Liofilchem® Non-Hazardous Product Statement

Code Number (REF):	80124 - 80219
Description:	Egg Yolk emulsion
Date of revision:	Rev. 4 of 02.11.2018

EN	**NON-HAZARDOUS PRODUCT STATEMENT** Liofilchem® certifies that the above-mentioned product is not considered hazardous according to the criteria described in GHS regulation or its transpositions (e.g. European regulation CLP – 1272/2008) about hazardous substances and hazardous mixtures. Consequently, a Material Safety Data Sheet is not provided for this product. (Regulation EC No. 1907/2006 - REACH).
IT	**ATTESTATO DI NON PERICOLOSITA'** Liofilchem® certifica che il prodotto su-indicato non è considerato pericoloso in base ai criteri descritti nella regolamentazione GHS o suoi recepimenti (i.e. Regolamento Europeo CLP – 1272/2008) relativi alle sostanze pericolose ed alle preparazioni pericolose. Di conseguenza, per questo prodotto non viene fornita una Scheda di Sicurezza. Regulation EC No. 1907/2006 - REACH).
BG	**УДОСТОВЕРЕНИЕ ЗА НЕЗАРАЗЕН ПРОДУКТ** на компанията Liofilchem® удостоверява, че посочения по- долу продукт не се счита за заразен, според критериите, описани в регламента GHS или неговите преводи (например Европейски регламент CLP - 1272/2008) за опасни вещества и опасни смеси. Следователно за този продукт не се предоставя Лист за техническа безопасност. (Regulation EC No. 1907/2006 - REACH).
CS	**PROHLÁŠENÍ O BEZPEČNOSTI VÝROBKU** Společnost Liofilchem® potvrzuje, že výše uvedený výrobek není považován za nebezpečný podle kritérií popsaných v nařízení GHS nebo v jeho překladech (např. Evropské nařízení CLP – 1272/2008) o nebezpečných látkách a nebezpečných směsích. K tomuto výrobku není tudíž přiložen bezpečnostní list. (Regulation EC No. 1907/2006 - REACH).
DA	**ERKLÆRING OM IKKE SUNDHEDSSKADELIGT PRODUKT** Liofilchem® bekræfter hermed, at ovenstående produkt ikke betragtes som farligt i henhold de kriterier, der er angivet i GHS-regulativet eller dets lokale versioner (f.eks. EU-regulativet CLP – 1272/2008) om farlige stoffer og blandinger. Et sikkerhedsdatablad er derfor ikke udstedt for dette produkt. (Regulation EC No. 1907/2006 - REACH).
DE	**UNGEFÄHRLICHKEITSBESCHEINIGUNG** Liofilchem® bestätigt, dass das oben genannte Produkt gemäß der Kriterien, die in der GHS-Verordnung für gefährliche Stoffe und Gemische oder in deren Umsetzungen (z. B. Europäische CLP Verordnung – 1272/2008) beschrieben sind, nicht als gefährlich eingestuft wird. Aus diesem Grund erstellen wir für dieses Produkt kein Sicherheitsdatenblatt. (Regulation EC No. 1907/2006 - REACH).
EL	**ΔΗΛΩΣΗ ΜΗ ΕΠΙΚΙΝΔΥΝΟΥ ΠΡΟΪΟΝΤΟΣ** Η Liofilchem® πιστοποιεί πως το ανωτέρω αναφερόμενο προϊόν δεν θεωρείται επικίνδυνο σύμφωνα με τα κριτήρια που περιγράφονται στις κανονισμό GHS ή στις μεταφορές του σε τοπικό δίκαιο (π.χ. Ευρωπαϊκός κανονισμός CLP – 1272/2008) σχετικά με επικίνδυνες ουσίες και επικίνδυνα μίγματα. Ως αποτέλεσμα, δεν παρέχεται Δελτίο Δεδομένων Ασφαλείας Υλικού (MSDS) για αυτό το προϊόν. (Regulation EC No. 1907/2006 - REACH).
ES	**CERTIFICADO DE NO PELIGROSIDAD** Liofilchem® certifica que el producto mencionado no está considerado como peligroso, según los criterios descritos en la reglamentación GHS o sus transposiciones (e.g. Regalamento europeo CLP-1272/2008) relativas a las substancias ymezclas peligrosas. Consecuentemente, no realizaremos ficha de seguridad para este producto. (Regulation EC No. 1907/2006 - REACH).
ET	**KINNITUS TOODETE OHUTUSE KOHTA** Liofilchem® kinnitab, et ülalmainitud tooteid ei loeta ohtlikeks nende kriteeriumide alusel, mida kirjeldatakse GHS määruses või ülevõetud direktiivides (nt Euroopa parlamendi ja nõukogu määrus CLP – 1272/2008) ohtlike ainete või ohtlike valmististe kohta. Eeltoodust tulenevalt puuvad antud toodetel ohutuskaardid. (Regulation EC No. 1907/2006 - REACH).
HU	**NEM VESZÉLYES TERMÉKNYILATKOZAT** A Liofilchem® kijelenti, hogy a fent említett termék nem minősül veszélyesnek a GHS veszélyes anyagokra és veszélyes keverékekre vonatkozó szabályozásában vagy annak átirataiban (pl. CLP Európai szabályozás –1272/2008) leírt kritériumok szerint. Ennek következtében a termékhez nem mellékelünk Anyagbiztonsági Adatlapot. (Regulation EC No. 1907/2006 - REACH).
FR	**ATTESTATION DE NON-DANGEROSITE** Liofilchem® certifie que le produit ci-dessus n'est pas consideré comme dangereux selon les critères décrits dans la règlementation GHS ou ses transpositions (e.g. Règlement européen CLP – 1272/2008) relatives aux substances et mélanges dangereux. En conséquence, nous ne délivrons pas de fiche de données de sécurité pour ce produit. (Regulation EC No. 1907/2006 - REACH).
LT	**PATVRTINIMAS DĖL PRODUKTO NEPAVOJINGUMO** Liofilchem® tvirtina, kad aukščiau minėtas produktas nėra pavojingas pagal GHS nuostatas ar pritaikymą (pvz. Europos reglamentas CLP – 1272/2008) dėl pavojingų substancijų ir pavojingų mišinių. Dėl šios priežasties, Medžiagos Saugos Duomenų Lapas nėra teikiamas kartu su šiuo produktu. (Regulation EC No. 1907/2006 – REACH).

