагностическими ботулиническими сыворотками.

7. 2. Методика постановки реакции нейтрализации.

В связи с тем, что в исследуемом материале могут быть два и даже три токсина, предварительно реакцию необходимо ставить со смесью моновалентных ботулинических сывороток типов А, В, С, Е, F. Сухую сыворотку каждого типа растворяют в 1 мл дистиллированной воды при легком встряхивании. После растворения составляют смесь из равного количества сывороток каждого типа. К 1 мл смеси сывороток типов А, В, С, Е, F добавляют 4 мл испытуемого материала, выдерживают при комнатной температуре не менее 45 мин, после чего по 1 мл смеси из испытуемого материала и сывороток вводят четырем мышам внутрибрюшинно. Четырем контрольным мышам вводят по 0,8 мл испытуемого материала без сыворотки.

Реакцию можно проводить также на двух морских свинках. Одной из них подкожно или внутрибрюшинно вводят 3,5 мл смеси сывороток и испытуемого материала (готовят смесь так же, как для мышей), другой – 3 мл испытуемого материала без сыворотки.

Наблюдение за животными ведут в течение четырех дней. Если животные, получившие испытуемый материал без сыворотки, за это время погибают, а получившие этот же материал с сывороткой остаются живыми, то это указывает на присутствие ботулинического токсина в исследуемом материале. Ориентировочный ответ может быть получен на вторые сутки.

Для определения типа токсина в 6 пробирок разливают по 2,4 мл исследуемой жидкости, затем в каждую пробирку приливают 0,6 мл сыворотки: в первую пробирку приливают сыворотку типа А, во вторую -типа В, в третью - типа С, в четвертую - типа Е, в пятую - типа F, в шестую приливают 0,6 мл 0,9 % раствора натрия хлорида. Смесь после выдерживания 45 мин при комнатной температуре вводят внутрибрюшинно или подкожно по 1 мл двум мышам из каждой пробирки.

Для каждой сыворотки берут отдельный шприц.

Для более быстрой идентификации типа токсина реакцию с исследуемым материалом ставят одновременно со смесью диагностических сывороток и с отдельными типоспецифическими сыворотками.

8. РЕГИСТРАЦИЯ РЕЗУЛЬТАТОВ

Учет проводят предварительно через 4-6 ч, через 24 ч и окончательно через 4 дня.

Мыши, получившие смесь гомологичного токсина и сыворотки, выживают при гибели всех остальных мышей. Если испытуемый субстрат нейтрализуется одновременно сыворотками типов E и F, что связано с наличием общих антигенов, дополнительно ставят реакцию нейтрализации с сыворотками, разведенными в 40 раз. Последние нейтрализуют только одноименный токсин.

9. УСЛОВИЯ ХРАНЕНИЯ И ЭКСПЛУАТАЦИИ НАБОРА

Набор реагентов Сыворотки диагностические ботулинические типов A, B, C, E, F нативные лошадиные сухие для реакции биологической нейтрализации хранят и транспортируют в соответствии с СП 3.3.2.1248-03 при температуре от 2 до 8 °С.

Срок годности 5 лет. Набор реагентов с истекшим сроком годности применению не подлежит.

Рекламации на качество набора реагентов, с обязательным указанием номера серии и срока годности, следует направлять в адрес предприятия-производителя: ФГУП «НПО «Микроген» Минздрава России, Россия, 115088, г. Москва, ул. 1-ая Дубровская, д. 15, тел. (495) 710-37-87.

Адрес производства: Россия, 355019, Ставропольский край, г. Ставрополь, ул. Биологическая, 20, тел. (8652) 24-40-84.

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 25 мая 2018 года № РЗН 2013/198

На медицинское изделие
Набор реагентов Сыворотки диагностические ботулинические типов A, B, C, E, F нативные лошадиные сухие для реакции биологической нейтрализации по ТУ 9389-154-14237183-10

Настоящее регистрационное удостоверение выдано
Акционерное общество "Научно-производственное объединение по медицинским иммунобиологическим препаратам "Микроген" (АО "НПО "Микроген"), Россия, 115088, Москва, ул. 1-я Дубровская, двлд. 15

Производитель
Акционерное общество "Научно-производственное объединение по медицинским иммунобиологическим препаратам "Микроген" (АО "НПО "Микроген"), Россия, 115088, Москва, ул. 1-я Дубровская, двлд. 15

Место производства медицинского изделия
Филиал АО "НПО "Микроген" в г. Ставрополь "Аллерген", Россия, 355019, г. Ставрополь, ул. Биологическая, д. 20

Номер регистрационного досье **№ РД-22191/24370 от 18.05.2018**

Вид медицинского изделия **198080**

Класс потенциального риска применения медицинского изделия **1**

Код Общероссийского классификатора продукции по видам экономической деятельности **21.20.21.110**

Настоящее регистрационное удостоверение имеет приложение на 1 листе

приказом Росздравнадзора от 25 мая 2018 года № 3418
допущено к обращению на территории Российской Федерации

Заместитель руководителя Федеральной службы по надзору в сфере здравоохранения **Д.Ю. Павлюков**

0036136

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

ПРИЛОЖЕНИЕ
К РЕГИСТРАЦИОННОМУ УДОСТОВЕРЕНИЮ
НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 25 мая 2018 года **№ РЗН 2013/198**

На медицинское изделие
Набор реагентов Сыворотки диагностические ботулинические типов A, B, C, E, F нативные лошадиные сухие для реакции биологической нейтрализации по ТУ 9389-154-14237183-10:
в составе:
- сыворотки диагностические;
- скарификатор ампульный или нож ампульный - 1 шт.

Заместитель руководителя Федеральной службы по надзору в сфере здравоохранения **Д.Ю. Павлюков**

0043100

NCTC derived CultiControl

ENGLISH

Freeze-dried bacterial strains

INTENDED USE

CultiControl microorganisms are lyophilized, reference stock culture preparations containing a single strain of a microorganism. These microorganism preparations are intended to be used for quality control of culture media, educational/instructional programs and industrial applications. The microorganism preparations are derived from NCTC® (National Collection of Type Cultures, operated by the UK Health Security Agency (UKHSA)).

SUMMARY AND HISTORY

A reliable source of reference stock cultures for use in microbiology quality assurance programs is essential.
Microorganisms with known and predictable characteristics are used in quality control, education and proficiency programs.
Lyophilization is a well-documented and recommended method for long-term preservation of microorganisms.
The use of this lyophilized material provides equivalent results to traditional methods used in preparing, storing and maintaining reference stock culture collections.

PRINCIPLE

CultiControl microorganisms incorporate a lyophilization method reported by Obara et.al. which uses a suspending medium consisting of gelatin, skim milk, ascorbic acid, dextrose, and charcoal. The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and dextrose protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage. The charcoal is included to neutralize any toxic substances formed during the lyophilization process.

PRODUCT DESCRIPTION

CultiControl microorganisms are packaged in a resealable vial that contains five (5) lyophilized pellets of a single microorganism strain and a desiccant to prevent adverse accumulations of moisture.

- Each lyophilized microorganism preparation is one (1) passage from the reference NCTC® culture.

MATERIALS REQUIRED BUT NOT PROVIDED

CultiControl microorganisms require sterile tubes and 0.5 ml of sterile liquid such as, Tryptic Soy Broth, Brain Heart Infusion Broth, saline, or deionized water to hydrate the lyophilized preparation. Sterile swabs or inoculating loops are needed to transfer the hydrated preparation to an agar plate.
CultiControl microorganisms require non-selective, nutrient or enriched agar media and specific incubation times and conditions to optimize growth and recovery.

INSTRUCTIONS FOR USE

Remove the unopened CultiControl vial from 2°C to 8°C storage and allow the unopened vial to reach the room temperature.
Aseptically remove one (1) pellet with sterile forceps from the vial. Do not remove desiccant.
Place the pellet in 0.5 mL of sterile fluid (water, saline, TSB, or BHIB).
Immediately stopper and recap vial and return the resealed vial to 2°C to 8°C storage.
Crush the pellet with a sterile swab until the suspension is homogenous.
Immediately heavily saturate the same swab with the hydrated material and transfer to agar medium.
Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.
Using a sterile loop, streak to facilitate colony isolation.
Using proper biohazard disposal, discard the remaining hydrated material.
Immediately incubate the inoculated media at temperature and conditions appropriate to the microorganism.

STORAGE AND EXPIRATION

Store the CultiControl microorganisms at 2°C to 8°C in the original, sealed vial or pouch containing the desiccant.
Stored as directed, the lyophilized microorganism preparation will retain, until the expiration date stated on the device label, its specifications and performance within the stated limits.
The CultiControl microorganisms should not be used if: • Stored improperly; • There is evidence of excessive exposure to heat or moisture; or, • The expiration date has passed.

QUALITY CONTROL

This product is developed, manufactured, and distributed:

- in conformance with the elements of ISO 9001; and,
- in conformance with CE Mark requirements.

Quality control functions may include, but are not limited to:

- purity and growth characteristics;
- morphological features;
- biochemical activity;
- the identity and traceability of the microorganism preparation to a reference culture; and,
- the number of passages the microorganism preparation has been removed from the reference culture.

The decision to perform additional quality control is the responsibility of each individual laboratory.

PRECAUTIONS AND LIMITATIONS

These products are for in-vitro use only. Refer to the MSDS for more detailed information.
The MSDS can be found on our website at
https://www.liofilchem.com/images/prodotti-evidenza/CultiControl-NCTC_MSDS_english.pdf
These devices, and growth of these microorganisms, are considered biohazard material. These devices contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth. The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain, store and dispose of biohazard material. Only trained laboratory personnel should use these devices. Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of, and comply with, the proper disposal of biohazard materials. The Liofilchem CultiControl products and packaging are latex free.

PRODUCT WARRANTY

These products are covered under warranty to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature. The warranty, expressed or implied, is limited when: the procedures employed in the laboratory are contrary to printed and illustrated directions and instructions or the products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

REFERENCES

The following reference cites the basis for the lyophilization method employed on these microorganism preparations.
1. Y. Obara, S. Yamai, T. Nikkawa, Y. Shimoda, and Y. Miyamoto. 1981. J. Clin. Microbiol. 14:61-66.
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7. Performance Standards for Antimicrobial Disk Susceptibility Tests. CLSI.
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10. Standard Methods for the Examination of Dairy Products.
11. Standard Methods for the Examination of Water and Wastewater.
12. US Pharmacopoeia and National Formulary.

TABLE OF SYMBOLS

Consult Instructions for Use	Biological risk	Manufacturer	Contains sufficient for <n> tests	Temperature limitation	Do not reuse
REF Catalogue number	Fragile, handle with care	Use by	Caution, consult accompanying documents	**LOT** Batch code	

Liofilchem®
Via Scozia zona industriale, 64026 Roseto degli Abruzzi (TE) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.com

NCTC National Collection of Type Cultures
Operated by Public Health England

ITALIANO

NCTC derived CultiControl

Ceppi batterici liofilizzati

DESTINAZIONE D'USO

CultiControl sono ceppi microbici di riferimento liofilizzati destinati alla preparazione di colture batteriche pure. Tali microrganismi possono essere utilizzati per il controllo di qualità dei terreni di coltura, in percorsi educativi/didattici e nei processi industriali. Queste preparazioni microbiche sono derivate da NCTC® (National Collection of Type Cultures, operated by the UK Health Security Agency (UKHSA)).

INTRODUZIONE E STORIA

Una fonte affidabile di colture microbiologiche di riferimento è essenziale nelle procedure di assicurazione della qualità.
I microrganismi con caratteristiche note e prevedibili sono utilizzati per il controllo qualità, nei programmi di istruzione e nei processi professionali. La liofilizzazione è un metodo ben documentato e raccomandato per conservare a lungo termine i microrganismi.
L'uso di questo materiale liofilizzato fornisce risultati equivalenti ai metodi tradizionali utilizzati nella preparazione, conservazione e mantenimento di collezioni batteriche di riferimento.

PRINCIPIO

I microrganismi CultiControl prevedono il metodo di liofilizzazione riportato da Obara et.al. che utilizza una sospensione a base di gelatina, latte scremato, acido ascorbico, destrosio e carbone vegetale. La gelatina serve per il trasporto dei microrganismi. Latte scremato, acido ascorbico e destrosio proteggono il microrganismo preservando l'integrità della parete cellulare durante la liofilizzazione e lo stoccaggio. Il carbone vegetale viene incluso per neutralizzare eventuali sostanze tossiche che si formano durante il processo di liofilizzazione.

DESCRIZIONE

I microrganismi CultiControl sono confezionati in una fiala richiudibile che contiene cinque (5) pastiglie liofilizzate di un singolo ceppo di microrganismi ed un essiccante per evitare accumuli indesiderati di umidità.
- Ogni preparazione liofilizzata di microrganismi è ad un (1) passaggio dalla coltura di riferimento NCTC®.

MATERIALE NECESSARIO MA NON FORNITO

I microrganismi CultiControl richiedono provette sterili e 0.5 ml di liquido sterile come, Tryptic Soy Broth, Brain Heart Infusion Broth, soluzione fisiologica, o acqua deionizzata per idratare la preparazione liofilizzata. Sono necessari tamponi sterili o anse per trasferire la preparazione idratata su una piastra agar.
I microrganismi CultiControl richiedono agar non selettivo, nutriente o arricchito e condizioni di incubazione specifiche per ottimizzare crescita e recupero del microrganismo.

ISTRUZIONI PER L'USO

Prelevare la fiala di CultiControl non ancora aperta dal frigo (2-8°C) e portare a temperatura ambiente.
Asetticamente, prelevare con una pinzetta un (1) pellet dalla fiala. Non rimuovere l'essiccante.
Immergere il pellet in 0.5 mL di liquido sterile (acqua, fisiologica, TSB o BHIB).
Subito dopo richiudere il tappo della fiala e riporre lo stessa in frigo (2-8°C).
Frantumare il pellet con un tampone sterile fino a quando la sospensione risulta omogenea.
Subito dopo, utilizzando lo stesso tampone trasferire la sospensione su un terreno agarizzato.
Inoculare una o più piastre con la coltura primaria ruotando gentilmente il tampone su un terzo della superficie del terreno.
Utilizzando un'ansa sterile, strisciare per facilitare l'isolamento delle colonie.
Scartare la sospensione rimanente utilizzando le idonee procedure per lo smaltimento dei rifiuti biologici.
Incubare le piastre inoculate alla temperatura ed alle condizioni appropriate per il microrganismo.

CONSERVAZIONE E SCADENZA

Conservare i microrganismi CultiControl a 2-8°C nella loro fiala o sacchetto originale contenente l'essiccante
Conservate nel modo corretto, le preparazioni di microrganismi liofilizzati mantengono le caratteristiche e le prestazioni entro i limiti stabiliti fino alla data di scadenza indicata sulla confezione.
I microrganismi CultiControl non dovrebbero essere utilizzati se: • Conservati impropriamente; • Ci sono segni evidenti di esposizione eccessiva a calore o umidità; o, • La confezione è scaduta.

CONTROLLO DI QUALITÀ

Questo prodotto è sviluppato, prodotto e distribuito:
- in conformità con le norme ISO 9001 e,
- in conformità con i requisiti del marchio CE.

Funzioni di controllo di qualità includono, ma non sono limitati a:
- purezza e caratteristiche di crescita;
- caratteristiche morfologiche;
- attività biochimica;
- identità e provenienza della preparazione di microrganismi dalla coltura di riferimento e,
- il numero di passaggi della preparazione di microrganismi è stata estratta dalla coltura di riferimento.

La decisione di effettuare un ulteriore controllo di qualità è responsabilità di ogni singolo laboratorio.

PRECAUZIONI E LIMITI

Questi prodotti sono solo per uso *in-vitro*.
Consultare la scheda di sicurezza (MSDS) per informazioni più dettagliate. Il documento MSDS è disponibile sul nostro sito web all'indirizzo https://www.liofilchem.com/images/prodotti-evidenza/CultiControl-NCTC_MSDS_italiano.pdf

Questi dispositivi, e la crescita di questi microrganismi, sono considerate materiale a rischio biologico. Questi dispositivi contengono microrganismi vitali che possono provocare malattie. Tecniche appropriate per evitare l'esposizione e il contatto con i microrganismi in crescita. Il laboratorio di microbiologia deve essere attrezzato ed essere in grado di ricevere, elaborare, mantenere, conservare e smaltire materiale a rischio biologico. Solo il personale di laboratorio addestrato dovrebbe utilizzare questi dispositivi. Enti e norme specifiche regolano lo smaltimento del materiale a rischio biologico. Ogni laboratorio deve conoscere e rispettare il corretto smaltimento dei materiali a rischio biologico. I prodotti e gli imballaggi Liofilchem CultiControl sono privi di lattice.

GARANZIA DEL PRODOTTO

Questi prodotti sono garantiti per soddisfare le specifiche e le prestazioni indicate e illustrate in inserti, istruzioni e bibliografia. La garanzia, esplicita o implicita, è limitata quando: le procedure impiegate in laboratorio sono contrarie alle direttive ed alle istruzioni indicate e illustrate o se i prodotti vengono impiegati per applicazioni diverse dall'uso previsto dagli specifici inserti, istruzioni e bibliografia.

BIBLIOGRAFIA

La seguente bibliografia cita le basi del metodo di liofilizzazione impiegato su queste preparazioni di microrganismi.
1. Y. Obara, S. Yamai, T. Nikkawa, Y. Shimoda, and Y. Miyamoto. 1981. J. Clin. Microbiol. 14:61-66.
La selezione delle colture di riferimento è solo una parte integrante delle tecniche e procedure del controllo di qualità. È essenziale far riferimento alle linee guida per ciascuna procedura di laboratorio. Esempi possono includere:
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TABELLA DEI SIMBOLI

Consultare le istruzioni per l'uso	Rischio biologico	Fabbricante	Contenuto sufficiente per <n> saggi	Limiti di temperatura	Non riutilizzare
REF Numero di catalogo	Fragile, maneggiare con cura	Utilizzare entro	Attenzione, consultare i documenti di accompagnamento	**LOT** Codice del lotto	

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NCTC National Collection of Type Cultures
Operated by Public Health England

ENGLISH

ATCC® derived CultiControl

Freeze-dried bacterial strains

INTENDED USE

CultiControl microorganisms are lyophilized, reference stock culture preparations containing a single strain of a microorganism. These microorganism preparations are intended to be used for quality control of culture media, educational/instructional programs and industrial applications. The microorganism preparations are derived from ATCC® (American Type Culture Collection).