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LV	**PAZIŅOJUMS PAR NE-BĪSTAMU PRODUKTU** Liofilchem® apliecina, ka iepriekš-minētais produkts netiek uzskatīts par bīstamu atbilstoši GHS normatīvu vai to tulkojumu kritērijiem (piem., Eiropas normatīvais akts CLP - 1272/2008) par apdraudošām vielām un bīstamiem maisījumiem. Līdz ar to, šim produktam netiek nodrošināta Materiāla Drošības Datu Lapa (Regulation EC No. 1907/2006 - REACH).
NO	**ERKLARING OM RISIKOFRITT PRODUKT** Liofilchem® bekrefter at det ovennevnte produktet ikke er betraktet som risikofylt ifølge kriteriene beskrevet i GHS-forskriftene eller dens tolkinger (f.eks. European regulation CLP – 1272/2008) om risikofylte substanser og risikofylte blandinger. Følgelig, er et materialsikkerhetsdatablad ikke tilgjengelig for dette produktet. (Regulation EC No. 1907/2006 - REACH).
PL	**OŚWIADCZENIE W SPRAWIE BIOLOGICZNEGO BEZPIECZEŃSTWA PRODUKTU** Firma Liofilchem® poświadcza, że wymieniony powyżej produkt nie jest uznawany za niebezpieczny zgodnie z kryteriami określonymi w rozporządzeniu GHS lub jego tłumaczeniach (np. Europejskie Rozporządzenie CLP 1272/2008) dotyczących niebezpiecznych substancji i mieszanin. W związku z powyższym, nie jest dostarczana z tym produktem Karta Bezpieczeństwa. (Regulation EC No. 1907/2006 - REACH).
PT	**CERTIFICADO DE PRODUTO NÃO PERIGOSO** A Liofilchem® certifica que o produto acima não é considerado perigoso em conformidade com os critérios descritos na regulamentação GHS ou suas transposições (por exemplo, Regulamento Europeu CLP – 1272/2008) relativas às substâncias e misturas perigosas. Em consequência, não é necessária ficha de segurança para este produto. (Regulation EC No. 1907/2006 - REACH).
RO	**DECLARATIE PRODUS NON-PERICULOS** Liofilchem® atesta faptul ca produsul mentionat mai sus nNu este considerat periculos în conformitate cu criteriile descrise în regulamentele GHS sau transpuneri lor (de exemplu, Regulamentul CLP European - 1272/2008) referitoare la substanțe și amestecuri periculoase. Astfel, nu se furnizeaza Fisa Datelor de Securitate pentru acest produs. (Regulation EC No. 1907/2006 - REACH).
RU	**УДОСТОВЕРЕНИЕ БЕЗОПАСНОСТИ ПРОДУКТА** Компания Liofilchem® удостоверяет, что данный продукт не является опасным, в соответствии с критериями, описанными в Согласованной на глобальном уровне системе классификации и маркировки химических веществ (GHS) или в ее локальных вариантах (например, European regulation CLP –1272/2008 (Европейское егупирование Классификации, Маркировки, Упаковки)), в отношении опасных веществ и опасных смесей. В соответствии с этим, для данного продукта не требуется предоставлять сертификат безопасности. Regulation EC No. 1907/2006 - REACH).
SK	**PREHLÁSENIE O BEZPEČNOSTI VÝROBKU** Liofilchem® potvrdzuje, že vyššie uvedený výrobok sa nepovažuje za nebezpečný podľa kritérií uvedených v nariadení GHS alebo jeho prekladoch (napr. nariadenie Európskeho parlamentu a Rady CLP č.1272/2008) o nebezpečných látkach a nebezpečných zmesiach. Z tohto dôvodu listok s údajmi o bezpečnosti materiálu nie je k výrobku poskytnutý. (Regulation EC No. 1907/2006 - REACH).
SV	**PÅSTÅENDE OM EJ HÄLSO-/MILJÖFARLIG PRODUKT** Liofilchem® intygar att ovanstående produkt inte anses vara hälsofarlig enligt kriterier beskrivna i GHS (Globalt Harmoniserat System) eller dess anpassningar (t. ex. den Europeiska Unionens anpassning av GHS – CLP –1272/2008) som handlar om farliga ämnen och farliga blandningar. Följaktigen förses inte den här produkten med ett säkerhetsdatablad. (Regulation EC No. 1907/2006 - REACH).
TH	**เอกสารยืนยันว่าผลิตภัณฑ์ที่ไม่เป็นอันตราย** ในนามของบริษัท Liofilchem® ขอรับรองว่าผลิตภัณฑ์ดังกล่าวข้างต้นไม่เป็นอันตราย ตามหลักเกณฑ์ที่ใช้อ้างอิงไว้ใน GHS regulation หรือหลักเกณฑ์ที่เทียบเคียงกัน ได้ (เช่น European regulation CLP-1272/2008) ที่เกี่ยวกับสารอันตรายหรือสารผสมอันตราย นอกจากนี้ผลิตภัณฑ์ดังกล่าวไม่อยู่ในระบบบ่ายที่จำเป็นต้องมี Safety Data Sheet (SDS) สำหรับ SDS ของผลิตภัณฑ์
TR	**TEHLİKESİZ ÜRÜN BEYANNAMESİ** Liofilchem® yukarıda belirtilen ürünün, tehlikeli ürünler ve karışımlara ilişkin GHS yönetmeliğinde veya tercümesinde belirtilen kriterlere göre (örn. European regulation CLP – 1272/2008) tehlikeli olmadığını beyan eder. Bu nedenle, bu ürün için Materyal Güvenlik Veri Belgesi sağlanmamaktadır (Regulation EC No. 1907/2006 - REACH).
ZH	**非危险物品声明** Liofilchem® 保证以上产品符合通用 GHS（全球化学品统一分类和标签制度）标准（例如：欧洲 CLP-1272/2008 标准），均为非有害物质或有害化合物。然而，由于以上产品暂无 SDS（安全数据）文件，因此暂不符合需要 SDS 文件的标准。