SUMMARY AND HISTORY

A reliable source of reference stock cultures for use in microbiology quality assurance programs is essential.
Microorganisms with known and predictable characteristics are used in quality control, education and proficiency programs.
Lyophilization is a well-documented and recommended method for long-term preservation of microorganisms.
The use of this lyophilized material provides equivalent results to traditional methods used in preparing, storing and maintaining reference stock culture collections.

PRINCIPLE

CultiControl microorganisms incorporate a lyophilization method reported by Obara et.al. which uses a suspending medium consisting of gelatin, skim milk, ascorbic acid, dextrose, and charcoal. The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and dextrose protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage. The charcoal is included to neutralize any toxic substances formed during the lyophilization process.

PRODUCT DESCRIPTION

CultiControl microorganisms are packaged in a resealable vial that contains five (5) lyophilized pellets of a single microorganism strain and a desiccant to prevent adverse accumulations of moisture.

- Each lyophilized microorganism preparation is less than or equal to four (4) passages from the reference ATCC® culture.

MATERIALS REQUIRED BUT NOT PROVIDED

CultiControl microorganisms require sterile tubes and 0.5 ml of sterile liquid such as, Tryptic Soy Broth, Brain Heart Infusion Broth, saline, or deionized water to hydrate the lyophilized preparation. Sterile swabs or inoculating loops are needed to transfer the hydrated preparation to an agar plate.
CultiContro microorganisms require non-selective, nutrient or enriched agar media and specific incubation times and conditions to optimize growth and recovery.
The Technical Sheet CC01 “Recommended Growth Requirements” lists the recommended media and incubation requirements ands is available from our website at https://www.liofilchem.com/images/prodotti-evidenza/TSCC01.pdf

INSTRUCTIONS FOR USE

Remove the unopened CultiControl vial from 2°C to 8°C storage and allow the unopened vial to reach the room temperature.
Aseptically remove one (1) pellet with sterile forceps from the vial. Do not remove desiccant.
Place the pellet in 0.5 mL of sterile fluid (water, saline, TSB, or BHIB).
Immediately stopper and recap vial and return the resealed vial to 2°C to 8°C storage.
Crush the pellet with a sterile swab until the suspension is homogenous.
Immediately heavily saturate the same swab with the hydrated material and transfer to agar medium.
Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.
Using a sterile loop, streak to facilitate colony isolation.
Using proper biohazard disposal, discard the remaining hydrated material.
Immediately incubate the inoculated media at temperature and conditions appropriate to the microorganism.

STORAGE AND EXPIRATION

Store the CultiControl microorganisms at 2°C to 8°C in the original, sealed vial or pouch containing the desiccant.
Stored as directed, the lyophilized microorganism preparation will retain, until the expiration date stated on the device label, its specifications and performance within the stated limits.
The CultiControl microorganisms should not be used if: • Stored improperly; • There is evidence of excessive exposure to heat or moisture; or, • The expiration date has passed.

QUALITY CONTROL

This product is developed, manufactured, and distributed:

- in conformance with the elements of ISO 9001; and,
- in conformance with CE Mark requirements.

Quality control functions may include, but are not limited to:

- purity and growth characteristics;
- morphological features;
- biochemical activity;
- the identity and traceability of the microorganism preparation to a reference culture; and,
- the number of passages the microorganism preparation has been removed from the reference culture.

The decision to perform additional quality control is the responsibility of each individual laboratory.

PRECAUTIONS AND LIMITATIONS

These products are for in-vitro use only. Refer to the MSDS for more detailed information.
The MSDS can be found on our website at
https://www.liofilchem.com/images/prodotti-evidenza/CultiControl_MSDS_english.pdf

These devices, and growth of these microorganisms, are considered biohazard material. These devices contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth. The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain, store and dispose of biohazard material. Only trained laboratory personnel should use these devices. Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of, and comply with, the proper disposal of biohazard materials. The Liofilchem CultiControl products and packaging are latex free.

PRODUCT WARRANTY

These products are covered under warranty to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature. The warranty, expressed or implied, is limited when: the procedures employed in the laboratory are contrary to printed and illustrated directions and instructions or the products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

REFERENCES

The following reference cites the basis for the lyophilization method employed on these microorganism preparations.
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TABLE OF SYMBOLS

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CE IVD

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Rev.3 / 21.12.2021

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Look for the ATCC Licensed Derivative® Emblem for products derived from ATCC® cultures.

ITALIANO

ATCC® derived CultiControl

Ceppi batterici liofilizzati

DESTINAZIONE D'USO

CultiControl sono ceppi microbici di riferimento liofilizzati destinati alla preparazione di colture batteriche pure. Tali microrganismi possono essere utilizzati per il controllo di qualità dei terreni di coltura, in percorsi educativi/didattici e nei processi industriali. Queste preparazioni microbiche sono derivate da ATCC® (American Type Culture Collection).

INTRODUZIONE E STORIA

Una fonte affidabile di colture microbiologiche di riferimento è essenziale nelle procedure di assicurazione della qualità.
I microrganismi con caratteristiche note e prevedibili sono utilizzati per il controllo qualità, nei programmi di istruzione e nei processi professionali. La liofilizzazione è un metodo ben documentato e raccomandato per conservare a lungo termine i microrganismi.
L'uso di questo materiale liofilizzato fornisce risultati equivalenti ai metodi tradizionali utilizzati nella preparazione, conservazione e mantenimento di collezioni batteriche di riferimento.

PRINCIPIO

I microrganismi CultiControl prevedono il metodo di liofilizzazione riportato da Obara et.al. che utilizza una sospensione a base di gelatina, latte scremato, acido ascorbico, destrosio e carbone vegetale. La gelatina serve per il trasporto dei microrganismi. Latte scremato, acido ascorbico e destrosio proteggono il microrganismo preservando l'integrità della parete cellulare durante la liofilizzazione e lo stoccaggio. Il carbone vegetale viene incluso per neutralizzare eventuali sostanze tossiche che si formano durante il processo di liofilizzazione.

DESCRIZIONE

I microrganismi CultiControl sono confezionati in una fiala richiudibile che contiene cinque (5) pastiglie liofilizzate di un singolo ceppo di microrganismi ed un essiccante per evitare accumuli indesiderati di umidità.
- Ogni preparazione liofilizzata di microrganismi è inferiore o uguale a quattro (4) passaggi dalla coltura di riferimento ATCC®.

MATERIALE NECESSARIO MA NON FORNITO

I microrganismi CultiControl™ richiedono provette sterili e 0.5 ml di liquido sterile come, Tryptic Soy Broth, Brain Heart Infusion Broth, soluzione fisiologica, o acqua deionizzata per idratare la preparazione liofilizzata. Sono necessari tamponi sterili o anse per trasferire la preparazione idratata su una piastra agar.
I microrganismi CultiControl™ richiedono agar non selettivo, nutriente o arricchito e condizioni di incubazione specifiche per ottimizzare crescita e recupero del microrganismo.
La Scheda Tecnica 01 "Requisiti di Crescita Raccomandati" elenca terreni e condizioni di incubazione specifiche ed1 è disponibile all'indirizzo web https://www.liofilchem.com/images/prodotti-evidenza/TSCC01.pdf

ISTRUZIONI PER L'USO

Prelevare la fiala di CultiControl non ancora aperta dal frigo (2-8°C) e portare a temperatura ambiente.
Asetticamente, prelevare con una pinzetta un (1) pellet dalla fiala. Non rimuovere l'essiccante.
Immergere il pellet in 0.5 mL di liquido sterile (acqua, fisiologica, TSB o BHIB).
Subito dopo richiudere il tappo della fiala e riporre lo stessa in frigo (2-8°C).
Frantumare il pellet con un tampone sterile fino a quando la sospensione risulta omogenea.
Subito dopo, utilizzando lo stesso tampone trasferire la sospensione su un terreno agarizzato.
Inoculare una o più piastre con la coltura primaria ruotando gentilmente il tampone su un terzo della superficie del terreno.
Utilizzando un'ansa sterile, strisciare per facilitare l'isolamento delle colonie.
Scartare la sospensione rimanente utilizzando le idonee procedure per lo smaltimento dei rifiuti biologici.
Incubare le piastre inoculate alla temperatura ed alle condizioni appropriate per il microrganismo.

CONSERVAZIONE E SCADENZA

Conservare i microrganismi CultiControl a 2-8°C nella loro fiala o sacchetto originale contenente l'essiccante
Conservate nel modo corretto, le preparazioni di microrganismi liofilizzati mantengono le caratteristiche e le prestazioni entro i limiti stabiliti fino alla data di scadenza indicata sulla confezione.
I microrganismi CultiControl™ non dovrebbero essere utilizzati se: • Conservati impropriamente; • Ci sono segni evidenti di esposizione eccessiva a calore o umidità; o, • La confezione è scaduta.

CONTROLLO DI QUALITÀ

Questo prodotto è sviluppato, prodotto e distribuito:
- in conformità con le norme ISO 9001 e,
- in conformità con i requisiti del marchio CE.

Funzioni di controllo di qualità includono, ma non sono limitati a:
- purezza e caratteristiche di crescita;
- caratteristiche morfologiche;
- attività biochimica;
- identità e provenienza della preparazione di microrganismi dalla coltura di riferimento e,
- il numero di passaggi della preparazione di microrganismi è stata estratta dalla coltura di riferimento.

La decisione di effettuare un ulteriore controllo di qualità è responsabilità di ogni singolo laboratorio.

PRECAUZIONI E LIMITI

Questi prodotti sono solo per uso *in-vitro*.
Consultare la scheda di sicurezza (MSDS) per informazioni più dettagliate. Il documento MSDS è disponibile sul nostro sito web all'indirizzo https://www.liofilchem.com/images/prodotti-evidenza/CultiControl_MSDS_italiano.pdf

Questi dispositivi, e la crescita di questi microrganismi, sono considerate materiale a rischio biologico. Questi dispositivi contengono microrganismi vitali che possono provocare malattie. Tecniche appropriate per evitare l'esposizione e il contatto con i microrganismi in crescita. Il laboratorio di microbiologia deve essere attrezzato ed essere in grado di ricevere, elaborare, mantenere, conservare e smaltire materiale a rischio biologico. Solo il personale di laboratorio addestrato dovrebbe utilizzare questi dispositivi. Enti e norme specifiche regolano lo smaltimento del materiale a rischio biologico. Ogni laboratorio deve conoscere e rispettare il corretto smaltimento dei materiali a rischio biologico. I prodotti e gli imballaggi Liofilchem CultiControl sono privi di lattice.

GARANZIA DEL PRODOTTO

Questi prodotti sono garantiti per soddisfare le specifiche e le prestazioni indicate e illustrate in inserti, istruzioni e bibliografia. La garanzia, esplicita o implicita, è limitata quando: le procedure impiegate in laboratorio sono contrarie alle direttive ed alle istruzioni indicate e illustrate o se i prodotti vengono impiegati per applicazioni diverse dall'uso previsto dagli specifici inserti, istruzioni e bibliografia.

BIBLIOGRAFIA

La seguente bibliografia cita le basi del metodo di liofilizzazione impiegato su queste preparazioni di microrganismi.
1. Y. Obara, S. Yamai, T. Nikkawa, Y. Shimoda, and Y. Miyamoto. 1981. J. Clin. Microbiol. 14:61-66.
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TABELLA DEI SIMBOLI

Consultare le istruzioni per l'uso	Rischio biologico	Fabbricante	Contenuto sufficiente per <n> saggi	Limiti di temperatura	Non riutilizzare
REF Numero di catalogo	Fragile, maneggiare con cura	Utilizzare entro	Attenzione, consultare i documenti di accompagnamento	**LOT** Codice del lotto	**IVD** *In-vitro* Diagnostic Medical Device

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ESPAÑOL

ATCC® derived CultiControl

Cepas bacterianas liofilizadas

USO PREVISTO

CultiControl son cepas microbianas de referencia liofilizadas para a la preparación de cultivos puros de microorganismos. Estas preparaciones de microorganismos están destinadas a ser utilizadas para el control de calidad de medios de cultivo, programas educativos/instructivos y aplicaciones industriales. Las preparaciones de microorganismos se derivan de ATCC® (American Type Culture Collection).

RESUMEN E HISTORIA

Una fuente confiable de cultivos microbiológico de referencia es esencial en los procedimientos de garantía de calidad.
Los microorganismos con características conocidas y predecibles se utilizan para el control de calidad, programas educación y proceso profesionales. La liofilización es un método bien documentado y recomendado para la conservación a largo plazo de microorganismos.
El uso de este material liofilizado proporciona resultados equivalentes a los métodos tradicionales utilizados en la preparación, almacenamiento y mantenimiento de colecciones de cultivos de referencia.

PRINCIPIO

Los microorganismos CultiControl incorporan un método de liofilización informado por Obara et al. que utiliza un medio de suspensión compuesto por gelatina, leche desnatada, ácido ascórbico, dextrosa y carbón vegetal. La gelatina sirve para el transporte de microorganismos. La leche desnatada, el ácido ascórbico y la dextrosa protegen al microorganismo preservando la integridad de la pared celular durante la liofilización y el almacenamiento. El carbón se incluye para neutralizar cualquier sustancia tóxica formada durante el proceso de liofilización.

DESCRIPCIÓN DEL PRODUCTO

Los microorganismos CultiControl están empaquetados en un vial resellable que contiene cinco (5) gránulos liofilizados de una única cepa de microorganismo y un desecante para evitar acumulaciones adversas de humedad.
• Cada preparación de microorganismos liofilizados es menor o igual a cuatro (4) pases del cultivo de referencia ATCC®.

MATERIALES REQUERIDOS PERO NO SUMINISTRADOS

Los microorganismos CultiControl requieren tubos estériles y 0,5 ml de líquido estéril como caldo TSB, o BHI, solución salina o agua desionizada para hidratar la preparación liofilizada. Se necesitan hisopos estériles o asas de inoculación para transferir la preparación hidratada a una placa de agar.
Los microorganismos CultiContro requieren medios de agar no selectivos, nutritivos o enriquecidos y tiempos y condiciones de incubación específicos para optimizar el crecimiento y la recuperación.
La Hoja Técnica CC01 “Requisitos de Crecimiento Recomendados” enumera los medios recomendados y los requisitos de incubación y está disponible en nuestro sitio web en https://www.liofilchem.com/images/prodotti-evidenza/TSCC01.pdf

INSTRUCCIONES DE USO

Saque el vial de CultiControl sin abrir del de la nevera (2-8°C) y déjelo a temperatura ambiente.
Asépticamente, retire un (1) pellet del vial con unas pinzas estériles. No retire el desecante.
Sumerja el pellet en 0,5 ml de líquido estéril (agua, solución salina, TSB o BHIB).
Inmediatamente después cierre el tapón del vial y devuelva el vial resellado a un lugar de almacenamiento a temperatura entre 2°C y 8°C.
Triturar el pellet con un hisopo estéril hasta que la suspensión sea homogénea.
Utilizando el mismo hisopo transferir la suspensión a un medio de agar.
Inocular la(s) placa(s) de cultivo primario haciendo rodar suavemente el hisopo sobre un tercio de la superficie del agar.
Usando un asa estéril, rayar para facilitar el aislamiento de la colonia.
Deseche la suspensión restante utilizando procedimientos apropiados de eliminación de desechos biológicos.
Incubar las placas inoculados a temperatura y condiciones apropiadas para el microorganismo.

ALMACENAMIENTO Y FECHA DE CADUCIDAD

Almacenar los microorganismos CultiControl entre 2°C y 8 °C en el vial o bolsa original sellado que contiene el desecante.
Almacenados correctamente, la preparación de microorganismos liofilizados mantienen su caracteristcicas y rendimiento dentro de los límites establecidos hasta la fecha de caducidad indicada en el paquete.
Los microorganismos CultiControl no deben usarse si: • Se almacenan incorrectamente; • Hay evidencia de exposición excesiva al calor o la humedad; o, • La fecha de caducudad ha pasado.

CONTROL DE CALIDAD

Este producto es desarrollado, fabricado y distribuido:
• de conformidad con los elementos de la norma ISO 9001; y,
• conforme a los requisitos de la marca CE.
Las funciones de control de calidad pueden incluir, entre otras:
• características de pureza y crecimiento;
• características morfológicas;
• actividad bioquímica;
• la identidad y trazabilidad de la preparación de microorganismos hasta un cultivo de referencia; y,
• el número de pases en los que se ha eliminado la preparación de microorganismos del cultivo de referencia.
La decisión de realizar controles de calidad adicionales es responsabilidad de cada laboratorio individual.

PRECAUCIONES Y LIMITACIONES

Estos productos son sólo para uso in vitro. Consulte la MSDS para obtener información más detallada.
La MSDS se puede encontrar en nuestro sitio web en
https://www.liofilchem.com/images/prodotti-evidenza/CultiControl-ATCC_MSDS_espanol.pdf

Estos dispositivos y el crecimiento de estos microorganismos se consideran materiales de riesgo biológico. Estos dispositivos contienen microorganismos viables que pueden producir enfermedades. Se deben emplear técnicas adecuadas para evitar la exposición y el contacto con cualquier crecimiento de microorganismos. El laboratorio de microbiología debe estar equipado y contar con las instalaciones para recibir, procesar, mantener, almacenar y disponer de material de riesgo biológico. Sólo personal de laboratorio capacitado debe utilizar estos dispositivos. Las agencias y los estatutos regulan la eliminación de todos los materiales con riesgo biológico. Cada laboratorio debe conocer y cumplir con la eliminación adecuada de materiales de riesgo biológico. Los productos y envases de Liofilchem CultiControl no contienen látex.

LA GARANTÍA DEL PRODUCTO

prospectos del producto, las instrucciones y la literatura de respaldo. La garantía, expresa o implícita, está limitada cuando: los procedimientos empleados en el laboratorio son contrarios a las direcciones e instrucciones impresas e ilustradas o los productos se emplean para aplicaciones distintas al uso previsto citado en los prospectos, instrucciones y literatura de respaldo del producto.