Repetto Saverio Regulatory Affairs (signature on file)	Liofilchem® 64026 Roseto degli Abruzzi, Italy Tel. +39 085 8930745 - Fax +39 085 8930330 www.liofilchem.com

Slanetz Bartley Agar Base

Selective medium for detection and enumeration of enterococci in water and other materials, according to ISO 7899-2.

TYPICAL FORMULA	(g/L)
Tryptose	20.0
Yeast Extract	5.0
Glucose	2.0
Dipotassium Hydrogen Phosphate	4.0
Sodium Azide	0.4
Agar	13.0

Final pH: 7.2 ± 0.2 at 25°C

DESCRIPTION
Slanetz Bartley Agar Base is a selective medium used with supplement for isolating and enumerating enterococci from environmental samples of sanitary importance and clinical specimens.
This medium complies with ISO 7899-2 for the detection of intestinal enterococci in water by the membrane filtration technique.

PRINCIPLE
Tryptose provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Glucose is the fermentable carbohydrate. Sodium phosphate acts as buffer. Sodium azide is the selective agent suppressing the growth of Gram-negative bacteria. Agar is the solidifying agent.
Supplementation with TTC 1% Supplement serves to add triphenyl tetrazolium chloride (TTC) as indicator of bacterial growth.

PREPARATION
Suspend 44.4 g of powder in 1 liter of distilled or deionized water. Bring to boil and shake until completely dissolved. Sterilize at 121°C for 15 minutes. Cool up to 45-50°C. Aseptically, add 10 ml of TTC 1% Supplement (ref. 612610), Mix well. Pour in Petri dishes.

TECHNIQUE
ISO 7899-2 recommends to filter the water sample through a filter membrane (0.45 µm pore diameter), transfer the membrane onto a Slanetz Bartley Agar plate and incubate aerobically at 35 ± 2 °C for 43-48 hours.
Alternatively, sample can be inoculated by spread plating, pour plating or by direct streaking on the medium surface.

INTERPRETATION OF RESULTS
Clean, all reddish colonies which show a red, maroon or pink color as enterococci.
Confirm by subculturing to Bile Aesculin Azide Agar (ref. 116572).