REFERENCIAS

La siguiente referencia cita la base del método de liofilización empleado en estas preparaciones de microorganismos.
1. Y. Obara, S. Yamai, T. Nikkawa, Y. Shimoda, and Y. Miyamoto. 1981. J. Clin. Microbiol. 14:61-66.
La selección de cultivos de referencia es sólo una parte integral del esquema general de procedimientos y técnicas de desafío de control de calidad. Es esencial hacer referencia a las directrices para las aplicaciones de cada laboratorio. Los ejemplos podrían incluir:
1. AOAC Compendium of Microbiological Methods.
2. Clinical Microbiology Procedures Handbook. ASM. Washington, D.C.
3. FDA Bacteriological Analytical Manual.
4. Manual of Clinical Microbiology, ASM, Washington, D.C.
5. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically. CLSI.
6. Official Methods of Analysis of the Association of Official Analytical Chemists.
7. Performance Standards for Antimicrobial Disk Susceptibility Tests. CLSI.
8. Quality Assurance for Commercially Prepared Microbiological Culture Media. CLSI.
9. Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria. CLSI.
10. Standard Methods for the Examination of Dairy Products.
11. Standard Methods for the Examination of Water and Wastewater.
12. US Pharmacopoeia and National Formulary

TABLA DE SIMBOLOS

Consultar Instrucciones de Uso	Riesgo biológico	Fabricante	Contiene suficiente para <n> pruebas	Limitación de temperatura	No reutilizar
REF Número de catalogo	Frágil, manipular con cuidado	Usar por	Precaución, consulte los documentos adjuntos.	**LOT** Código de lote	**IVD** Dispositivo Médico de Diagnóstico *In-Vitro*

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CE IVD

ref. F00044
Rev.3 / 21.12.2021

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Busque el emblema ATCC Licensed Derivative® para productos derivados de cultivos ATCC®.

CultiControl™

Technical Sheet 01

CultiControl™ freeze-dried microorganisms
Packaging: 1 vial containing 5 pellets
Non-enumerated CFU
Applications: Culture purposes, QC of ID devices, QC of AST devices

Quanti-CultiControl™ freeze-dried microorganisms
Packaging: 1 vial containing 1 pellet + 1 rehydration fluid vial
Quantitative: <100 CFU / 0.1 mL inoculum
Applications: Growth Promotion Testing, Microbial Limits Testing, Microbial Enumeration Testing

BioSafety Levels

The Liofilchem® CultiControl™ freeze-dried microorganisms have a BioSafety level (BSL) of 1 or 2.

BSL 1 organisms have no, or low, risk to individuals and communities. BSL 1 organisms may cause disease in individuals with immune systems that are suppressed or compromised.

BSL 2 organisms pose a moderate risk of individual infection, but low risk of community infection.

Liofilchem adheres to the BSL level designation as determined by the Reference Culture Collection from which the microorganism strain was obtained. Responsibility for safe handling of biological agents ultimately rests with the user. All infectious materials should be handled under the supervision of a competent and knowledgeable microbiologist.

Recommended Growth Methods

Primary growth on a nonselective agar medium is preferred. Primary growth in a fluid medium should only occur in special instances or when recommended. Because of the manipulations required during hydration, it is difficult to obtain purity of a lyophilized strain in a fluid medium. A contaminant may completely overgrow and obscure the presence of the lyophilized strain.
A list of microorganisms and relevant Recommended Growth Method is showed at page 4.

Method 1
Tryptic Soy Agar (Soybean Casein Digest Agar), nonselective Sheep Blood Agar, Standard Methods Agar (Plate Count Agar) or Nutrient Agar - 35°C in aerobic atmosphere – 24 to 48 hours.

Method 2
Nonselective Sheep Blood Agar - 35°C in aerobic atmosphere – 24 to 72 hours. Growth of some species such as *Streptococcus* and *Arcanobacterium* are enhanced by CO_2 enrichment of the incubation atmosphere. 5% CO2 is recommended for the culture of *Streptococcus pneumonia*e and other streptococcal species of the viridians group.

Method 3
Chocolate Agar - 35°C in 5% to 7% CO_2 – 24 to 48 hours.

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Method 4
Anaerobic Blood Agar 35°C in Anaerobic Environment – 48 to 72 hours.
Some obligate anaerobes may require 5 to 7 days to demonstrate sufficient growth.
Fresh prepared Nutrient Agar, Tryptic Soy Agar (Soybean Casein Digest Agar), Standard Methods Agar (Plate Count Agar) are appropriate alternatives for some *Clostridium* species together with an additional period (24 hours) of incubation.

Method 5
Sabouraud Dextrose Emmons Agar - 25°C in aerobic atmosphere – 2 to 7 days.
Nonselective Sheep Blood Agar is an appropriate alternative.
Nutrient Agar, Tryptic Soy Agar, Potato Dextrose Agar and Standard Plate Count Agar are appropriate alternatives together with an additional period (24 hours) of incubation.
Sabouraud Dextrose Emmons Agar is the best medium for growth of *Saccharomyces* sp.

Method 6
Chocolate Agar - 35°C in Microaerophilic Environment – 48 to 72 hours.

Method 7
Lowenstein Jensen Agar or Middlebrook Agar - 35°C in 5 to 7% CO_2 or aerobic atmosphere – up to one week.
M. fortuitum subsp. *fortuitum, M. peregrinum and M. smegmatis* will also grow on Tryptic Soy Agar (Soybean Casein Digest Agar) as well as Lowenstein Jensen and Middlebrook Agar but additional incubation time may be required.

Method 8
Buffered Charcoal Yeast Extract Agar - 35°C in aerobic atmosphere – 3 to 5 days.

Method 9
V Agar or Chocolate Agar - 35°C in 5% to 7% CO_2– 48 hours.

Method 10
Rehydrate in sterile Brain Heart Infusion Broth, Tryptic Soy Broth (Soybean Casein Digest Agar) or 0.85% Saline. Rehydration with water may result in decreased or no recovery. Grow on Tryptic Soy Agar (Soybean Casein Digest Agar) - 35°C in aerobic atmosphere – 24 to 48 hrs. *Vibrio* sp. also grows on Marine Agar.

Method 11
The primary growth medium is MRS (Man, Rogosa, Sharpe) Broth. Incubate at 35°C in aerobic atmosphere for 48 hours. Transfer to either Columbia CNA with Sheep Blood or Tryptic Soy Agar with Sheep Blood. Incubate at 35°C in 5 to 7% CO_2 for 48 hrs. A few *Lactobacilli* species, such as *L. fermentum*, *L. paracasei* subsp. *paracasei*, *L. plantarum*, *L. rhamnosus*, and *L. sakei*, do not need to be started in Lactobacilli MRS broth. They may be plated directly to Columbia CNA with Sheep Blood or Tryptic Soy Agar with Sheep Blood and incubated at 35°C in 5 to 7% CO_2 for 48 hrs.

Method 12
Potato Dextrose Agar - 55 C in aerobic atmosphere – 24 to 48 hours.

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Method 13
Rehydrate I pellet of *M. hominis* or *Ureaplasma* sp. in 10B Arginine Broth. Make serial dilutions (for example, 1:10, 1:100, 1:1000, 1:10,000). Incubate at 35 C in aerobic atmosphere. As soon as the Arginine vial turns pink (24 to 48 hours), sub 0.1 mL of broth to A8 Agar and streak for isolation. Do not use cotton swab or wooden shaft. Incubate mycoplasma at 35 C in 5 to 7% CO_2. Incubate ureaplasma at 35 C anaerobically for up to 96 hours. In order to see colonies, examine plates microscopically.

Method 14
Rehydrate 1 pellet of *M. pneumoniae* in SP4 Glucose Broth. Make serial dilutions (for example, 1:10, 1:100, 1:1000, 1:10,000). Incubate at 35°C in aerobic atmosphere. As soon as the broth turns from red to yellow (1-4 weeks), sub 0.2 mL of broth to SP4 Glucose Agar and streak for isolation. Do not use cotton swab or wooden shaft. Incubate at 35°C in CO_2 atmosphere, preferably in a candle jar, for 5 to 15 days. In order to see colonies, examine plates microscopically.

Method 15
Rehydrate 1 pellet of *M. orale* in 10B Arginine Broth. Make serial dilutions (for example, 1:10, 1:100, 1:1000). Incubate at 35°C, in aerobic atmosphere. As soon as the broth turns from yellow to pink (48 to 72 hours), sub 0.2 mL of broth to SP4 Glucose Agar and streak for isolation. Do not use cotton swab or wooden shaft. Incubate plates at 35°C in anaerobic conditions for 3 to 6 days. In order to see colonies, examine plates microscopically.

Method 16
Leeming Notman Agar - 30°C in aerobic atmosphere – 72 hours.

Method 17
Rehydrate 1 pellet of *M. gallisepticum* in SP4 Glucose Broth. Make serial dilutions (for example, 1:2, 1:4). Incubate at 35°C in aerobic atmosphere. As soon as the broth turns from red to yellow (4 days to 2 weeks), sub 0.2 mL of broth to SP4 Glucose Agar and streak for isolation. Do not use cotton swab or wooden shaft. Incubate at 35°C in CO_2 atmosphere, preferably in a candle jar, for 3 days to 2 weeks. In order to see colonies, examine plates microscopically.

Method 18
Rehydrate 1 pellet of *M. hyorhinis* in SP4 Glucose Broth. Make serial dilutions (for example, 1:10, 1:100, 1:1000). Incubate at 35°C in aerobic atmosphere. As soon as the broth turns from red to yellow (4 days to 2 weeks), sub 0.2 mL of broth to SP4 Glucose Agar and streak for isolation. Do not use cotton swab or wooden shaft. Incubate at 35°C in CO_2 atmosphere, preferably in a candle jar, for 2 to 10 days. In order to see colonies, examine plates microscopically.

Method 19
Rehydrate 1 pellet of *M. synoviae* in SP4 Glucose Broth. Make serial dilutions (for example, 1:2, 1:4, 1:8, 1:16, 1:32). Incubate at 35°C in 5 to 10% CO_2 for 7 days. After 7 days (no color change will be noted), sub 0.2 mL of broth to SP4 Glucose Agar and streak for isolation. Do not use cotton swab or wooden shaft. Incubate at 35°C in CO_2 atmosphere, preferably in a candle jar, for 1 to 4 weeks. In order to see colonies, examine plates microscopically.

Method 20
Chocolate agar, Sheep Blood Agar, Tryptic Soy Agar, Bordet Gengou Agar with 15% Defibrinated Sheep Blood - 35°C in aerobic atmosphere – 24 to 48 hours. Standard Methods (Plate Count Agar) or Nutrient Agar are appropriate alternatives together with an additional period (24 hours) of incubation.

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Method 21
Chocolate or Bordet Gengou Agar with 15% Defibrinated Sheep Blood - 35°C in aerobic atmosphere – 2 days to one week. *B. pertussis*, Microbiologics #100, and *B. pertussis*, Microbiologics #0843, require Bordet Gengou Agar with 15% Defibrinated Sheep Blood.

Method 22
Prepare ISF (modified Infant Soy Formula) Broth using the following steps: 1) fill tubes with 10 mL Infant Soy Formula, 2) place a four-penny nail in each tube, and 3) sterilize the broth. Infant Soy Formula may be purchased at a grocery store. A four-penny nail is approximately 1.5 inches or 38 mm in length. It should contain steel or iron.
Inoculate ISF Broth with one pellet. Make two dilutions, 1:10 and 1:100. Plate undiluted sample and plate the 1:10 and 1:100 dilutions. It is necessary to plate the diluted samples because at higher concentrations the colonies are pin-point which makes colony characteristics difficult to see. Grow at 55°C in anaerobic conditions for 48 hours. The broth will turn grey, indicating growth. Sub with a swab to Sulfite Agar. Sulfite Agar is used for detecting thermophilic anaerobes which produce sulfite. Incubate the agar in anaerobic environment at 55°C for 7 days.

Method 23
Inoculate Mycoplasma Broth with a pellet. Prepare serial dilutions of 1:10, 1:100, and 1:1000 using the broth. Incubate at 35°C for 48 hours. Then plate 0.2 mL of the turbid broth culture to Mycoplasma Agar. Incubate agar in 5 to 7% CO_2 at 35° for 3 to 7 days. Do not use cotton swabs or wooden sticks. In order to see colonies, examine plates microscopically.

Method 24
Sheep Blood Agar supplemented with Pyridoxal - 35° C in 5% to 7% CO2 – 24 to 48 hours.

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CultiControl™ and **Quanti-CultiControl™** freeze-dried microorganisms

Description	CultiControl™ Ref. CE IVD	Quanti-CultiControl™ Ref.	notes	BioSafety Level	recommended growth method
Acinetobacter baumannii ATCC® BAA-747™*	89141	-		2	1
Acinetobacter baumannii ATCC® 19606™*	89174	-		2	1
Actinomyces odontolyticus ATCC® 17929™*	89114	-		2	4
Aeromonas hydrophila ATCC® 7966™*	89119	-		2	2
Aeromonas hydrophila ATCC® 35654™*	89169	-		2	2
Aggregatibacter aphrophilus ATCC® 7901™*	89091	-		2	3
Aspergillus brasiliensis ATCC® 16404™*	89021	89501		1	5
Bacillus cereus ATCC® 11778™*	89022	-		1	1
Bacillus cereus ATCC® 10876™*	89155	89502		1	1
Bacillus subtilis subsp. spizizenii ATCC® 6633™*	89023	89503		1	1
Bacteroides fragilis ATCC® 25285™*	89078	89505		2	4
Bacteroides fragilis ATCC® 23745™*	89113	-		2	4
Bacteroides ovatus ATCC® 8483™*	89111	-		2	4
Bacteroides ovatus ATCC® BAA-1296™*	89193	-		2	4
Bacteroides thetaiotaomicron ATCC® 29741™*	89079	-		2	4
Bifidobacterium animalis subsp. animalis ATCC® 25527™*	-	89539		1	4
Bordetella bronchiseptica ATCC® 4617™*	89139	-		2	15
Brevundimonas diminuta ATCC® 19146™*	-	89506		1	1
Burkholderia cepacia ATCC® 25416™*	89147	89507		2	1
Burkholderia cepacia ATCC® 25608™*	89166	-		2	1
Campylobacter jejuni subsp. jejuni ATCC® 33291™*	89086	-		2	6
Campylobacter jejuni subsp. jejuni ATCC® 33560™*	89145	-		2	6
Campylobacter jejuni subsp. jejuni ATCC® 29428™*	89167	-		2	6
Candida albicans ATCC® 10231™*	89024	89508		1	5
Candida albicans ATCC® 2091™*	-	89510		1	5
Candida albicans ATCC® 90028™*	89072	-		1	5
Candida albicans ATCC® 18804™*	89177	-		1	5
Candida albicans ATCC® 64124™*	89178	-		1	5
Candida albicans ATCC® 14053™*	89183	-		1	5
Candida krusei ATCC® 14243™*	89098	-		1	5
Candida parapsilosis ATCC® 22019™*	89071	-		1	5
Candida tropicalis ATCC® 750™*	89097	-		1	5
Citrobacter freundii ATCC® 43864™*	89146	-		1	1
Citrobacter freundii ATCC® 8090™*	89159	-		1	1
Clostridium difficile ATCC® 9689™*	89090	-	produces cytotoxin	2	4
Clostridium histolyticum ATCC® 19401™*	89112	-		2	4
Clostridium perfringens ATCC® 13124™*	89053	89512		2	4
Clostridium sordellii ATCC® 9714™*	89059	-		2	4

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CultiControl™ and **Quanti-CultiControl™** freeze-dried microorganisms

Description	**CultiControl™ Ref.** CE IVD	**Quanti-CultiControl™ Ref.**	**notes**	**BioSafety Level**	**recommended growth method**
Clostridium sporogenes ATCC® 11437™*	-	89513		1	4
Clostridium sporogenes ATCC® 19404™*	89095	89514		1	4
Cronobacter muytjensii ATCC® 51329™*	89158	-		1	1
Cronobacter sakazakii ATCC® 29544™*	89138	-	formerly *Enterobacter sakazakii*	1	1
Eikenella corrodens ATCC® BAA-1152™*	89196	-		2	3
Enterobacter aerogenes ATCC® 13048™*	89156	89516		1	1
Enterobacter cloacae subsp. cloacae ATCC® 49141™*	89200	-		1	1
Enterobacter cloacae subsp. cloacae ATCC® BAA-1143™*	89065	-	control strain for the AmpC disk test; strong positive	2	1
Enterococcus casseliflavus ATCC® 700327™*	89195	-		1	1
Enterococcus faecalis ATCC® 19433™*	89025	-		2	1
Enterococcus faecalis ATCC® 29212™*	89026	89517		2	1
Enterococcus faecalis ATCC® 7080™*	-	89518		2	1
Enterococcus faecalis ATCC® 33186™*	89115	-		2	1
Enterococcus faecalis ATCC® 49532™*	89066	-	high level Gentamicin-resistant and Streptomycin-sensitive	2	1
Enterococcus faecalis ATCC® 49533™*	89067	-	high level Gentamicin-sensitive and Streptomycin-resistant	2	1
Enterococcus faecalis ATCC® 51299™*	89173	-	Vancomycin resistant and high level aminoglycosides, vanB	2	1
Enterococcus faecium ATCC® 51559™*	89117	-		2	1
Enterococcus faecium ATCC® 6057™*	89152	-		2	1
Enterococcus faecium ATCC® 19434™*	89171	-		2	1
Enterococcus faecium ATCC® BAA-2319™*	89172	-	vanA resistance	2	1
Erysipelothrix rhusiopathiae ATCC® 19414™*	89187	-		2	2
Escherichia coli ATCC® 11303™*	89184	-		1	1
Escherichia coli ATCC® 25922™*	89027	-		1	1
Escherichia coli ATCC® 8739™*	89028	89519		1	1
Escherichia coli ATCC® 35218™*	89163	-	beta lactamase producer	1	1
Escherichia coli NCTC 11954	89068	-	beta lactamase producer	1	1
Fluoribacter bozemanae ATCC® 33217™*	89157	-		2	8
Fusobacterium nucleatum subsp. nucleatum ATCC® 25586™*	89118	-		2	4
Gardnerella vaginalis ATCC® 14018™*	89099	-		2	9
Geobacillus stearothermophilus ATCC® 12980™*	-	89521		1	1

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CultiControl™ and **Quanti-CultiControl™** freeze-dried microorganisms

Description	CultiControl™ Ref. CE IVD	Quanti-CultiControl™ Ref.	notes	BioSafety Level	recommended growth method
Geobacillus stearothermophilus ATCC® 7953™*	89203	89522		1	1
Haemophilus haemolyticus ATCC® 33390™*	89123	-		2	3
Haemophilus influenzae ATCC® 49766™*	89076	-		2	3
Haemophilus influenzae ATCC® 49247™*	89077	-		2	3
Haemophilus influenzae ATCC® 19418™*	89160	-		2	3
Haemophilus influenzae ATCC® 10211™*	89120	-	type b; beta lactamase negative	2	3
Haemophilus influenzae ATCC® 33533™*	89124	-	type b; beta lactamase producer	2	3
Haemophilus influenzae NCTC 8468	89136	-		2	3
Haemophilus influenzae ATCC® 9007™*	89142	-	type c	2	3
Haemophilus influenzae ATCC® 33391™*	89176	-		2	3
Issatchenkia orientalis ATCC® 6258™*	89073	-		1	5
Klebsiella pneumoniae ATCC® BAA-1144™*	89150	-	control strain for the AmpC disk test; weak positive	2	1
Klebsiella pneumoniae ATCC® BAA-1705™*	89088	-	Modified Hodge Test (MHT) positive control	2	1
Klebsiella pneumoniae ATCC® BAA-2146™*	89069	-	New Delhi metallo-beta-lactamase (NDM-1) positive	2	1
Klebsiella pneumoniae subsp. pneumoniae ATCC® 700603™*	89070	-	ESBL positive	2	1
Klebsiella pneumoniae subsp. pneumoniae ATCC® 13883™*	89089	-		2	1
Klebsiella pneumoniae subsp. pneumoniae ATCC® 4352™*	89192	-		2	1
Klebsiella pneumoniae subsp. pneumoniae ATCC® 31488™*	89199	-		2	1
Kocuria rhizophila ATCC® 9341™*	-	89523		1	1
Lactobacillus acidophilus ATCC® 4356™*	89080	-		1	11
Lactobacillus fermentum ATCC® 9338™*	89100	89524		1	11
Lactobacillus paracasei subsp. paracasei ATCC® BAA-52™*	89055	-		1	11
Lactobacillus leichmannii ATCC® 4797™*	89081	-		1	11
Lactococcus lactis subsp. lactis ATCC® 19435™*	89082	-		1	2
Legionella pneumophila subsp. fraseri ATCC® 33156™*	89151	-		2	8
Legionella pneumophila subsp. pneumophila ATCC® 33152™*	89052	-		2	8
Listeria grayi ATCC® 25401™*	89101	-		1	1
Listeria innocua ATCC® 33090™*	89029	-		1	1
Listeria ivanovii subsp. ivanovii ATCC® 19119™*	89030	-		2	1
Listeria monocytogenes ATCC® 19111™*	89031	-	serotype 1	2	1

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CultiControl™ and **Quanti-CultiControl™** freeze-dried microorganisms

Description	**CultiControl™ Ref.** CE IVD	**Quanti-CultiControl™ Ref.**	**notes**	**BioSafety Level**	**recommended growth method**
Listeria monocytogenes ATCC® 19115™*	89051	89525	serotype 4b	2	1
Listeria monocytogenes ATCC® 13932™*	89085	-	serotype 4b	2	1
Listeria monocytogenes ATCC® 7644™*	89060	-		2	1
Listeria monocytogenes ATCC® 35152™*	89148	-		2	1
Listeria monocytogenes ATCC® BAA-751™*	89143	-		2	1
Listeria monocytogenes ATCC® 15313™*	89188	-	non-hemolytic on sheep blood	2	1
Micrococcus luteus ATCC® 4698™*	89102	89526		1	1
Micrococcus luteus ATCC® 10240™*	89096	-		1	1
Moraxella (Branhamella) catarrhalis ATCC® 25238™*	89103	-		1	2
Neisseria gonorrhoeae ATCC® 19424™*	89074	-		2	3
Neisseria gonorrhoeae ATCC® 31426™*	89075	-	beta lactamase producer	2	3
Neisseria gonorrhoeae ATCC® 49226™*	89104	-		2	3
Neisseria gonorrhoeae ATCC® 49981™*	89122	-	Penicillin resistant	2	3
Neisseria meningitidis ATCC® 13090™*	89164	-	serogroup B	2	3
Nocardia brasiliensis ATCC® 19296™*	89189	-		2	1
Peptostreptococcus anaerobius ATCC® 27337™*	89165	-		1	4
Plesiomonas shigelloides ATCC® 14029™*	89094	-		2	1
Porphyromonas gingivalis ATCC® 33277™*	89162	-		2	4
Prevotella melaninogenica ATCC® 25845™*	89134	-		2	4
Propionibacterium acnes ATCC® 11827™*	89135	-		1	4
Proteus hauseri ATCC® 13315™*	89190	-		2	1
Proteus mirabilis ATCC® 25933™*	89032	-		2	1
Proteus mirabilis ATCC® 12453™*	89049	-		2	1
Proteus mirabilis ATCC® 29906™*	89083	-		2	1
Proteus mirabilis ATCC® 35659™*	89105	-		2	1
Proteus mirabilis ATCC® 43071™*	89106	-		2	1
Proteus vulgaris ATCC® 6380™*	89107	-		2	1
Providencia stuartii ATCC® 33672™*	89125	-		1	1
Pseudomonas aeruginosa ATCC® 15442™*	89109	-	Pyocyanin not produced	2	1
Pseudomonas aeruginosa ATCC® 10145™*	89108	-		2	1
Pseudomonas aeruginosa ATCC® 27853™*	89033	89527		2	1
Pseudomonas aeruginosa ATCC® 9027™*	89034	89528		2	1
Pseudomonas fluorescens ATCC® 13525™*	89110	-		1	1
Rhodococcus equi ATCC® 6939™*	89035	-	recommended for CAMP test for *Listeria monocytogenes*	2	2
Saccharomyces cerevisiae ATCC® 9763™*	89036	-		1	5
Salmonella enterica subsp. arizonae ATCC® 13314™*	89154	-		2	1

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CultiControl™ and **Quanti-CultiControl™** freeze-dried microorganisms

Description	CultiControl™ Ref. CE IVD	Quanti-CultiControl™ Ref.	notes	BioSafety Level	recommended growth method
Salmonella enterica subsp. enterica serovar Abony NCTC 6017	89132	89532		2	1
Salmonella enterica subsp. enterica serovar Choleraesuis ATCC® 10708™*	-	89529	H_2S negative	2	1
Salmonella enterica subsp. enterica serovar Enteritidis ATCC® 13076™*	89084	-	group D	2	1
Salmonella enterica subsp. enterica serovar Paratyphi ATCC® 9150™*	89161	-	group A; H_2S negative	2	1
Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 14028™*	89037	89531		2	1
Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 13311™*	89054	89530		2	1
Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 49416™*	89197	-	highly mutable; recommended for Ames test	2	1
Salmonella enterica subsp. enterica serovar Hillingdon ATCC® 9184™*	89185	-		2	1
Serratia marcescens ATCC® 8100™*	89121	-		1	1
Serratia marcescens ATCC® 14756™*	89191	-	pigmented	1	1
Shigella boydii ATCC® 9207™*	89179	-	serotype 1	2	1
Shigella flexneri ATCC® 12022™*	89038	-	serotype 2b	2	1
Shigella flexneri ATCC® 9199™*	89198	-	serotype 1a	2	1
Shigella sonnei ATCC® 25931™*	89058	-		2	1
Shigella sonnei ATCC® 9290™*	89180	-		2	1
Staphylococcus aureus ATCC® 33862™*	89042	-	recommended for CAMP test	2	1
Staphylococcus aureus subsp. aureus ATCC® 29213™*	89041	-		2	1
Staphylococcus aureus subsp. aureus ATCC® 25923™*	89040	89533	recommended for CAMP test	2	1
Staphylococcus aureus subsp. aureus ATCC® 33591™*	89116	-	methicillin resistant	2	1
Staphylococcus aureus subsp. *aureus* ATCC® 43300™*	89043	-	methicillin resistant; mec A positive	2	1
Staphylococcus aureus subsp. aureus ATCC® 700699™*	89093	-	Methicillin resistant; Mu50; reduced Vancomycin susceptibility	2	1
Staphylococcus aureus subsp. aureus ATCC® 700698™*	89092	-	Methicillin resistant; GRD MIC Test Strip control	2	1
Staphylococcus aureus subsp. aureus ATCC® 19095™*	89137	-		2	1
Staphylococcus aureus subsp. aureus ATCC® 49476™*	89181	-		2	1
Staphylococcus aureus subsp. aureus ATCC® 9144™*	89182	-		2	1

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CultiControl™ and **Quanti-CultiControl™** freeze-dried microorganisms

Description	**CultiControl™ Ref.** CE IVD	**Quanti-CultiControl™ Ref.**	**notes**	**BioSafety Level**	**recommended growth method**
Staphylococcus aureus subsp. aureus ATCC® BAA-44™*	89170	-	Methicillin resistant	2	1
Staphylococcus aureus ATCC® 6538™*	89044	89535		2	1
Staphylococcus aureus ATCC® 6538P™*	-	89534		2	1
Staphylococcus aureus NCTC 12493	89039	-	methicillin resistant	2	1
Staphylococcus epidermidis ATCC® 12228™*	89045	89537		1	1
Staphylococcus epidermidis ATCC® 14990™*	89202	-		1	1
Staphylococcus haemolyticus ATCC® 29970™*	89126	-		2	1
Staphylococcus saprophyticus ATCC® 15305™*	89153	-		1	1
Staphylococcus xylosus ATCC® 29971™*	89133	-		2	1
Stenotrophomonas maltophilia ATCC® 13637™*	89149	-		1	1
Stenotrophomonas maltophilia ATCC® 17666™*	89194	-		1	1
Streptococcus agalactiae ATCC® 13813™*	89046	-	group B; non-hemolytic in absence of CAMP Factor	2	2
Streptococcus anginosus ATCC® 33397™*	89127	-	group G; type 1	2	2
Streptococcus bovis ATCC® 33317™*	89061	-		1	2
Streptococcus dysgalactiae subsp. equisimilis ATCC® 12388™*	89128	-	group C	2	2
Streptococcus mitis ATCC® 6249™*	89129	-		2	2
Streptococcus mutans ATCC® 25175™*	89062	-		1	2
Streptococcus pneumoniae ATCC® 27336™*	89063	-		2	2
Streptococcus pneumoniae ATCC® 49619™*	89047	-	low level penicillin resistance by oxacillin test	2	2
Streptococcus pneumoniae ATCC® 700671™*	89175	-		2	2
Streptococcus pyogenes ATCC® 19615™*	89048	89538	group A	2	2
Streptococcus pyogenes ATCC® 49399™*	89130	-	group A	2	2
Streptococcus salivarius ATCC® 13419™*	89131	-		1	2
Streptococcus salivarius subsp. thermophilus ATCC® 19258™*	89186	-		1	2
Streptococcus sanguinis ATCC® 10556™*	89064	-		2	2
Trichophyton mentagrophytes ATCC® 9533™*	89140	-		2	5
Vibrio alginolyticus ATCC® 17749™*	89144	-		1	10
Vibrio parahaemolyticus ATCC® 17802™*	89056	-		2	10
Yersinia enterocolitica subsp. enterocolitica ATCC® 9610™*	89050	-	biovar 1; serogroup O:8	2	1
Yersinia enterocolitica subsp. enterocolitica ATCC® 23715™*	89168	-	biotype 1; serotype 8	2	1

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Liofilchem®

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 dei dispositivi medico-diagnostici *in vitro* elencati nella tabella sotto riportata Revisione 37.3 del 26.05.2022

dichiara sotto la propria responsabilità

1. che i dispositivi sottoindicati soddisfano 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 i dispositivi sottoindicati non sono inclusi 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 i dispositivi sottoindicati sono stati messi in commercio muniti 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 devices listed in the table below, Revision 37.3 of 26.05.2022

hereby certifies under its own responsibility

1. that the below mentioned devices comply with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the below mentioned devices are 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 below mentioned devices, were introduced into the market provided with CE mark.

Roseto degli Abruzzi (TE),
26.05.2022

Signature:

LIOFILCHEM s.r.l.
BACTERIOLOGY PRODUCTS
Via Scozia
64026 Roseto degli Abruzzi (TE)
Cod. Fisc. e Partita IVA 00530130673

Technical Director
(Dr. Silvio Brocco)

Liofilchem®

Table no.1

CODE	DESCRIPTION
90 mm agar plates	
11612	Chromatic Candida
11632	Chromatic Clostridium difficile
11640	Chromatic Colistin
11619	Chromatic CRE
11622	Chromatic ESBL
11629	Chromatic ESBL + AmpC
10599	Chromatic MRSA
11631	Chromatic OXA-48
11621	Chromatic VRE
11639	Chromatic GBS
2 sector agar plates	
CODE	**DESCRIPTION**
18021	Chromatic CRE / Chromatic ESBL
18023	Chromatic CRE / Chromatic OXA-48
18007	Chromatic Staph Aureus / MRSA
18011	Chromatic Detection / ESBL
18024	MSA / Chromatic MRSA
Tubes - Bottles	
CODE	**DESCRIPTION**
481110	Chromatic Candida
490010	Hemo-aerobic Culturing
490050	Hemo-aerobic Culturing Neonatal
490030	Hemo-aerobic Culturing Pediatric
490020	Hemo-anaerobic Culturing
490060	Hemo-anaerobic Culturing Neonatal
490040	Hemo-anaerobic Culturing Pediatric
Dip-Slide	
CODE	**DESCRIPTION**
50021	Dermatest
500222	Dermatest modified
500152	Uritest
51015	Uritest
51030	Uritest 2
500302	Uritest 2
51024	Uritest C
500242	Uritest C
51041	Uritest EC
500412	Uritest EC
500702	Uritest EF
51070	Uritest EF
51170	Uritest EF
500182	Uritest M
51018	Uritest M
51040	Uritest Malto
500402	Uritest Malto
51023	Uritest N
51123	Uritest N
500232	Uritest N
51014	Uritest Penta
500142	Uritest Penta
50020	Vagitest

CODE	DESCRIPTION
Dehydrated culture media	
610613	Chromatic candida
620613	Chromatic Candida
611619	Chromatic CRE
621619	Chromatic CRE
610629	Chromatic ESBL
620629	Chromatic ESBL
610615	Chromatic MRSA
620615	Chromatic MRSA
610617	Chromatic Strepto B
620617	Chromatic Strepto B
610501	VRE Agar Base
ComASP	
CODE	**DESCRIPTION**
75011	ComASP® Benzylpenicillin 0.002-32
75009	ComASP® Cefiderocol 0.0008-128
75004	ComASP® Ceftolozane-tazobactam / Ceftazidime-avibactam
75006	ComASP® Ceftolozane-tazobactam 0.008/4 – 128/4
75003	ComASP® Colistin / Piperacillin-tazobactam
75001	ComASP® Colistin 0.25-16
75010	ComASP® Oritavancin 0.001-16
75002	ComASP® Piperacillin-tazobactam 0.008/4-128/4
75005	ComASP® Vancomycin / Teicoplanin
75007	ComASP® Vancomycin 0.008-128
ID-AST Systems	
CODE	**DESCRIPTION**
79156	A.F. Genital System
74156	AF Genital System
71620	Anaerobe System
79620	Anaerobe System
71670	Copro System
79670	Copro System
71675	Copro System Plus
79675	Copro System Plus
71618	Enterosystem 18R
79618	Enterosystem 18R
71619	Enterosystem 24R
71714	Integral System Enterobacteria
79714	Integral System Enterobacteria
71724	Integral System Gardnerella
79724	Integral system Gardnerella
71718	Integral System Stafilococchi
79718	Integral System Stafilococchi
71720	Integral System Streptococchi
79720	Integral system Streptococchi
71822	Integral System Yeasts Plus
79822	Integral System Yeasts Plus
72592	Mycoplasma System Plus
79592	Mycoplasma System Plus
71679	Pathogenic System
71681	Pathogenic System AST
79681	Pathogenic System AST
76033	SensiQuattro Candida
79033	SensiQuattro Candida

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CODE	DESCRIPTION
76031	SensiQuattro Gram-negative
79031	SensiQuattro Gram-negative
76032	SensiQuattro Gram-positive
79032	SensiQuattro Gram-positive
76010	SensiTest Gram-negative
79010	SensiTest Gram-negative
76020	SensiTest Gram-positive
79020	SensiTest Gram-positive
71630	Staf System 18R
79630	Staf System 18R
72560	Strepto System 12R
79560	Strepto System 12R
74161	Urin System Chrom
79161	Urin System Chrom
74160	Urin System Plus
79160	Urin System Plus
80258	AF Genital System Reagent
80252	Enterosystem 18R Reagent
80260	Identification System Reagent

NP Tests

CODE	DESCRIPTION
76036	Rapid ESBL NP® Test
76046	RapidResa Polymyxin Acinetobacter NP® Test

Agar Dilution AST

CODE	DESCRIPTION
77001	AD Fosfomycin 0.25-256
77061	AD Fosfomycin 0.25-256

EPT

CODE	DESCRIPTION
78618	Entero Pluri Test
78619	Entero Pluri Test
78621	Oxi/ferm Pluri Test
78620	Oxi/ferm Pluri Test

Supplements

CODE	DESCRIPTION
81088	Chromatic CRE supplement
81090	Chromatic ESBL + AmpC supplement
81089	Chromatic ESBL supplement
81078	Chromatic MRSA supplement
81083	Meropenem supplement
81062	Vancomycin supplement

CultiControl ATCC

CODE	DESCRIPTION
89139	Bordetella bronchiseptica ATCC ® 4617
89174	Acinetobacter baumannii ATCC ® 19606
89141	Acinetobacter baumannii ATCC ® BAA-747
89114	Actinomyces odontolyticus ATCC ® 17929
89169	Aeromonas hydrophila ATCC ® 35654
89119	Aeromonas hydrophila ATCC ® 7966
89091	Aggregatibacter aphrophilus ATCC ® 7901
89021	Aspergillus brasiliensis ATCC® 16404
89057	Aspergillus fumigatus ATCC ® 204305
89155	Bacillus cereus ATCC ® 10876