STORAGE
The powder is very hygroscopic, store the powder at 15-30°C. In a dry environment, in its original container tightly closed and use it before the expiry date on the label or visible signs of deterioration or contamination are evident. Store protected from light.

WARNING AND PRECAUTIONS
The product contains hazardous substances and is classified as dangerous. It is recommended to consult the safety data sheet for its correct use. The product is designed for in vitro diagnostic use only and must be used by properly trained operators.

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

REFERENCES
- ISO 7899-2:2000. Water quality – Detection and enumeration of intestinal enterococci – Part 2: Membrane filtration method.
- **Slanetz L.W. and C.H. Bartley (1957) Numbers of enterococci in water, sewage and faeces determined by the membrane filtration technique with an improved medium. J. Bact. 74:591-595.**

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CE IVD

PRODUCT SPECIFICATIONS

NAME
Slanetz Bartley Agar Base

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

Ref.	Content	Packaging
610134	500 g	500 g of powder in plastic bottle
526134	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
7.2 ± 0.2

USE
Slanetz Bartley Agar Base is a selective medium used with supplement for isolating and enumerating enterococci from water and other samples according to ISO 7899-2

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Powder medium
Appearance: free-flowing, homogeneous
Colour: light beige
Rehydrated medium
Appearance: slightly opalescent
Colour: light amber

SHELFLIFE
4 years

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Microbiological control
   Incubation conditions: 44-48 h at 35 ± 2°C, in aerobiosis

Microorganisms		Growth	Colony color
Enterococcus faecalis	WDCM 00009	Good	Red-maroon-pink
Enterococcus faecium	WDCM 00177	Good	Red-maroon-pink
Escherichia coli	WDCM 00013	Inhibited	—
Staphylococcus aureus	WDCM 00034	Inhibited	—

TABLE OF SYMBOLS

LOT Batch code	IVD In vitro Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult instructions for use	Do not reuse

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CE IVD

Slanetz Bartley Agar Base

Terreno selettivo per la ricerca ed il conteggio degli enterococchi nelle acque ed in altri materiali, secondo ISO 7899-2.

FORMULA TIPICA	(g/L)
Triptosio	20.0
Estratto di Lievito	5.0
Glucosio	2.0
Sodio Fosfato Bibasico	4.0
Sodio Azide	0.4
Agar	13.0

pH Finale 7.2 ± 0.2 a 25°C

DESCRIZIONE
Slanetz Bartley Agar Base è un terreno selettivo utilizzato con supplementi per l'isolamento ed il conteggio di enterococchi da campioni ambientali di importanza sanitaria e campioni clinici.
Questo terreno è conforme alla ISO 7899-2 per la ricerca degli enterococchi intestinali nelle acque con la tecnica della membrana filtrante.

PRINCIPIO
Triptosio fornisce aminoacidi, azoto, carbonio, vitamine e minerali per la crescita dei microrganismi. L'estratto di lievito è una fonte di vitamine, specialmente del gruppo-B. Il glucosio è il carboidrato fermentabile. Il sodio fosfato agisce da tampone. Il sodio azide è l'agente selettivo che sopprime la crescita dei batteri Gram negativi. L'agar è l'agente solidificante.
TTC 1% Supplement contenente trifeniltetrazolo cloruro (TTC) viene aggiunto al terreno come indicatore di crescita batterica.

PREPARAZIONE
Sospendere 44.4 g di polvere in 1 litro di acqua demineralizzata o distillata. Portare ad ebollizione ed agitare fino a completa dissoluzione. Sterilizzare a 121°C per 15 minuti. Raffreddare a 45-50°C. In condizioni asettiche, aggiungere 10 ml di TTC 1% Supplement (ref. 612610). Mescolare bene. Versare in piastre Petri.

TECNICA
ISO 7899-2 raccomanda di filtrare il campione d'acqua attraverso una membrana filtrante (con diametro di 0.45 µm), trasferire la membrana su una piastra di Slanetz Bartley Agar ed incubare a 35 ± 2°C per 44-48 ore in atmosfera aerobica.
In alternativa, il campione può essere inoculato per spatolamento, inclusione o per stirato diretto sulla superficie del terreno.

INTERPRETAZIONE DEI RISULTATI
Contare e considerare enterococchi tutte le colonie rotonde che appaiono rosse, marrone o rosa.
Confermare con subcoltura su Bile Aesculin Azide Agar (ref. 116572).

CONSERVAZIONE
La polvere è fortemente igroscopica, conservare a 15-30°C, in ambiente asciutto, nel suo contenitore originale chiuso ermeticamente. Non usare il prodotto dopo la sua data di scadenza indicata sull'etichetta o se il prodotto mostra segni di contaminazione o deterioramento. Conservare la polvere protetta dalla luce.

AVVERTENZE E PRECAUZIONI
Il prodotto contiene sostanze nocive ed è classificato come pericoloso. Si consiglia di consultare la scheda di sicurezza per il suo corretto impiego. Il prodotto è destinato esclusivamente ad uso diagnostico in vitro e deve essere utilizzato da parte di personale qualificato.

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

RIFERIMENTI BIBLIOGRAFICI
1. ISO 7899-2:2000. Water quality – Detection and enumeration of intestinal enterococci – Part 2: Membrane filtration method.
2. Slanetz L.W. and C.H. Bartley (1957) Numbers of enterococci in water, sewage and faeces determined by the membrane filtration technique with an improved medium. J. Bact. 74:591-595.

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CE IVD

SPECIFICHE DI PRODOTTO

DENOMINAZIONE
Slanetz Bartley Agar Base

PRESENTAZIONE
Terreno disidratato

CONSERVAZIONE
10-30°C

CONFEZIONAMENTO

Ref.	Contenuto	Confezionamento
610134	500 g	500 g in flacone di plastica
526134	100 g	100 g in flacone di plastica

pH DEL TERRENO
7.2 ± 0.2

IMPIEGO
Slanetz Bartley Agar Base è un terreno selettivo utilizzato con supplementi per l'isolamento ed il conteggio di enterococchi nelle acque ed in altri campioni secondo ISO 7899-2

TECNICA
Fare riferimento alla scheda tecnica del prodotto

CARATTERISTICHE DEL TERRENO
Terreno in polvere
Aspetto: omogeneo, fine granulometria
Colore: beige chiaro
Terreno pronto all'uso
Aspetto: leggermente opalescente
Colore: ambra chiaro

VALIDITÀ DALLA DATA DI PRODUZIONE
4 anni

CONTROLLO DI QUALITÀ
1. Controllo caratteristiche generali, etichettatura e stampa
2. Controllo microbiologico
   Condizioni di incubazione: 44-48 h a 35 ± 2°C, in aerobiosi

Microrganismi		Crescita	Colonie colore
Enterococcus faecalis	WDCM 00009	Buona	Rosso-marrone-rosa
Enterococcus faecium	WDCM 00177	Buona	Rosso-marrone-rosa
Escherichia coli	WDCM 00013	Inibita	—
Staphylococcus aureus	WDCM 00034	Inibita	—

TABELLA DEI SIMBOLI

LOT Numero di lotto	IVD Per uso diagnostico in vitro	Fabbricante	Data di scadenza	Fragile, maneggiare con cura
REF Numero di catalogo	Limiti di temperatura	Contenuto sufficiente per <n> test	Attenzione, consultare le istruzioni per l'uso	Non riutilizzare

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CE IVD

ITALIANO

COAGULASE TEST

Plasma di coniglio liofilo per il test della coagulasi

DESCRIZIONE

COAGULASE TEST è costituito da plasma di coniglio liofilo con EDTA (Acido Etilen-diammino-tetra-acetico), utilizzato per la determinazione dell'enzima coagulasi prodotto da *Staphylococcus aureus*.

CONTENUTO DELLE CONFEZIONI

Ciascuna confezione contiene :

- 5 flaconi contenenti 4 mL di plasma di coniglio
- 1 foglio di istruzioni

PRODOTTI NECESSARI NON CONTENUTI

- Physiological Solution (cod. 20095)
- Brain Heart Infusion Broth (cod. 20104)

PRINCIPIO DEL METODO

La coagulasi prodotta da *Staphylococcus aureus* agisce sul fibrinogeno trasformandolo in fibrina. La reazione avviene in assenza di calcio che viene chelato dall' EDTA.

COMPOSIZIONE	(mL/flacone)
Plasma di coniglio liofilo	4.0

PROCEDURA DEL TEST

- Prelevare un flacone di **COAGULASE TEST** dalla confezione e ricostituire asetticamente con 4 mL di Physiological Solution (cod. 20095).
- Allestire una coltura in Brain Heart Infusion Broth (cod. 20104) prelevando una o più colonie da terreni selettivi per l' isolamento di *Staphylococcus aureus* ed incubare a 36 ± 1°C per 4-6 ore.
- In una provetta sterile miscelare 0,5 mL di **COAGULASE TEST** con 0.5 mL di brodocoltura ed incubare a 36 ± 1°C per 1-2-4-8-24 ore.

INTERPRETAZIONE DEI RISULTATI

- Verificare la formazione di un coagulo, eventualmente utilizzando un' ansa sterile. Non incubare oltre le 24 ore perché possono verificarsi fenomeni di fibrinolisi.

CONTROLLO QUALITA'

Ogni lotto di **COAGULASE TEST** è sottoposto al controllo qualità utilizzando i seguenti microrganismi di riferimento:

Microrganismo		Coagulazione
Escherichia coli	ATCC 25922	-
Staphylococcus aureus	ATCC 25923	+

PRECAUZIONI

Il prodotto, **COAGULASE TEST**, non è classificato come pericoloso ai sensi della legislazione vigente, né contiene sostanze nocive in concentrazioni ≥1%; non richiede pertanto la disponibilità della Scheda di Sicurezza.
COAGULASE TEST è un dispositivo monouso da usare solo per uso diagnostico *in vitro*, è destinato ad un ambito professionale e deve essere usato in laboratorio da operatori adeguatamente addestrati, con metodi approvati di asepsi e di sicurezza nei confronti degli agenti patogeni.