CODE	DESCRIPTION
89022	Bacillus Cereus ATCC® 11778
89023	Bacillus subtilis ATCC® 6633
89113	Bacteroides fragilis ATCC ® 23745
89078	Bacteroides fragilis ATCC® 25285
89111	Bacteroides ovatus ATCC ® 8483
89193	Bacteroides ovatus ATCC ® BAA-1296
89079	Bacteroides thetaiotaomicron ATCC® 29741
89147	Burkholderia cepacia ATCC ® 25416
89166	Burkholderia cepacia ATCC ® 25608
89086	Campylobacter jejuni ATCC ® 33291
89167	Campylobacter jejuni subsp. jejuni ATCC ® 29428
89145	Campylobacter jejuni subsp. jejuni ATCC ® 33560
89183	Candida albicans ATCC ® 14053
89177	Candida albicans ATCC ® 18804
89178	Candida albicans ATCC ® 64124
89072	Candida albicans ATCC ® 90028
89024	Candida albicans ATCC® 10231
89098	Candida krusei ATCC ® 14243
89071	Candida parapsilosis ATCC ® 22019
89097	Candida tropicalis ATCC ® 750
89146	Citrobacter freundii ATCC ® 43864
89159	Citrobacter freundii ATCC ® 8090
89090	Clostridium difficile ATCC ® 9689
89112	Clostridium histolyticum ATCC ® 19401
89053	Clostridium perfringens ATCC® 13124
89059	Clostridium sordellii ATCC ® 9714
89095	Clostridium sporogenes ATCC ® 19404
89158	Cronobacter muytjensii ATCC ® 51329
89138	Cronobacter sakazakii ATCC ® 29544
89196	Eikenella corrodens ATCC ® BAA-1152
89156	Enterobacter aerogenes ATCC ® 13048
89200	Enterobacter cloacae ATCC ® 49141
89065	Enterobacter cloacae subsp. cloacae ATCC ® BAA-1143
89195	Enterococcus casseliflavus ATCC ® 700327
89115	Enterococcus faecalis ATCC ® 33186
89066	Enterococcus faecalis ATCC ® 49532
89067	Enterococcus faecalis ATCC ® 49533
89173	Enterococcus faecalis ATCC ® 51299
89025	Enterococcus faecalis ATCC® 19433
89026	Enterococcus faecalis ATCC® 29212
89171	Enterococcus faecium ATCC ® 19434
89117	Enterococcus faecium ATCC ® 51559
89152	Enterococcus faecium ATCC ® 6057
89172	Enterococcus faecium ATCC ® BAA-2319
89184	Escherichia coli ATCC ® 11303
89163	Escherichia coli ATCC ® 35218
89027	Escherichia coli ATCC® 25922
89028	Escherichia coli ATCC® 8739
89118	Fusobacterium nucleatum ATCC ® 25586
89099	Gardnerella vaginalis ATCC ® 14018
89123	Haemophilus haemolyticus ATCC ® 33390
89120	Haemophilus influenzae ATCC ® 10211
89176	Haemophilus influenzae ATCC ® 33391
89124	Haemophilus influenzae ATCC ® 33533
89077	Haemophilus influenzae ATCC® 49247
89076	Haemophilus influenzae ATCC® 49766
89142	Haemophilus influenzae Type c ATCC ® 9007

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CODE	DESCRIPTION
89073	Issatchenkia orientalis ATCC ® 6258
89150	Klebsiella pneumoniae ATCC ® BAA-1144
89088	Klebsiella pneumoniae ATCC ® BAA-1705
89087	Klebsiella pneumoniae ATCC ® BAA-1706
89069	Klebsiella pneumoniae ATCC ® BAA-2146
89089	Klebsiella pneumoniae subsp. pneumoniae ATCC ® 13883
89199	Klebsiella pneumoniae subsp. pneumoniae ATCC ® 31488
89192	Klebsiella pneumoniae subsp. pneumoniae ATCC ® 4352
89070	Klebsiella pneumoniae subsp. pneumoniae ATCC ® 700603
89080	Lactobacillus acidophilus ATCC ® 4356
89100	Lactobacillus fermentum ATCC ® 9338
89055	Lactobacillus paracasei subsp. paracasei ATCC ® BAA-52
89081	Lactobacillus leichmannii ATCC ® 4797
89082	Lactococcus lactis ATCC ® 19435
89151	Legionella pneumophila subsp. fraseri ATCC ® 33156
89052	Legionella pneumophila subsp. pneumophila ATCC® 33152
89101	Listeria grayi ATCC ® 25401
89029	Listeria innocua ATCC® 33090
89030	Listeria ivanovii ATCC® 19119
89085	Listeria monocytogenes ATCC ® 13932
89148	Listeria monocytogenes ATCC ® 35152
89060	Listeria monocytogenes ATCC ® 7644
89143	Listeria monocytogenes ATCC ® BAA-751
89031	Listeria monocytogenes ATCC® 19111
89051	Listeria monocytogenes ATCC® 19115
89096	Micrococcus luteus ATCC ® 10240
89102	Micrococcus luteus ATCC ® 4698
89103	Moraxella (Branhamella) catarrhalis ATCC ® 25238
89074	Neisseria gonorrhoeae ATCC ® 19424
89075	Neisseria gonorrhoeae ATCC ® 31426
89104	Neisseria gonorrhoeae ATCC ® 49226
89122	Neisseria gonorrhoeae ATCC ® 49981
89164	Neisseria meningitidis ATCC ® 13090
89189	Nocardia brasiliensis ATCC ® 19296
89165	Peptostreptococcus anaerobius ATCC ® 27337
89094	Plesiomonas shigelloides ATCC ® 14029
89162	Porphyromonas gingivalis ATCC ® 33277
89134	Prevotella melaninogenica ATCC ® 25845
89135	Propionibacterium acnes ATCC® 11827
89190	Proteus hauseri ATCC ® 13315
89049	Proteus mirabilis ATCC® 12453
89083	Proteus mirabilis ATCC ® 29906
89105	Proteus mirabilis ATCC ® 35659
89106	Proteus mirabilis ATCC ® 43071
89032	Proteus mirabilis ATCC® 25933
89107	Proteus vulgaris ATCC ® 6380
89125	Providencia stuartii ATCC ® 33672
89033	Pseudomonas aeruginosa ATCC® 27853
89034	Pseudomonas aeruginosa ATCC® 9027
89108	Pseudomonas aeruginosa ATCC ® 10145
89109	Pseudomonas aeruginosa ATCC ® 15442

CODE	DESCRIPTION
89110	Pseudomonas fluorescens ATCC ® 13525
89035	Rhodococcus equi ATCC® 6939
89036	Saccharomyces cerevisiae ATCC® 9763
89154	Salmonella enterica subsp. arizonae ATCC ® 13314
89084	Salmonella enterica subsp. enterica serovar Enteritidis ATCC ® 13076
89185	Salmonella enterica subsp. enterica serovar Hillingdon ATCC® 9184
89161	Salmonella enterica subsp. enterica serovar Paratyphi A ATCC ® 9150
89197	Salmonella enterica subsp. enterica serovar Typhimurium ATCC ® 49416
89054	Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 13311
89037	Salmonella typhimurium ATCC® 14028
89191	Serratia marcescens ATCC ® 14756
89121	Serratia marcescens ATCC ® 8100
89179	Shigella boydii ATCC ® 9207
89198	Shigella flexneri ATCC ® 9199
89038	Shigella flexneri ATCC® 12022
89058	Shigella sonnei ATCC ® 25931
89180	Shigella sonnei ATCC ® 9290
89040	Staphylococcus aureus ATCC® 25923
89041	Staphylococcus aureus ATCC® 29213
89042	Staphylococcus aureus ATCC® 33862
89043	Staphylococcus aureus ATCC® 43300
89044	Staphylococcus aureus ATCC® 6538
89182	Staphylococcus aureus subsp. aureus ATCC ® 9144
89137	Staphylococcus aureus subsp. aureus ATCC ® 19095
89116	Staphylococcus aureus subsp. aureus ATCC ® 33591
89181	Staphylococcus aureus subsp. aureus ATCC ® 49476
89093	Staphylococcus aureus subsp. aureus ATCC ® 700699
89170	Staphylococcus aureus subsp. aureus ATCC ® BAA-44
89092	Staphylococcus aureus subsp. aureus ATCC® 700698
89202	Staphylococcus epidermidis ATCC ® 14990
89045	Staphylococcus epidermidis ATCC® 12228
89126	Staphylococcus haemolyticus ATCC ® 29970
89153	Staphylococcus saprophyticus ATCC ® 15305
89133	Staphylococcus xylosus ATCC ® 29971
89149	Stenotrophomonas maltophilia ATCC ® 13637
89194	Stenotrophomonas maltophilia ATCC ® 17666
89046	Streptococcus agalactiae ATCC® 13813
89127	Streptococcus anginosus ATCC ® 33397
89061	Streptococcus bovis ATCC ® 33317
89128	Streptococcus dysgalactiae subsp.equisimilis ATCC ® 12388
89129	Streptococcus mitis ATCC ® 6249
89062	Streptococcus mutans ATCC ® 25175
89063	Streptococcus pneumoniae ATCC ® 27336
89175	Streptococcus pneumoniae ATCC ® 700671
89047	Streptococcus pneumoniae ATCC® 49619
89130	Streptococcus pyogenes ATCC ® 49399
89048	Streptococcus pyogenes ATCC® 19615

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CODE	DESCRIPTION
89131	Streptococcus salivarius ATCC® 13419
89186	Streptococcus salivarius subsp. thermophilus ATCC ® 19258
89064	Streptococcus sanguinis ATCC ® 10556
89140	Trichophyton mentagrophytes ATCC ® 9533
89144	Vibrio alginolyticus ATCC ® 17749
89056	Vibrio parahaemolyticus ATCC ® 17802
89050	Yersinia enterocolitica ATCC® 9610
89168	Yersinia enterocolitica subsp. enterocolitica ATCC ® 23715

Antibiotic disc in cartridges

CODE	DESCRIPTION
9004	Amikacin AK 30 µg
9004/1	Amikacin AK 30 µg
9191	Amoxicillin + Clavulanic acid AUG 3 (2+1) µg
9191/1	Amoxicillin + Clavulanic acid AUG 3 (2+1) µg
9133	Amoxicillin AML 10 µg
9133/1	Amoxicillin AML 10 µg
9151/1	Amoxicillin AML 2 µg
9151	Amoxicillin AML 2 µg
9179	Amoxicillin AML 25 µg
9179/1	Amoxicillin AML 25 µg
9005	Amoxicillin AML 30 µg
9005/1	Amoxicillin AML 30 µg
9048	Amoxicillin-clavulanic acid AUG 30 µg
9048/1	Amoxicillin-clavulanic acid AUG 30 µg
9255	Amoxicillin-clavulanic acid AUG 7.5 µg
9255/1	Amoxicillin-clavulanic acid AUG 7.5 µg
9137	Amphotericin B AMB 10 µg
9137/1	Amphotericin B AMB 10 µg
9071	Amphotericin B AMB 20 µg
9071/1	Amphotericin B AMB 20 µg
9006	Ampicillin AMP 10 µg
9006/1	Ampicillin AMP 10 µg
9115/1	Ampicillin AMP 2 µg
9115	Ampicillin AMP 2 µg
9031	Ampicillin-sulbactam AMS 20 µg
9031/1	Ampicillin-sulbactam AMS 20 µg
9122	Ampliclox (Ampicillin-cloxacillin) ACL 30 (25+5) µg
9122/1	Ampliclox (Ampicillin-cloxacillin) ACL 30 (25+5) µg
9105	Azithromycin AZM 15 µg
9105/1	Azithromycin AZM 15 µg
9007	Azlocillin AZL 75 µg
9007/1	Azlocillin AZL 75 µg
9008	Aztreonam ATM 30 µg
9008/1	Aztreonam ATM 30 µg
9051	Bacitracin BA 10 IU
9051/1	Bacitracin BA 10 IU
9009	Carbenicillin CAR 100 µg
9009/1	Carbenicillin CAR 100 µg
9165	Caspofungin CAS 5 µg
9165/1	Caspofungin CAS 5 µg
9010/1	Cefaclor 30 µg
9010	Cefaclor 30 µg
9052	Cefadroxil CDX 30 µg
9052/1	Cefadroxil CDX 30 µg

CODE	DESCRIPTION
9014	Cefamandole MA 30 µg
9014/1	Cefamandole MA 30 µg
9015	Cefazolin KZ 30 µg
9015/1	Cefazolin KZ 30 µg
9143	Cefepime + Clavulanic acid FEL 40 µg
9143/1	Cefepime + Clavulanic acid FEL 40 µg
9220	Cefepime FEP 10 µg
9220/1	Cefepime FEP 10 µg
9104	Cefepime FEP 30 µg
9104/1	Cefepime FEP 30 µg
9266/1	Cefiderocol FDC 30 µg
9266	Cefiderocol FDC 30 µg
9089	Cefixime CFM 5 µg
9089/1	Cefixime CFM 5 µg
9016	Cefoperazone CFP 30 µg
9016/1	Cefoperazone CFP 30 µg
9108	Cefoperazone CFP 75 µg
9108/1	Cefoperazone CFP 75 µg
9203	Cefotaxime + Clavulanic acid + Cloxacillin CTLC
9203/1	Cefotaxime + Clavulanic acid + Cloxacillin CTLC
9182	Cefotaxime + Clavulanic acid CTL 40 (30+10) µg
9182/1	Cefotaxime + Clavulanic acid CTL 40 (30+10) µg
9224	Cefotaxime + Cloxacillin CTC
9224/1	Cefotaxime + Cloxacillin CTC
9017	Cefotaxime CTX 30 µg
9017/1	Cefotaxime CTX 30 µg
9152	Cefotaxime CTX 5 µg
9152/1	Cefotaxime CTX 5 µg
9134/1	Cefotaxime CTX 75 µg
9081	Cefotetan CTT 30 µg
9081/1	Cefotetan CTT 30 µg
9144	Cefoxitin + Cloxacillin FOC 230 µg
9144/1	Cefoxitin + Cloxacillin FOC 230 µg
9018	Cefoxitin FOX 30 µg
9018/1	Cefoxitin FOX 30 µg
9185	Cefpirome CR 30 µg
9190	Cefpodoxime + Clavulanic acid PXL 11 (10+1) µg
9190/1	Cefpodoxime + Clavulanic acid PXL 11 (10+1) µg
9064	Cefpodoxime PX 10 µg
9064/1	Cefpodoxime PX 10 µg
9112	Cefprozil CPR 30 µg
9112/1	Cefprozil CPR 30 µg
9053/1	Cefsulodin CSD 30 µg
9053	Cefsulodin CSD 30 µg
9198	Ceftaroline CPT 30 µg
9198/1	Ceftaroline CPT 30 µg
9195	Ceftaroline CPT 5 µg
9195/1	Ceftaroline CPT 5 µg
9204	Ceftazidime + Clavulanic acid + Cloxacillin CALC
9204/1	Ceftazidime + Clavulanic acid + Cloxacillin CALC
9145	Ceftazidime + Clavulanic acid CAL 40 (30+10) µg
9145/1	Ceftazidime + Clavulanic acid CAL 40 (30+10) µg
9225	Ceftazidime + Cloxacillin CAC
9225/1	Ceftazidime + Cloxacillin CAC
9153	Ceftazidime CAZ 10 µg
9153/1	Ceftazidime CAZ 10 µg
9019	Ceftazidime CAZ 30 µg
9019/1	Ceftazidime CAZ 30 µg

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CODE	DESCRIPTION
9206	Ceftazime-avibactam CZA 14 µg
9206/1	Ceftazime-avibactam CZA 14 µg
9205	Ceftazime-avibactam CZA 50 µg
9205/1	Ceftazime-avibactam CZA 50 µg
9101	Ceftibuten CTB 30 µg
9101/1	Ceftibuten CTB 30 µg
9054	Ceftizoxime CZX 30 µg
9054/1	Ceftizoxime CZX 30 µg
9242/1	Ceftobiprole BPR 5 µg
9242	Ceftobiprole BPR 5 µg
9246/1	Ceftolozane-tazobactam C/T 40 µg
9246	Ceftolozane-tazobactam C/T 40 µg
9020	Ceftriaxone CRO 30 µg
9020/1	Ceftriaxone CRO 30 µg
9232/1	Cefuroxime CXM 1 µg
9232	Cefuroxime CXM 1 µg
9021	Cefuroxime CXM 30 µg
9021/1	Cefuroxime CXM 30 µg
9011	Cephalexin CL 30 µg
9011/1	Cephalexin CL 30 µg
9013	Cephalothin KF 30 µg
9013/1	Cephalothin KF 30 µg
9055	Cephradine CE 30 µg
9055/1	Cephradine CE 30 µg
9128	Chloramphenicol C 10 µg
9128/1	Chloramphenicol C 10 µg
9022	Chloramphenicol C 30 µg
9022/1	Chloramphenicol C 30 µg
9057	Cinoxacin CIN 100 µg
9057/1	Cinoxacin CIN 100 µg
9056	Ciprofloxacin CIP 5 µg
9056/1	Ciprofloxacin CIP 5 µg
9098	Clarithromycin CLR 15 µg
9098/1	Clarithromycin CLR 15 µg
9146	Clindamycin CD 10 µg
9146/1	Clindamycin CD 10 µg
9047	Clindamycin CD 2 µg
9047/1	Clindamycin CD 2 µg
9097	Clotrimazole CLO 50 µg
9097/1	Clotrimazole CLO 50 µg
9058	Cloxacillin CX 5 µg
9058/1	Cloxacillin CX 5 µg
9023	Colistin sulfate CS 10 µg
9023/1	Colistin sulfate CS 10 µg
9184	Colistin sulfate CS 25 µg
9184/1	Colistin sulfate CS 25 µg
9141	Colistin Sulfate CS 30 IU
9141/1	Colistin Sulfate CS 30 IU
9090	Daptomycin DAP 30 µg
9090/1	Daptomycin DAP 30 µg
9093	Dicloxacillin DCX 1 µg
9093/1	Dicloxacillin DCX 1 µg
9194	Dipicolinic acid DP
9194/1	Dipicolinic acid DP
9154	Doripenem DOR 10 µg
9154/1	Doripenem DOR 10 µg
9059	Doxycycline DXT 30 µg
9059/1	Doxycycline DXT 30 µg