CONSERVAZIONE

Conservare **COAGULASE TEST** a 2-8 °C nella sua confezione originale. Non conservare vicino a fonti di calore ed evitare eccessive variazioni di temperatura. In queste condizioni **COAGULASE TEST** è valido fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento.

ELIMINAZIONE DEL MATERIALE USATO

Dopo l'utilizzazione **COAGULASE TEST** ed il materiale venuto a contatto con il campione devono essere decontaminati e smaltiti in accordo con le tecniche in uso in laboratorio per la decontaminazione e lo smaltimento di materiale potenzialmente infetto.

BIBLIOGRAFIA

- W.E. Kloos and J.H. Jorgensen "Staphylococci" p. 143-153. In E.H. Lennette, A. Balows, W.J. Hausler Jr., H.J. Shadomy. Manual of Clinical Microbiology, 4th Edition, American Society for Microbiology, Washington, D.C. 1985.

PRESENTAZIONE

Prodotto	REF	Σ
COAGULASE TEST	88030	5

TABELLA DEI SIMBOLI

IVD	Dispositivo medico diagnostico *in vitro*		Non riutilizzare
REF	Numero di catalogo		Fragile, maneggiare con cura
	Fabbricante	Σ	Contenuto sufficiente per <n> saggi
	Utilizzare entro		Attenzione, vedere le istruzioni per l'uso
	Limiti di temperatura	LOT	Codice del lotto

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CE IVD F00020 Rev.2 / 16.05.2011

ENGLISH

COAGULASE TEST

Lyophilic citrate rabbit plasma for coagulase test

DESCRIPTION

COAGULASE TEST is constituted by lyophilic rabbit plasma containing EDTA (Ethylenediaminetetraacetic Acid) used for the detection of coagulase enzyme produced by *Staphylococcus aureus*.

CONTENT OF THE PACKAGES

Each package contains :

- 5 vials containing 4 mL of rabbit plasma
- 1 instruction sheet

ITEMS NECESSARY NOT INCLUDED IN THE PACKAGES

- Physiological Solution (ref. 20095)
- Brain Heart Infusion Broth (ref. 20104)

PRINCIPLE OF THE METHOD

The coagulase produced by *Staphylococcus aureus* acts on fibrinogen transforming it into fibrin. The reaction takes place without calcium which is chelated by EDTA.

COMPOSITION	(mL/vial)
Lyophilic rabbit plasma	4.0

USE

- Take one vial of **COAGULASE TEST** from the package and aseptically reconstitute with 4 mL of Physiological Solution (ref. 20095).
- Prepare a culture in Brain Heart Infusion Broth (ref. 20104) picking up one or more colonies from selective media for *Staphylococcus aureus* isolation and incubate at 36 ± 1°C for 4-6 hours.
- In a sterile tube mix 0.5 mL of **COAGULASE TEST** with 0.5 mL of culture broth and incubate at 36 ± 1°C for 1-2-4-8-24 hours.

INTERPRETATION OF RESULTS

- Verify the formation of the clot, in case using a sterile loop. Do not incubate over 24 hours because cases of fibrinolysis can take place.

QUALITY CONTROL

Each batch of **COAGULASE TEST** is submitted to the quality control using the following microorganisms:

Microorganism		Coagulation
Escherichia coli	ATCC 25922	-
Staphylococcus aureus	ATCC 25923	+

PRECAUTIONS

COAGULASE TEST cannot be classified as being hazardous according to the current legislation, nor does it contain harmful substances in concentrations ≥1%, it therefore does not require a Safety Data Sheet to be available.
COAGULASE TEST is a disposable device to be used only for diagnostic use *in vitro*. It must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

Store **COAGULASE TEST** at 2-8°C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions, **COAGULASE TEST** will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL

After use, **COAGULASE TEST** and material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

BIBLIOGRAPHY

- W.E. Kloos and J.H. Jorgensen "Staphylococci" p. 143-153. In E.H. Lennette, A. Balows, W.J. Hausler Jr., H.J. Shadomy. Manual of Clinical Microbiology, 4th Edition, American Society for Microbiology, Washington, D.C. 1985.

PRESENTATION

Product	REF	Σ
COAGULASE TEST	88030	5

TABLE OF SYMBOLS

IVD	*In Vitro* Diagnostic Medical Device		Do not reuse
REF	Catalogue number		Fragile,handle with care
	Manufacturer	Σ	Contains sufficient for <n> tests
	Use by		Caution, consult accompanying documents
	Temperature limitation	LOT	Batch code

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CE IVD F00020 Rev.2 / 16.05.2011

COLUMBIA AGAR BASE

Medium for fastidious microorganisms isolation from clinical samples.

TYPICAL FORMULA (g/l)

Peptospecial	23.0
Starch	1.0
Sodium Chloride	5.0
Agar	14.0

Final pH = 7.3 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 43.0 g of powder in 1 liter of distilled or deionized water. Heat to boiling until completely dissolved. Sterilize in autoclave at 121 °C for 15 minutes. Cool to 45-50 °C and aseptically add 5% defibrinated sterile sheep blood. Mix well. Dispense in petri dishes.
Columbia Agar Base can be also enriched in various way:
· with 2 vials of CNA (Staf / Strep) supplement (colistin sulphate 5 mg/vial, nalidixic acid 8 mg/vial, code 81048), each one reconstituted with 5 ml of sterile distilled water; final medium will contain colistin sulphate 10 mg/l and nalidixic acid 16 mg/l.
· with 2 vials of *Gardnerella vaginalis* supplement (gentamicin 3 mg/vial, amphotericin B 1mg/vial, nalidixic acid 15 mg/vial, code 81040), each one reconstituted with 5 ml of a 1:1 solution of ethyl alcohol and sterile distilled water; final medium will contain gentamicin 6 mg/l, amphotericin B 2 mg/l and nalidixic acid 30 mg/l.

DESCRIPTION

COLUMBIA AGAR BASE, enriched with sterile sheep blood (5%), is suitable for isolation and growth of fastidious microorganisms such as streptococci, staphylococci, pneumococci and listeriae from clinical samples.

TECHNIQUE

Inoculate the medium with the specimen streaking by a sterile loop and incubate at 36 ± 1 °C for 18-48 hours aerobically, anaerobically or under conditions of increased CO_2 (5-10%), in accordance with established laboratory procedures.
Examine plates for growth and hemolytic reactions. Four types of hemolysis on blood agar media can be described:
1. α-hemolysis is the reduction of hemoglobin to methemoglobin in the medium surrounding the colony, causing a greenish discolorization of the medium.
2. β-hemolysis is the lysis of red blood cells, producing a clear zone surrounding the colony.
3. γ-hemolysis indicates no destruction of red blood cells and no change in the color of the medium.
4. ά-hemolysis indicates a partial lysis.

QUALITY CONTROL

Dehydrated medium
Appearance: free-flowing, homogeneous.
Color: beige.
Prepared medium
Appearance: opaque.
Color: cherry red.
Incubation conditions: 36 ± 1°C for 18-48 hours at 5-10% CO_2.

Microorganism	ATCC	Growth	Characteristics
Streptococcus pyogenes	19615	good	β-hemolysis
Streptococcus pneumoniae	6303	good	α -hemolysis
Staphylococcus aureus	25923	good	β-hemolysis
Gardnerella vaginalis	14018	good	β-hemolysis

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CE IVD

PERFORMANCE AND LIMITATIONS

When this medium is enriched with 10% sterile sheep blood, heated at 80 °C for 10 minutes until a chocolate color is obtained, and an antibiotic mixture is added (vancomycin, colimycin, trimethoprim, amphoterycin B) it is suitable for the selective isolation of the pathogens neisseria. If used without the addition of blood, the medium is suitable for growing of *Brucella abortus, Yersinia pestis, Clostridium perfrigens and enterobacteria.* Hemolytic reactions of some strains of Group D streptococci have been shown to be affected by differences in animal blood. Such strains are beta –hemolytic on horse and rabbit blood agar and alpha-hemolytic on sheep blood agar.

STORAGE

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

REFERENCES

1. Ellner, P.D., C.J. Stoessel., E. Drakeford, and F. Vasi (1966). A new culture medium for medical bacteriology. Am. J.Clin. Path. **45**, 502-504.
2. Isenberg, H.D. (ed.) (1992). Clinical microbiology procedures handbook, vol. 1 American Society for Microbiolgy, Washington, DC.

PRESENTATION

Product	REF	Σ
COLUMBIA AGAR BASE (11.6 l)	610013	500 g
COLUMBIA AGAR BASE (2.3 l)	620013	100 g
COLUMBIA AGAR BASE (116.2 l)	6100135	5 Kg
SHEEP BLOOD DEFIBRINATED	83296	50 ml
CNA (Staf / Strep) supplement	81048	10 vials
Gardnerella vaginalis supplement	81040	10 vials

TABLE OF SYMBOLS

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

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CE IVD

Optochine Test

ITALIANO

Dischi diagnostici per l'identificazione degli pneumococchi.

DESCRIZIONE
Optochine Test è costituito da dischi di carta, ciascuno contenente 5 µg di Optochina (Etilidrocupreina cloridrato), utilizzati per la differenziazione di *Streptococcus pneumoniae* dagli altri streptococchi alfa-emolitici.