CODE	DESCRIPTION
9072	Econazole ECN 10 µg
9072/1	Econazole ECN 10 µg
9087	EDTA ED
9087/1	EDTA ED
9238/1	Eravacycline ERV 20 µg
9238	Eravacycline ERV 20 µg
9199	Ertapenem + Cloxacillin ET + CL
9199/1	Ertapenem + Cloxacillin ET + CL
9202	Ertapenem + Phenylboronic acid ET + BO
9202/1	Ertapenem + Phenylboronic acid ET + BO
9061	Ertapenem ETP 10 µg
9061/1	Ertapenem ETP 10 µg
9024	Erythromycin E 15 µg
9024/1	Erythromycin E 15 µg
9180/1	Erythromycin E 2 µg
9180	Erythromycin E 2 µg
9069	Fluconazole FLU 100 µg
9069/1	Fluconazole FLU 100 µg
9166	Fluconazole FLU 25 µg
9166/1	Fluconazole FLU 25 µg
9073	Flucytosine AFY 1 µg
9073/1	Flucytosine AFY 1 µg
9148	Flucytosine AFY 10 µg
9148/1	Flucytosine AFY 10 µg
9121	Fosfomycin FOS 100 µg
9121/1	Fosfomycin FOS 100 µg
9109	Fosfomycin FOS 200 µg
9109/1	Fosfomycin FOS 200 µg
9025	Fosfomycin FOS 50 µg
9025/1	Fosfomycin FOS 50 µg
9099	Furazolidon FR 50 µg
9099/1	Furazolidon FR 50 µg
9049	Fusidic acid FC 10 µg
9049/1	Fusidic acid FC 10 µg
9111	Fusidic acid FC 30 µg
9111/1	Fusidic acid FC 30 µg
9169	Gatifloxacin GAT 5 µg
9169/1	Gatifloxacin GAT 5 µg
9026	Gentamicin CN 10 µg
9026/1	Gentamicin CN 10 µg
9124	Gentamicin CN 120 µg
9124/1	Gentamicin CN 120 µg
9125	Gentamicin CN 30 µg
9125/1	Gentamicin CN 30 µg
9074	Griseofulvin AGF 10 µg
9074/1	Griseofulvin AGF 10 µg
9086	Imipenem + Cloxacillin IMI + CL
9183	Imipenem + EDTA IMI + ED 760 (10+750) µg
9183/1	Imipenem + EDTA IMI + ED 760 (10+750) µg
9085	Imipenem + Phenylboronic acid IMI + BO
9085/1	Imipenem + Phenylboronic acid IMI + BO
9079	Imipenem IMI 10 µg
9079/1	Imipenem IMI 10 µg
9107	Itraconazole ITC 50 µg
9107/1	Itraconazole ITC 50 µg
9139	Itraconazole ITC 8 µg
9139/1	Itraconazole ITC 8 µg
9027	Kanamycin K 30 µg

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CODE	DESCRIPTION
9027/1	Kanamycin K 30 µg
9075	Ketoconazole KCA 10 µg
9075/1	Ketoconazole KCA 10 µg
9140	Ketoconazole KCA 15 µg
9140/1	Ketoconazole KCA 15 µg
9102	Levofloxacin LEV 5 µg
9102/1	Levofloxacin LEV 5 µg
9267	Levonadifloxacin LND 10 µg
9267/1	Levonadifloxacin LND 10 µg
9116	Lincomycin MY 15 µg
9116/1	Lincomycin MY 15 µg
9028	Lincomycin MY 2 µg
9028/1	Lincomycin MY 2 µg
9155	Linezolid LNZ 10 µg
9155/1	Linezolid LNZ 10 µg
9136	Linezolid LNZ 30 µg
9136/1	Linezolid LNZ 30 µg
9113	Lomefloxacin LOM 10 µg
9113/1	Lomefloxacin LOM 10 µg
9156	Mecillinam MEC 10 µg
9156/1	Mecillinam MEC 10 µg
9175/1	Meropenem + Cloxacillin MR + CL
9178	Meropenem + EDTA MR + ED
9178/1	Meropenem + EDTA MR + ED
9176	Meropenem + Phenylboronic acid MR + BO
9176/1	Meropenem + Phenylboronic acid MR + BO
9068	Meropenem MRP 10 µg
9068/1	Meropenem MRP 10 µg
9175	Meropenm + Cloxacillin MR + CL
9029/1	Methicillin MET 5 µg
9029	Methicillin MET 5 µg
9076	Metronidazole MTZ 5 µg
9076/1	Metronidazole MTZ 5 µg
9119/1	Metronidazole MTZ 50 µg
9119	Metronidazole MTZ 50 µg
9062	Mezlocillin MEZ 75 µg
9062/1	Mezlocillin MEZ 75 µg
9077	Miconazole MCL 10 µg
9077/1	Miconazole MCL 10 µg
9030	Minocycline MN 30 µg
9030/1	Minocycline MN 30 µg
9103	Moxifloxacin MXF 5 µg
9103/1	Moxifloxacin MXF 5 µg
9157	Mupirocin MUP 200 µg
9157/1	Mupirocin MUP 200 µg
9189	Mupirocin MUP 5 µg
9174	Nafcillin NAF 1 µg
9174/1	Nafcillin NAF 1 µg
9001	Nalidixic acid NA 30 µg
9001/1	Nalidixic acid NA 30 µg
9032	Neomycin N 30 µg
9032/1	Neomycin N 30 µg
9170	Netilmicin NET 10 µg
9170/1	Netilmicin NET 10 µg
9033	Netilmicin NET 30 µg
9033/1	Netilmicin NET 30 µg
9158	Nitrofurantoin F 100 µg
9158/1	Nitrofurantoin F 100 µg

CODE	DESCRIPTION
9034	Nitrofurantoin F 300 µg
9034/1	Nitrofurantoin F 300 µg
9181	Nitrofurantoin F 50 µg
9181/1	Nitrofurantoin F 50 µg
9209/1	Nitroxolin NI 30 µg
9209	Nitroxolin NI 30 µg
9035	Norfloxacin NOR 10 µg
9035/1	Norfloxacin NOR 10 µg
9063	Novobiocin NO 30 µg
9063/1	Novobiocin NO 30 µg
9117/1	Novobiocin NO 5 µg
9117	Novobiocin NO 5 µg
9078	Nystatin NY 100 IU
9078/1	Nystatin NY 100 IU
9080	Ofloxacin OFX 5 µg
9080/1	Ofloxacin OFX 5 µg
9201	Oritavancin ORI 5 µg
9201/1	Oritavancin ORI 5 µg
9036	Oxacillin OX 1 µg
9036/1	Oxacillin OX 1 µg
9135	Oxacillin OX 5 µg
9135/1	Oxacillin OX 5 µg
9002	Oxolinic acid OA 2 µg
9002/1	Oxolinic acid OA 2 µg
9065	Oxytetracycline OT 30 µg
9065/1	Oxytetracycline OT 30 µg
9091	Pefloxacin PEF 5 µg
9091/1	Pefloxacin PEF 5 µg
9130/1	Penicillin G P 1 IU
9130	Penicillin G P 1 IU
9037	Penicillin G P 10 IU
9037/1	Penicillin G P 10 IU
9127	Penicillin G P 2 IU
9127/1	Penicillin G P 2 IU
9171	Phenoxymethylpenicillin PV 10 µg
9171/1	Phenoxymethylpenicillin PV 10 µg
9193	Phenylboronic acid BO
9193/1	Phenylboronic acid BO
9003	Pipemidic acid PI 20 µg
9003/1	Pipemidic acid PI 20 µg
9038	Piperacillin PRL 100 µg
9038/1	Piperacillin PRL 100 µg
9159	Piperacillin PRL 30 µg
9159/1	Piperacillin PRL 30 µg
9100/1	Piperacillin-tazobactam TZP 110 µg
9100	Piperacillin-tazobactam TZP 110 µg
9160	Piperacillin-tazobactam TZP 36 µg
9160/1	Piperacillin-tazobactam TZP 36 µg
9066	Polymyxin B PB 100 IU
9066/1	Polymyxin B PB 100 IU
9120	Polymyxin B PB 300 IU
9120/1	Polymyxin B PB 300 IU
9167	Posaconazole POS 5 µg
9167/1	Posaconazole POS 5 µg
9039	Rifampicin RD 30 µg
9039/1	Rifampicin RD 30 µg
9118	Rifampicin RD 5 µg
9118/1	Rifampicin RD 5 µg

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CODE	DESCRIPTION
9192	Rokitamycin ROK 30 µg
9192/1	Rokitamycin ROK 30 µg
9060	Roxithromycin RXT 15 µg
9060/1	Roxithromycin RXT 15 µg
9046	Sisomycin SIS 30 µg
9046/1	Sisomycin SIS 30 µg
9131	Sodium Fusidate FC 30 µg
9067	Spectinomycin SPC 100 µg
9067/1	Spectinomycin SPC 100 µg
9088	Spiramycin SP 100 µg
9088/1	Spiramycin SP 100 µg
9040	Streptomycin S 10 µg
9040/1	Streptomycin S 10 µg
9162	Streptomycin S 300 µg
9162/1	Streptomycin S 300 µg
9129/1	Sulbactam SU 20 µg
9129	Sulbactam SU 20 µg
9150	Sulfadiazine SUZ 300 µg
9150/1	Sulfadiazine SUZ 300 µg
9041	Sulfafurazole SF 300 µg
9041/1	Sulfafurazole SF 300 µg
9187	Sulfamethoxazole SMX 100 µg
9187/1	Sulfamethoxazole SMX 100 µg
9084	Sulfamethoxazole SMX 50 µg
9084/1	Sulfamethoxazole SMX 50 µg
9132	Sulfaprim SXT 50 µg
9132/1	Sulfaprim SXT 50 µg
9126	Sulfonamide S3 300 µg
9126/1	Sulfonamide S3 300 µg
9243/1	Tedizolid TZD 2 µg
9243	Tedizolid TZD 2 µg
9245/1	Tedizolid TZD 20 µg
9245	Tedizolid TZD 20 µg
9050	Teicoplanin TEC 30 µg
9050/1	Teicoplanin TEC 30 µg
9172	Telithromycin TEL 15 µg
9172/1	Telithromycin TEL 15 µg
9186	Temocillin TMO 30 µg
9186/1	Temocillin TMO 30 µg
9043	Tetracycline TE 30 µg
9043/1	Tetracycline TE 30 µg
9094	Tiamulin T 30 µg
9094/1	Tiamulin T 30 µg
9070	Ticarcillin TC 75 µg
9070/1	Ticarcillin TC 75 µg
9096	Ticarcillin-clavulanic acid TTC 85 µg
9096/1	Ticarcillin-clavulanic acid TTC 85 µg
9147	Tigecyclin TGC 15 µg
9147/1	Tigecyclin TGC 15 µg
9044	Tobramycin TOB 10 µg
9044/1	Tobramycin TOB 10 µg
9163	Tobramycin TOB 30 µg
9163/1	Tobramycin TOB 30 µg
9042	Trimethoprim – Sulfamethoxazole SXT 25 µg
9042/1	Trimethoprim – Sulfamethoxazole SXT 25 µg
9083	Trimethoprim TM 2.5 µg
9083/1	Trimethoprim TM 2.5 µg
9110	Trimethoprim TM 5 µg

CODE	DESCRIPTION
9110/1	Trimethoprim TM 5 µg
9082	Tylosin TY 30 µg
9082/1	Tylosin TY 30 µg
9045	Vancomycin VA 30 µg
9045/1	Vancomycin VA 30 µg
9164	Vancomycin VA 5 µg
9164/1	Vancomycin VA 5 µg
9168	Voriconazole VO 1 µg
9168/1	Voriconazole VO 1 µg
99002	ESBL disc kit (acc. to EUCAST)
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

Antibiotic disc in canister

CODE	DESCRIPTION
9004/2	Amikacin AK 30 µg
9133/2	Amoxicillin AML 10 µg
9005/2	Amoxicillin AML 30 µg
9048/2	Amoxicillin-clavulanic acid AUG 30 µg
9137/2	Amphotericin B AMB 10 µg
9071/2	Amphotericin B AMB 20 µg
9006/2	Ampicillin AMP 10 µg
9115/2	Ampicillin AMP 2 µg
9031/2	Ampicillin-sulbactam AMS 20 µg
9105/2	Azithromycin AZM 15 µg
9007/2	Azlocillin AZL 75 µg
9008/2	Aztreonam ATM 30 µg
9051/2	Bacitracin BA 10 IU
9009/2	Carbenicillin CAR 100 µg
9010/2	Cefaclor 30 µg
9052/2	Cefadroxil CDX 30 µg
9014/2	Cefamandole MA 30 µg
9015/2	Cefazolin KZ 30 µg
9143/2	Cefepime + Clavulanic acid FEL 40 µg
9104/2	Cefepime FEP 30 µg
9266/2	Cefiderocol FDC 30 µg
9089/2	Cefixime CFM 5 µg
9016/2	Cefoperazone CFP 30 µg
9108/2	Cefoperazone CFP 75 µg
9182/2	Cefotaxime + Clavulanic acid CTL 40 (30+10) µg
9017/2	Cefotaxime CTX 30 µg
9152/2	Cefotaxime CTX 5 µg
9018/2	Cefoxitin FOX 30 µg
9064/2	Cefpodoxime PX 10 µg
9053/2	Cefsulodin CSD 30 µg
9198/2	Ceftaroline CPT 30 µg
9195/2	Ceftaroline CPT 5 µg
9145/2	Ceftazidime + Clavulanic acid CAL 40 (30+10) µg
9153/2	Ceftazidime CAZ 10 µg
9019/2	Ceftazidime CAZ 30 µg
9206/2	Ceftazime-avibactam CZA 14 µg
9101/2	Ceftibuten CTB 30 µg

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CODE	DESCRIPTION
9054/2	Ceftizoxime CZX 30 µg
9242/2	Ceftobiprole BPR 5 µg
9246/2	Ceftolozane-tazobactam C/T 40 µg
9020/2	Ceftriaxone CRO 30 µg
9232/2	Cefuroxime CXM 1 µg
9021/2	Cefuroxime CXM 30 µg
9011/2	Cephalexin CL 30 µg
9013/2	Cephalothin KF 30 µg
9055/2	Cephradine CE 30 µg
9022/2	Chloramphenicol C 30 µg
9057/2	Cinoxacin CIN 100 µg
9056/2	Ciprofloxacin CIP 5 µg
9098/2	Clarithromycin CLR 15 µg
9146/2	Clindamycin CD 10 µg
9047/2	Clindamycin CD 2 µg
9097/2	Clotrimazole CLO 50 µg
9058/2	Cloxacillin CX 5 µg
9023/2	Colistin sulfate CS 10 µg
9141/2	Colistin Sulfate CS 30 IU
9090/2	Daptomycin DAP 30 µg
9154/2	Doripenem DOR 10 µg
9059/2	Doxycycline DXT 30 µg
9238/2	Eravacycline ERV 20 µg
9061/2	Ertapenem ETP 10 µg
9024/2	Erythromycin E 15 µg
9180/2	Erythromycin E 2 µg
9166/2	Fluconazole FLU 25 µg
9148/2	Flucytosine AFY 10 µg
9121/2	Fosfomycin FOS 100 µg
9109/2	Fosfomycin FOS 200 µg
9025/2	Fosfomycin FOS 50 µg
9049/2	Fusidic acid FC 10 µg
9026/2	Gentamicin CN 10 µg
9124/2	Gentamicin CN 120 µg
9125/2	Gentamicin CN 30 µg
9079/2	Imipenem IMI 10 µg
9107/2	Itraconazole ITC 50 µg
9139/2	Itraconazole ITC 8 µg
9027/2	Kanamycin K 30 µg
9075/2	Ketoconazole KCA 10 µg
9102/2	Levofloxacin LEV 5 µg
9116/2	Lincomycin MY 15 µg
9028/2	Lincomycin MY 2 µg
9155/2	Linezolid LNZ 10 µg
9156/2	Mecillinam MEC 10 µg
9176/2	Meropenem + Phenylboronic acid MR + BO
9068/2	Meropenem MRP 10 µg
9029/2	Methicillin MET 5 µg
9119/2	Metronidazole MTZ 50 µg
9077/2	Miconazole MCL 10 µg
9030/2	Minocycline MN 30 µg
9103/2	Moxifloxacin MXF 5 µg
9157/2	Mupirocin MUP 200 µg
9189/2	Mupirocin MUP 5 µg
9174/2	Nafcillin NAF 1 µg
9001/2	Nalidixic acid NA 30 µg
9032/2	Neomycin N 30 µg
9033/2	Netilmicin NET 30 µg

CODE	DESCRIPTION
9158/2	Nitrofurantoin F 100 µg
9034/2	Nitrofurantoin F 300 µg
9181/2	Nitrofurantoin F 50 µg
9209/2	Nitroxolin NI 30 µg
9035/2	Norfloxacin NOR 10 µg
9063/2	Novobiocin NO 30 µg
9117/2	Novobiocin NO 5 µg
9078/2	Nystatin NY 100 IU
9080/2	Ofloxacin OFX 5 µg
9201/2	Oritavancin ORI 5 µg
9036/2	Oxacillin OX 1 µg
9002/2	Oxolinic acid OA 2 µg
9065/2	Oxytetracycline OT 30 µg
9091/2	Pefloxacin PEF 5 µg
9130/2	Penicillin G P 1 IU
9037/2	Penicillin G P 10 IU
9193/2	Phenylboronic acid BO
9003/2	Pipemidic acid PI 20 µg
9038/2	Piperacillin PRL 100 µg
9159/2	Piperacillin PRL 30 µg
9100/2	Piperacillin-tazobactam TZP 110 µg
9160/2	Piperacillin-tazobactam TZP 36 µg
9066/2	Polymyxin B PB 100 IU
9120/2	Polymyxin B PB 300 IU
9039/2	Rifampicin RD 30 µg
9118/2	Rifampicin RD 5 µg
9060/2	Roxithromycin RXT 15 µg
9046/2	Sisomycin SIS 30 µg
9067/2	Spectinomycin SPC 100 µg
9040/2	Streptomycin S 10 µg
9041/2	Sulfafurazole SF 300 µg
9243/2	Tedizolid TZD 2 µg
9050/2	Teicoplanin TEC 30 µg
9043/2	Tetracycline TE 30 µg
9094/2	Tiamulin T 30 µg
9070/2	Ticarcillin TC 75 µg
9096/2	Ticarcillin-clavulanic acid TTC 85 µg
9147/2	Tigecyclin TGC 15 µg
9044/2	Tobramycin TOB 10 µg
9042/2	Trimethoprim – Sulfamethoxazole SXT 25 µg
9083/2	Trimethoprim TM 2.5 µg
9110/2	Trimethoprim TM 5 µg
9045/2	Vancomycin VA 30 µg
9164/2	Vancomycin VA 5 µg
9168/2	Voriconazole VO 1 µg

MIC Test Strip

CODE	DESCRIPTION
92018	Amikacin AK 0.016-256 mg/L
920180	Amikacin AK 0.016-256 mg/L
920181	Amikacin AK 0.016-256 mg/L
920210	Amoxicillin AmL 0.016-256 mg/L
92021	Amoxicillin AmL 0.016-256 mg/L
920211	Amoxicillin AmL 0.016-256 mg/L
921800	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0.016-256* mg/L
921801	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0.016-256* mg/L

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CODE	DESCRIPTION
92180	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0.016-256* mg/L 30 MICTest
92024	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L
920240	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L
920241	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L
92153	Amphotericin B AMB 0.002-32 mg/L
921531	Amphotericin B AMB 0.002-32 mg/L
921530	Amphotericin B AMB 0.002-32 mg/L 100 MICTest
920030	Ampicillin AMP 0.016-256 mg/L
920031	Ampicillin AMP 0.016-256 mg/L
92003	Ampicillin AMP 0.016-256 mg/L
92027	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L
920270	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L
920271	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L
92181	Ampicillin* - sulbactam (4 mg/L) SAM 0.016-256* mg/L
921810	Ampicillin* - sulbactam (4 mg/L) SAM 0.016-256* mg/L
921811	Ampicillin* - sulbactam (4 mg/L) SAM 0.016-256* mg/L
92155	Anidulafungin AND 0.002-32 mg/L
921551	Anidulafungin AND 0.002-32 mg/L
921550	Anidulafungin AND 0.002-32 mg/L 100 Test
92030	Azithromycin AZM 0.016-256 mg/L
920300	Azithromycin AZM 0.016-256 mg/L
920301	Azithromycin AZM 0.016-256 mg/L
92033	Aztreonam ATM 0.016-256 mg/L
920330	Aztreonam ATM 0.016-256 mg/L
920331	Aztreonam ATM 0.016-256 mg/L
92173	Aztreonam ATM 0.064-1024 mg/L
921730	Aztreonam ATM 0.064-1024 mg/L
921731	Aztreonam ATM 0.064-1024 mg/L
92019	Bacitracin BA 0.016-256 mg/L
920190	Bacitracin BA 0.016-256 mg/L
920191	Bacitracin BA 0.016-256 mg/L
92154	Caspofungin CAS 0.002-32 mg/L
921541	Caspofungin CAS 0.002-32 mg/L
921540	Caspofungin CAS 0.002-32 mg/L
920360	Cefaclor CEC 0.016-256 mg/L
92036	Cefaclor CEC 0.016-256 mg/L
920361	Cefaclor CEC 0.016-256 mg/L
92174	Cefazolin KZ 0.016-256 mg/L
921740	Cefazolin KZ 0.016-256 mg/L
921741	Cefazolin KZ 0.016-256 mg/L
92127	Cefepime FEP 0.002-32 mg/L
921270	Cefepime FEP 0.002-32 mg/L
921271	Cefepime FEP 0.002-32 mg/L
92126	Cefepime FEP 0.016-256 mg/L
921260	Cefepime FEP 0.016-256 mg/L
921261	Cefepime FEP 0.016-256 mg/L
92161	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0.25-16 / 0.064-4 mg/L
921610	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0.25-16 / 0.064-4 mg/L

CODE	DESCRIPTION
921611	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0.25-16 / 0.064-4 mg/L
92067	Cefiderocol FDC 0,016-256 mg/L
920671	Cefiderocol FDC 0,016-256 mg/L
920670	Cefiderocol FDC 0,016-256 mg/L
92060	Cefixime CFM 0.016-256 mg/L
920601	Cefixime CFM 0.016-256 mg/L
920600	Cefixime CFM 0.016-256 mg/L
92023	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L
920230	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L
920231	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L
92007	Cefotaxime CTX 0.002-32 mg/L
920070	Cefotaxime CTX 0.002-32 mg/L
920071	Cefotaxime CTX 0.002-32 mg/L
920061	Cefotaxime CTX 0.016-256 mg/L
92006	Cefotaxime CTX 0.016-256 mg/L
920060	Cefotaxime CTX 0.016-256 mg/L
92160	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0.25-16/0.016-1 mg/L
921600	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0.25-16/0.016-1 mg/L
921601	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0.25-16/0.016-1 mg/L
920200	Cefotetan CTT 0.016-256 mg/L
920201	Cefotetan CTT 0.016-256 mg/L
92020	Cefotetan CTT 0.016-256 mg/L
92164	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0.5-32/0.5-32 mg/L
921641	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0.5-32/0.5-32 mg/L
921640	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0.5-32/0.5-32 mg/L
92066	Cefoxitin FOX 0.016-256 mg/L
920660	Cefoxitin FOX 0.016-256 mg/L
920661	Cefoxitin FOX 0.016-256 mg/L
92008	Cefpirome CR 0.016-256 mg/L
920080	Cefpirome CR 0.016-256 mg/L
920081	Cefpirome CR 0.016-256 mg/L
920050	Cefpodoxime PX 0.016-256 mg/L
92005	Cefpodoxime PX 0.016-256 mg/L
920051	Cefpodoxime PX 0.016-256 mg/L
920560	Ceftaroline CPT 0.002-32 mg/L
920561	Ceftaroline CPT 0.002-32 mg/L
92056	Ceftaroline CPT 0.002-32 mg/L
92049	Ceftaroline CPT 0.016-256 mg/L
920491	Ceftaroline CPT 0.016-256 mg/L
920490	Ceftaroline CPT 0.016-256 mg/L
92138	Ceftazidime CAZ 0.016-256 mg/L
921380	Ceftazidime CAZ 0.016-256 mg/L
921381	Ceftazidime CAZ 0.016-256 mg/L
92139	Ceftazidime*- avibactam CZA 0.016/4-256/4 mg/L
921390	Ceftazidime*- avibactam CZA 0.016/4-256/4 mg/L
921391	Ceftazidime*- avibactam CZA 0.016/4-256/4 mg/L
92159	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0.5-32/0.064-4 mg/L
921590	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0.5-32/0.064-4 mg/L

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CODE	DESCRIPTION
921591	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0.5-32/0.064-4 mg/L
92058	Ceftibuten CTB 0.002-32 mg/L
920580	Ceftibuten CTB 0.002-32 mg/L
920581	Ceftibuten CTB 0.002-32 mg/L
920160	Ceftizoxime CZX 0.016-256 mg/L
920161	Ceftizoxime CZX 0.016-256 mg/L
92016	Ceftizoxime CZX 0.016-256 mg/L
92140	Ceftobiprole BPR 0.002-32 mg/L
921400	Ceftobiprole BPR 0.002-32 mg/L
921401	Ceftobiprole BPR 0.002-32 mg/L
92146	Ceftolozane-Tazobactam C/T 0.016/4-256/4 mg/L
921460	Ceftolozane-Tazobactam C/T 0.016/4-256/4 mg/L
921461	Ceftolozane-Tazobactam C/T 0.016/4-256/4 mg/L
920430	Ceftriaxone CRO 0.002-32 mg/L
92043	Ceftriaxone CRO 0.002-32 mg/L
920431	Ceftriaxone CRO 0.002-32 mg/L
92042	Ceftriaxone CRO 0.016-256 mg/L
920420	Ceftriaxone CRO 0.016-256 mg/L
920421	Ceftriaxone CRO 0.016-256 mg/L
921290	Cefuroxime CXM 0.016-256 mg/L
92129	Cefuroxime CXM 0.016-256 mg/L
921291	Cefuroxime CXM 0.016-256 mg/L
92039	Cephalothin KF 0.016-256 mg/L
920391	Cephalothin KF 0.016-256 mg/L
920390	Cephalothin KF 0.016-256 mg/L 0.016-256
92075	Chloramphenicol C 0.016-256 mg/L
920750	Chloramphenicol C 0.016-256 mg/L
920751	Chloramphenicol C 0.016-256 mg/L
92045	Ciprofloxacin CIP 0.002-32 mg/L
920450	Ciprofloxacin CIP 0.002-32 mg/L
920451	Ciprofloxacin CIP 0.002-32 mg/L
92048	Clarithromycin CLR 0.016-256 mg/L
920480	Clarithromycin CLR 0.016-256 mg/L
920481	Clarithromycin CLR 0.016-256 mg/L
92072	Clindamycin CD 0.016-256 mg/L
920720	Clindamycin CD 0.016-256 mg/L
920721	Clindamycin CD 0.016-256 mg/L
920440	Cloxacillin CX 0.016-256 mg/L
920441	Cloxacillin CX 0.016-256 mg/L
92044	Cloxacillin CX 0.016-256 mg/L
92141	Colistin CS 0.016-256 mg/L
921411	Colistin CS 0.016-256 mg/L
921410	Colistin CS 0.016-256 mg/L
921420	Colistin CS 0.064-1024 mg/L
921421	Colistin CS 0.064-1024 mg/L
92142	Colistin CS 0.064-1024 mg/L
92137	Dalbavancin DAL 0.002-32 mg/L
921370	Dalbavancin DAL 0.002-32 mg/L
921371	Dalbavancin DAL 0.002-32 mg/L
921451	Daptomycin DAP 0.016-256 mg/L
92145	Daptomycin DAP 0.016-256 mg/L
921450	Daptomycin DAP 0.016-256 mg/L
92080	Delafloxacin DLX 0.002-32 mg/L
920800	Delafloxacin DLX 0.002-32 mg/L
920801	Delafloxacin DLX 0.002-32 mg/L
92040	Doripenem DOR 0.002-32 mg/L
920401	Doripenem DOR 0.002-32 mg/L

CODE	DESCRIPTION
920400	Doripenem DOR 0.002-32 mg/L
92156	Doxycycline DXT 0.016-256 mg/L
921560	Doxycycline DXT 0.016-256 mg/L
921561	Doxycycline DXT 0.016-256 mg/L
920130	Enrofloxacin ENR 0.002-32 mg/L
92013	Enrofloxacin ENR 0.002-32 mg/L
920131	Enrofloxacin ENR 0.002-32 mg/L
92104	Eravacycline ERV 0.002-32 mg/L
921040	Eravacycline ERV 0.002-32 mg/L
921041	Eravacycline ERV 0.002-32 mg/L
921570	Ertapenem ETP 0.002-32 mg/L
92157	Ertapenem ETP 0.002-32 mg/L
921571	Ertapenem ETP 0.002-32 mg/L
92169	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0.125-8/ 0.032-2 mg/L
921690	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0.125-8/ 0.032-2 mg/L
921691	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0.125-8/ 0.032-2 mg/L
92168	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0.125-8/0.032-2 mg/L
921680	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0.125-8/0.032-2 mg/L
921681	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0.125-8/0.032-2 mg/L
92051	Erythromycin E 0.016-256 mg/L
920511	Erythromycin E 0.016-256 mg/L
920510	Erythromycin E 0.016-256 mg/L
92170	Ethambutol EB 0.016-256 mg/L
921701	Ethambutol EB 0.016-256 mg/L
921700	Ethambutol EB 0.016-256 mg/L
92172	Ethionamide ET 0.016-256 mg/L
921720	Ethionamide ET 0.016-256 mg/L
921721	Ethionamide ET 0.016-256 mg/L
92147	Fluconazole FLU 0.016-256 mg/L
921470	Fluconazole FLU 0.016-256 mg/L
921471	Fluconazole FLU 0.016-256 mg/L
92149	Flucytosine FC 0.002-32 mg/L
921490	Flucytosine FC 0.002-32 mg/L
921491	Flucytosine FC 0.002-32 mg/L
92078	Fosfomycin FOS 0.016-256 mg/L
920780	Fosfomycin FOS 0.016-256 mg/L
920781	Fosfomycin FOS 0.016-256 mg/L
92079	Fosfomycin FOS 0.064-1024 mg/L
920790	Fosfomycin FOS 0.064-1024 mg/L
920791	Fosfomycin FOS 0.064-1024 mg/L
920500	Fosmidomycin FOM 0.016-256 mg/L
920501	Fosmidomycin FOM 0.016-256 mg/L
92050	Fosmidomycin FOM 0.016-256 mg/L
92002	Fusidic acid FU 0.016-256 mg/L
920020	Fusidic acid FU 0.016-256 mg/L
920021	Fusidic acid FU 0.016-256 mg/L
920110	Gatifloxacin GAT 0.002-32 mg/L
920111	Gatifloxacin GAT 0.002-32 mg/L
92011	Gatifloxacin GAT 0.002-32 mg/L
92035	Gemifloxacin GEM 0.002-32 mg/L
920350	Gemifloxacin GEM 0.002-32 mg/L
920351	Gemifloxacin GEM 0.002-32 mg/L
92009	Gentamicin CN 0.016-256 mg/L

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CODE	DESCRIPTION
920090	Gentamicin CN 0.016-256 mg/L
920091	Gentamicin CN 0.016-256 mg/L
920100	Gentamicin CN 0.064-1024 mg/L
920101	Gentamicin CN 0.064-1024 mg/L
92010	Gentamicin CN 0.064-1024 mg/L
92054	Imipenem IMI 0.002-32 mg/L
920541	Imipenem IMI 0.002-32 mg/L
920540	Imipenem IMI 0.002-32 mg/L
92068	Imipenem IMI 0.016-256 mg/L
920680	Imipenem IMI 0.016-256 mg/L
920681	Imipenem IMI 0.016-256 mg/L
92166	Imipenem/Imipenem + EDTA IMI/IMD 0.125-8/0.032-2 mg/L
921660	Imipenem/Imipenem + EDTA IMI/IMD 0.125-8/0.032-2 mg/L
921661	Imipenem/Imipenem + EDTA IMI/IMD 0.125-8/0.032-2 mg/L
92162	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L
921620	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L
921621	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L
92076	Imipenem-relebactam I/R 0.002/4-32/4
920760	Imipenem-relebactam I/R 0.002/4-32/4
920761	Imipenem-relebactam I/R 0.002/4-32/4
92184	Isavuconazole IVU 0.002-32 mg/L
921840	Isavuconazole IVU 0.002-32 mg/L
921841	Isavuconazole IVU 0.002-32 mg/L
92171	Isoniazide IZ 0.016-256 mg/L
921710	Isoniazide IZ 0.016-256 mg/L
921711	Isoniazide IZ 0.016-256 mg/L
92148	Itraconazole ITC 0.002-32 mg/L
921480	Itraconazole ITC 0.002-32 mg/L
921481	Itraconazole ITC 0.002-32 mg/L
92034	Kanamycin K 0.016-256 mg/L
920340	Kanamycin K 0.016-256 mg/L
920341	Kanamycin K 0.016-256 mg/L
921510	Ketoconazole KE 0.002-32 mg/L
921511	Ketoconazole KE 0.002-32 mg/L
92151	Ketoconazole KE 0.002-32 mg/L
92064	Lefamulin LMU 0,016-256 mg/L
920641	Lefamulin LMU 0,016-256 mg/L
920640	Lefamulin LMU 0,016-256 mg/L
920810	Levofloxacin LEV 0.002-32 mg/L
920811	Levofloxacin LEV 0.002-32 mg/L
92081	Levofloxacin LEV 0.002-32 mg/L
921350	Linezolid LNZ 0.016-256 mg/L
921351	Linezolid LNZ 0.016-256 mg/L
92135	Linezolid LNZ 0.016-256 mg/L
920170	Mecillinam MEC 0.016-256 mg/L
92017	Mecillinam MEC 0.016-256 mg/L
920171	Mecillinam MEC 0.016-256 mg/L
92084	Meropenem MRP 0.002-32 mg/L
920841	Meropenem MRP 0.002-32 mg/L
920840	Meropenem MRP 0.002-32 mg/L
92085	Meropenem MRP 0.016-256 mg/L
920850	Meropenem MRP 0.016-256 mg/L
920851	Meropenem MRP 0.016-256 mg/L

CODE	DESCRIPTION
92165	Meropenem/Meropenem + EDTA MRP/MRD 0.125-8/0.032-2 mg/L
921650	Meropenem/Meropenem + EDTA MRP/MRD 0.125-8/0.032-2 mg/L
921651	Meropenem/Meropenem + EDTA MRP/MRD 0.125-8/0.032-2 mg/L
92167	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0.125-8/0.032-2 mg/L
921670	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0.125-8/0.032-2 mg/L
921671	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0.125-8/0.032-2 mg/L
92074	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L
920740	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L
920741	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L
92087	Metronidazole MTZ 0.016-256 mg/L
920870	Metronidazole MTZ 0.016-256 mg/L
920871	Metronidazole MTZ 0.016-256 mg/L
921820	Micafungin MYC 0.002-32 mg/L
921821	Micafungin MYC 0.002-32 mg/L
92182	Micafungin MYC 0.002-32 mg/L
92032	Minocycline MN 0.016-256 mg/L
920321	Minocycline MN 0.016-256 mg/L
920320	Minocycline MN 0.016-256 mg/L
92090	Moxifloxacin MXF 0.002-32 mg/L
920900	Moxifloxacin MXF 0.002-32 mg/L
920901	Moxifloxacin MXF 0.002-32 mg/L
920380	Mupirocin MUP 0.064-1024 mg/L
92038	Mupirocin MUP 0.064-1024 mg/L
920381	Mupirocin MUP 0.064-1024 mg/L
92132	Nalidixic acid NA 0.016-256 mg/L
921320	Nalidixic acid NA 0.016-256 mg/L
921321	Nalidixic acid NA 0.016-256 mg/L
92093	Netilmicin NET 0.016-256 mg/L
920930	Netilmicin NET 0.016-256 mg/L
920931	Netilmicin NET 0.016-256 mg/L
920220	Nitrofurantoin F 0.032-512 mg/L
92022	Nitrofurantoin F 0.032-512 mg/L
920221	Nitrofurantoin F 0.032-512 mg/L
920960	Norfloxacin NOR 0.016-256 mg/L
920961	Norfloxacin NOR 0.016-256 mg/L
92096	Norfloxacin NOR 0.016-256 mg/L
920990	Ofloxacin OFX 0.002-32 mg/L
92099	Ofloxacin OFX 0.002-32 mg/L
920991	Ofloxacin OFX 0.002-32 mg/L
92071	Omadacycline OMC 0.002-32 mg/L
920710	Omadacycline OMC 0.002-32 mg/L
920711	Omadacycline OMC 0.002-32 mg/L
92015	Oxacillin OX 0.016-256 mg/L
920150	Oxacillin OX 0.016-256 mg/L
920151	Oxacillin OX 0.016-256 mg/L
92041	Pefloxacin PEF 0.016-256 mg/L
920410	Pefloxacin PEF 0.016-256 mg/L
920411	Pefloxacin PEF 0.016-256 mg/L
92103	Penicillin G P 0.002-32 mg/L
921030	Penicillin G P 0.002-32 mg/L
921031	Penicillin G P 0.002-32 mg/L

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CODE	DESCRIPTION
921020	Penicillin G P 0.016-256 mg/L
92102	Penicillin G P 0.016-256 mg/L
921021	Penicillin G P 0.016-256 mg/L
92105	Piperacillin PIP 0.016-256 mg/L
921050	Piperacillin PIP 0.016-256 mg/L
921051	Piperacillin PIP 0.016-256 mg/L
921080	Piperacillin* - tazobactam TZP 0.016-256* mg/L
921081	Piperacillin* - tazobactam TZP 0.016-256* mg/L
92108	Piperacillin* - tazobactam TZP 0.016-256* mg/L
92070	Plazomicin PLZ 0.016-256 mg/L
920700	Plazomicin PLZ 0.016-256 mg/L
920701	Plazomicin PLZ 0.016-256 mg/L
92004	Polymyxin B PB 0.064-1024 mg/L
920041	Polymyxin B PB 0.064-1024 mg/L
920040	Polymyxin B PB 0.064-1024 mg/L
92152	Posaconazole POS 0.002-32 mg/L
921520	Posaconazole POS 0.002-32 mg/L
921521	Posaconazole POS 0.002-32 mg/L
92026	Quinupristin-dalfopristin QDA 0.002-32 mg/L
920260	Quinupristin-dalfopristin QDA 0.002-32 mg/L
920261	Quinupristin-dalfopristin QDA 0.002-32 mg/L
920010	Rifampicin RD 0.002-32 mg/L
920011	Rifampicin RD 0.002-32 mg/L
92001	Rifampicin RD 0.002-32 mg/L
92025	Rifampicin RD 0.016-256 mg/L
920250	Rifampicin RD 0.016-256 mg/L
920251	Rifampicin RD 0.016-256 mg/L
92014	Spectinomycin SPC 0.064-1024 mg/L
920140	Spectinomycin SPC 0.064-1024 mg/L
920141	Spectinomycin SPC 0.064-1024 mg/L
920460	Spiramycin SP 0.002-32 mg/L
920461	Spiramycin SP 0.002-32 mg/L
92046	Spiramycin SP 0.002-32 mg/L
92112	Streptomycin S 0.016-256 mg/L
921120	Streptomycin S 0.016-256 mg/L
921121	Streptomycin S 0.016-256 mg/L
92111	Streptomycin S 0.064-1024 mg/L
921110	Streptomycin S 0.064-1024 mg/L
921111	Streptomycin S 0.064-1024 mg/L
92028	Sulbactam SUL 0.016-256 mg/L
920280	Sulbactam SUL 0.016-256 mg/L
920281	Sulbactam SUL 0.016-256 mg/L
920310	Sulfamethoxazole SMX 0.064-1024 mg/L
920311	Sulfamethoxazole SMX 0.064-1024 mg/L
92031	Sulfamethoxazole SMX 0.064-1024 mg/L
921360	Tedizolid TZD 0.002-32 mg/L
921361	Tedizolid TZD 0.002-32 mg/L
92136	Tedizolid TZD 0.002-32 mg/L
920120	Teicoplanin TEC 0.016-256 mg/L
920121	Teicoplanin TEC 0.016-256 mg/L
92012	Teicoplanin TEC 0.016-256 mg/L
920520	Telavancin TLV 0.002-32 mg/L
92052	Telavancin TLV 0.002-32 mg/L
920521	Telavancin TLV 0.002-32 mg/L
92053	Telavancin TLV 0.016-256 mg/L
920530	Telavancin TLV 0.016-256 mg/L
920531	Telavancin TLV 0.016-256 mg/L
92029	Temocillin TMO 0.064-1024 mg/L

CODE	DESCRIPTION
920290	Temocillin TMO 0.064-1024 mg/L
920291	Temocillin TMO 0.064-1024 mg/L
92114	Tetracycline TE 0.016-256 mg/L
921140	Tetracycline TE 0.016-256 mg/L
921141	Tetracycline TE 0.016-256 mg/L
92200	Tiamulin TIA 0.002-32 mg/L
922000	Tiamulin TIA 0.002-32 mg/L
922001	Tiamulin TIA 0.002-32 mg/L
92183	Ticarcillin TC 0.016-256 mg/L
921830	Ticarcillin TC 0.016-256 mg/L
921831	Ticarcillin TC 0.016-256 mg/L
92117	Ticarcillin* - clavulanic acid TTC 0.016-256* mg/L
921170	Ticarcillin* - clavulanic acid TTC 0.016-256* mg/L
921171	Ticarcillin* - clavulanic acid TTC 0.016-256* mg/L
92144	Tigecycline TGC 0.016-256 mg/L
921440	Tigecycline TGC 0.016-256 mg/L
921441	Tigecycline TGC 0.016-256 mg/L
92201	Tilmicosin TIL 0.002-32 mg/L
922010	Tilmicosin TIL 0.002-32 mg/L
922011	Tilmicosin TIL 0.002-32 mg/L
92121	Tobramycin TOB 0.016-256 mg/L
921210	Tobramycin TOB 0.016-256 mg/L
921211	Tobramycin TOB 0.016-256 mg/L
921200	Tobramycin TOB 0.064-1024 mg/L
921201	Tobramycin TOB 0.064-1024 mg/L
92120	Tobramycin TOB 0.064-1024 mg/L
92037	Trimethoprim TM 0.002-32 mg/L
920370	Trimethoprim TM 0.002-32 mg/L
920371	Trimethoprim TM 0.002-32 mg/L
92123	Trimethoprim* - sulfamethoxazole (1/19) SXT 0.002-32* mg/L
921230	Trimethoprim*-sulfamethoxazole (1/19) SXT 0.002-32* mg/L
921231	Trimethoprim*-sulfamethoxazole (1/19) SXT 0.002-32* mg/L
920570	Vancomycin VA 0.016-256 mg/L
92057	Vancomycin VA 0.016-256 mg/L
920571	Vancomycin VA 0.016-256 mg/L
92163	Vancomycin//Teicoplanin VA/TEC 0.5-32/0.5-32 mg/L
921630	Vancomycin//Teicoplanin VA/TEC 0.5-32/0.5-32 mg/L
921631	Vancomycin//Teicoplanin VA/TEC 0.5-32/0.5-32 mg/L
921500	Voriconazole VO 0.002-32 mg/L
921501	Voriconazole VO 0.002-32 mg/L
92150	Voriconazole VO 0.002-32 mg/L
RID plates	
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

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CODE	DESCRIPTION
93012	Easy Rid h-Antitrombin III
93013	Easy Rid h-Ig Light Chain K
93014	Easy Rid h-Ig Light Chain Lambda
93015	Easy Rid h-Alfa 1 Antitrypsin
93016	Easy Rid h-Ceruloplasmin
93018	Easy Rid 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

Multodiscs

CODE	DESCRIPTION
95270	Multodisc Acinetobacter
95200	Multodisc Anaerobes
95220	Multodisc Enterobacteria 1
95240	Multodisc Enterobacteria 2
95230	Multodisc Enterobacteria Urine
95210	Multodisc Enterococci
95250	Multodisc Pseudomonas
95260	Multodisc Staph
95290	Multodisc Strepto
95280	Multodisc Yeasts

Bacterial suspension - rapid Kit

CODE	DESCRIPTION
96001	Salmonella typhi H Macro
96002	Salmonella typhi O Macro
96003	Salmonella paratyphi AH Macro
96004	Salmonella paratyphi AO Macro
96005	Salmonella paratyphi BH Macro
96006	Salmonella paratyphi BO Macro
96007	Brucella Totale Macro
96008	Brucella abortus Macro
96009	Salmonella typhi A Totale Macro
96010	Salmonella paratyphi A Totale Macro
96011	Proteus OX2 Macro
96012	Proteus OXK Macro
96013	Proteus OX19 Macro
96015	Febrile Multitest Kit
96016	Strep-Check Kit
96017	Staph Latex Kit
96018	Salmonella paratyphi B Totale Macro
96019	Salmonella paratyphi CH Macro
96020	Salmonella paratyphi CO Macro
96021	Salmonella paratyphi B Totale Macro

CODE	DESCRIPTION
96022	Brucella melitensis Macro
96023	Brucella suis Macro
96031	Salmonella typhi H Slide
96032	Salmonella typhi O Slide
96033	Salmonella typhi Totale Slide
96034	Salmonella paratyphi AH Slide
96035	Salmonella paratyphi AO Slide
96036	Salmonella paratyphi A Totale Slide
96037	Salmonella paratyphi BH Slide
96038	Salmonella paratyphi BO Slide
96039	Salmonella paratyphi B Totale Slide
96040	Salmonella paratyphi CH Slide
96041	Salmonella paratyphi CO Slide
96042	Salmonella paratyphi C Totale Slide
96043	Brucella Totale Slide
96044	Brucella abortus Slide
96045	Brucella melitensis Slide
96046	Brucella Bengal Rose Slide
96047	Proteus OX2 Slide
96048	Proteus OXK Slide
96049	Proteus OX19 Slide
96093	Negative Control
96096	Positive Control for Salmonella
96097	Positive Control for Proteus
96098	Positive Control for Brucella
96142	Legionella Latex Kit
96143	Campylobacter 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
96316	Clostridium difficile GDH Card
96317	Clostridium difficile Toxin A+B Card
96318	Giardia Card
96319	Listeria Monocytogenes Card
96320	Salmonella Ag Card
96415/20	Fecal Occult Blood Card
96418	Strepto A Card
96441	Gonorrea Ag Card
96442	Gardnerella Vaginalis Card
96443	Trichomonas Vaginalis Card
97800	One Step Rotavirus Card
97801	RSV Stick One Step
97802	One Step Rota-Adenovirus Combo Panel
97803	Helicobacter pylori Antigen Card
97807	One Step Adenovirus Test

ITALCERT

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.
Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

Si certifica che il

this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da

implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di

Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma

is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi

concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

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L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2023-10-24	2026-10-29

Settore IAF 14 - 29

SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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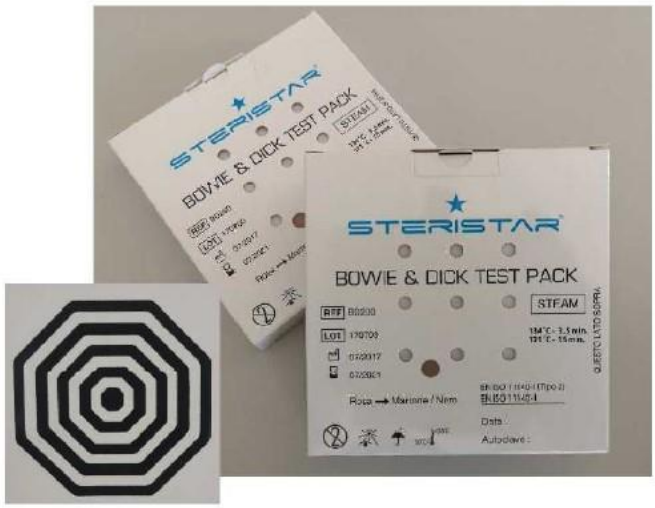
CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
12.01.2024

CODICE ARTICOLO: / *ITEM CODE:* **5380**

DESCRIZIONE / *DESCRIPTION*



TEST DI BOWIE-DICK
Il test di Bowie-Dick è una tecnica per controllare periodicamente il corretto funzionamento di un autoclave.
Questo test è utilizzato per verificare la rimozione dell'aria in autoclave a vapore saturo con vuoto frazionato durante cicli per carichi porosi a 134 °C per 3.5 minuti e 121 °C per 15 minuti. A seguito del ciclo di sterilizzazione, il viraggio delle strisce indica che l'aria residua è stata sufficientemente rimossa per consentire la completa penetrazione del vapore all'interno del foglio indicatore e l'efficacia del processo di sterilizzazione.
Foglio indicatore plastificato con viraggio da rosa a nero. Ogni pacco è contenuto in una pratica scatoletta da inserire direttamente in autoclave.
Il Bowie & Dick test pack è classificato di Tipo 2 in conformità con le norme ISO 11140-1 e ISO 11140-4.
Equivalente al pacco test indicato nella EN 285.
Il prodotto è privo di lattice e non contiene sostanze tossiche o metalli pesanti.

BOWIE-DICK TEST
Bowie-Dick type test is a method to control periodically the correct autoclave function. This test is used to verify air removal in a saturated steam autoclave with fractional vacuum during cycles for porous loads at 134°C for 3.5 minutes and 121°C for 15 minutes. Following the sterilization cycle, the color change of the stripes indicates that the residual air has been sufficiently removed to allow the complete penetration of the steam inside the indicator sheet and the effectiveness of the sterilization process.
Laminated indicator sheet with pink to black colour tone. Each package is contained in a practical box to be inserted directly into the autoclave.
The Bowie & Dick test pack is classified as Type 2 in accordance with ISO 11140-1 and ISO 11140-4.
Equivalent to the test pack indicated in EN 285.
The product is latex-free and does not contain toxic substances or heavy metals.

CARATTERISTICHE PRINCIPALI	TECHNICAL FEATURES	
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbiological status*
Dimensioni pacco (mm)	130 x 130 x 20	*Pack dimensions*
Validità del prodotto	4 ANNI / *YEARS*	*Shelf life*

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DESTINAZIONE D'USO / *INTENDED PURPOSE*

Il Bowie-Dick test cod. 5380 è utilizzabile per verificare la rimozione dell'aria in autoclavi a vapore saturo con vuoto frazionato durante cicli per carichi porosi a 134° C per 3.5 minuti e 121°C per 15 minuti.
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.

Bowie-Dick test is used to verify air removal in a saturated steam autoclave with fractional vacuum during cycles for porous loads at 134°C for 3.5 minutes and 121°C for 15 minutes
For use in professional test laboratory only

VIRAGGIO / *COLOR CHANGE*

Il foglio indicatore cambia colore dal rosa al nero quando sottoposto a ciclo di sterilizzazione a vapore con adeguate fasi di vuoto.

The indicator sheet will change from pink to black when exposed to steam sterilization cycle with acceptable vacuum cycles.

PARAMETRI CRITICI / *CRITICAL PARAMETERS*

Cicli di sterilizzazione a vapore effettuati ad una temperatura di 134°C per 3.5 minuti e 121°C per 15 minuti.

Steam sterilization cycle functioning at 134° C for 3.5 minutes and 121°C for 15 minutes.

ISTRUZIONI PER L'USO / *INSTRUCTION FOR USE*

Bowie & Dick Test Pack deve essere utilizzato ogni giorno, prima del primo ciclo di sterilizzazione.
- Eseguire un ciclo abbreviato per portare la camera di sterilizzazione alla temperatura di utilizzo.
- Posizionare il Bowie & Dick Test Pack all'interno della camera di sterilizzazione vuota e sul ripiano inferiore al di sopra dello scarico. Se il pacco è posizionato correttamente la scritta "QUESTO LATO SOPRA" deve essere visibile.
- Eseguire un ciclo di sterilizzazione a vapore a 134 °C per 3.5 minuti oppure a 121 °C per 15 minuti.

Bowie & Dick Test Pack must be used every day, before the first sterilization cycle.
- *Run a shortened cycle to bring the sterilization chamber to use temperature.*
- *Place the Bowie & Dick Test Pack inside the empty sterilization chamber and on the bottom shelf above the drain. If the package is positioned correctly the writing "THIS SIDE UP" must be visible.*
- *Perform a steam sterilization cycle at 134°C for 3.5 minutes or at 121°C for 15 minutes*

INTERPRETAZIONE / *INTERPRETATION*

- Rimuovere il pacco test dall'autoclave e, aiutandosi con la linguetta, aprire la scatola.
- Rimuovere il foglio indicatore all'interno del pacco test.
- Esaminare l'indicatore e registrare i risultati.
  Tutte le strisce indicatore devono virare uniformemente al nero, se la prova ha dato esito positivo.
  Se è presente dell'aria all'interno del foglio durante le fasi del ciclo, il viraggio delle strisce di indicatore risulterebbe incompleto o irregolare.
- Registrare data ed autoclave sul pacco test e tutte le altre informazioni sul retro del foglio indicatore.
- Archiviare.

- *Remove the test pack from the autoclave and, using the tab, open the box.*
- *Remove the indicator sheet inside the test pack.*
- *Examine the indicator and record the results.*
  All indicator strips must turn uniformly black if the test is successful.
  If there is air inside the sheet during the cycle phases, the color change of the indicator strips will be incomplete or irregular.
- *Record the date and autoclave on the test pack and all other information on the back of the indicator sheet.*
- *Archive.*

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TEST RIUSCITO / *TEST SUCCESSFUL*

Il foglio indicatore è virato in modo uniforme al nero, indicando che la prova è perfettamente riuscita.
The indicator sheet has turned uniformly black, indicating that the test was perfectly successful.

Anomalie Gravi / *Serious anomalies*
TEST FALLITO / *TEST FAILED*

Il foglio indicatore non è virato al centro oppure non è virato completamente, indicando che l'autoclave non funziona correttamente ed è quindi necessario l'intervento dell'assistenza tecnica.
The indicator sheet is not changed in the center or is not changed completely, indicating that the autoclave is not working correctly and therefore technical assistance is required.

Anomalie Lievi / *Minor anomalies*
TEST RIUSCITO / *TEST SUCCESSFUL*

Il foglio indicatore presenta macchie o aloni di colore grigio e talvolta un sollevamento della pellicola di protezione, evidenziando la presenza di vapore umido. Il test si considera riuscito.
The indicator sheet has gray stains or rings and sometimes a lifting of the protective film, highlighting the presence of damp steam. The test is considered successful.

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SICUREZZA / *SAFETY*

Il Test di Bowie & Dick potrebbe essere caldo, si consiglia di maneggiarlo con attenzione per evitare scottature.
L'indicatore non rilascia sostanze tossiche che potrebbero causare rischi alla salute o compromettere le proprietà del prodotto.

The Bowie & Dick Test could be hot, we recommend handling it carefully to avoid burns.
The indicator does not release toxic substances that could cause health risks or compromise the properties of the product.

CONDIZIONI DI CONSERVAZIONE / *STORAGE*

Conservare il prodotto a temperature 10 - 30 °C e umidità relativa 30 - 60 %.
Mantenere in un luogo fresco ed asciutto, lontano da fonti di calore e da luce solare diretta.

Store the product at temperatures 10 - 30 °C and relative humidity 30 - 60%.
Keep in a cool, dry place, away from heat sources and direct sunlight.

DICHIARAZIONE DI CONFORMITÀ' / *DECLARATION OF CONFORMITY*

Classificato di Tipo 2 in conformità con le norme EN ISO 1140-1 e EN ISO 11140-4.

Classified as Type 2 in accordance with EN ISO 1140-1 and EN ISO 11140-4.

DATA DI SCADENZA / *EXPIRY DATE*

Il prodotto è da utilizzarsi entro 4 anni dalla data di produzione.

The product must be used within 4 years from date of manufacture.

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	20	Confezione interna (pz): *Internal packing (pcs):*	20 pacchi test *20 test box*	QUANTITÀ MINIMA VENDIBILE / *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	29 x 17,5 x 17	Peso (Kg): *Weight (Kg):*	2,8	Volume (m^3): *Volume (m^3):*	0,009