CONTENUTO DELLE CONFEZIONI
Ciascuna confezione contiene:
- 2 cartucce con 50 dischi ciascuna, confezionate in un contenitore termosaldato.
- Essiccatore.

PRINCIPIO DEL METODO
L'Optochina è un agente attivo specificamente nei confronti di *Streptococcus pneumoniae*, gli altri streptococchi alfa-emolitici risultano resistenti. Il disco viene applicato sulla superficie di un terreno di coltura idoneo per la crescita degli streptococchi, inoculato con una brodocoltura pura del microrganismo in esame. Dopo l'incubazione vengono esaminate le piastre e verificata la presenza o l'assenza di un alone di inibizione attorno al disco di Optochina.

COMPOSIZIONE
Ciascun disco contiene 5 µg di Optochina.

PREPARAZIONE DEL CAMPIONE
1. Colture miste o campioni clinici non devono essere utilizzati per determinare la sensibilità all'Optochina.
2. Inoculare una provetta di Brain Heart Infusion Broth (ref. 20104) con colonie pure del microrganismo da saggiare.
3. Incubare a 36 ± 1°C per una notte.

PROCEDURA DEL TEST
1. Prelevare il contenitore delle cartucce dal frigorifero e lasciarlo sul banco di lavoro fino al raggiungimento della temperatura ambiente (circa 30 minuti). In tal modo si evita che all'apertura della confezione si depositi umidità di condensa sui dischi, pregiudicandone la stabilità nel tempo.
2. Utilizzando un tampone sterile, inoculare uniformemente la superficie di una piastra di agar-sangue quale Tryptic Soy Blood Agar (ref. 11037), Columbia Blood Agar (ref. 11025) o altro terreno al sangue, con la sospensione dello streptococco da saggiare.
3. Utilizzando strumenti sterili, depositare, esercitando una lieve pressione, il disco di Optochina sulla superficie inoculata.
4. Capovolgere la piastra ed incubare 18-24 ore a 36 ± 1°C in atmosfera con il 5% di CO_2.
5. Verificare la presenza o l'assenza di un alone di inibizione attorno al disco di Optochina.

INTERPRETAZIONE DEI RISULTATI
Il microrganismo testato viene considerato sensibile all'Optochina e presumibilmente *Streptococcus pneumoniae* se l'alone di inibizione è ≥ 14 mm di diametro. L'identificazione presuntiva deve essere confermata con test sierologici.

CONTROLLO QUALITÀ
Ogni lotto di Optochine Test viene sottoposto al test di sensibilità all'Optochina, utilizzando una brodocoltura di *Streptococcus pneumoniae* ATCC® 6305 per il controllo positivo, e una brodocoltura di *Streptococcus pyogenes* ATCC® 19615 per il controllo negativo, inoculate su Columbia Blood Agar con il 5% di sangue defibrinato di montone.

PRECAUZIONI
Il prodotto Optochine Test non è classificabile come pericoloso ai sensi della legislazione vigente. Optochine Test è un dispositivo monouso, da usare solo per uso diagnostico *in vitro*, è destinato ad una ambito professionale e deve essere usato in laboratorio da personale adeguatamente addestrato, con metodi approvati di asepsi e sicurezza nei confronti di agenti patogeni.

CONSERVAZIONE
Conservare Optochine Test a -20°C/+8°C nella sua confezione originale. Non conservare vicino a fonti di calore ed evitare eccessive variazioni di temperatura. In queste condizioni Optochine Test mantiene la sua validità fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento.

ELIMINAZIONE DEL MATERIALE USATO
Dopo l'utilizzazione, Optochine Test ed il materiale venuto a contatto con il campione devono essere decontaminati e smaltiti in accordo con le tecniche in uso in laboratorio per la decontaminazione e lo smaltimento di materiale potenzialmente infetto.

BIBLIOGRAFIA

- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/394193/TP_25i3.pdf
- J. Lab. Clin. Med., 49: 641, 1957.
- J. Clin. Path., 8: 58, 1955.
- Serological Studies on Pneumococci, Munksgaard, Copenhagen, Oxford University Press, London, 1943.
- J. Exp. Med. 22: 269, 1915.

PRESENTAZIONE

Prodotto	Ref.	Test
Optochine Test	9501	100

TABELLA DEI SIMBOLI

IVD	Dispositivo medico diagnostico *in vitro*		Non riutilizzare
REF	Numero di catalogo		Fragile, maneggiare con cura
	Fabbricante	Σ	Contenuto sufficiente per <n> saggi
	Utilizzare entro		Attenzione, vedere le istruzioni per l'uso
	Limiti di temperatura	LOT	Codice del lotto

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CE IVD F00010

Optochine Test

ENGLISH

Diagnostic discs for pneumococci identification.

DESCRIPTION
Optochine Test is constituted by paper discs, each one containing 5 µg of Optochin (Ethylhydrocupreine hydrochloride), used for differentiating *Streptococcus pneumoniae* from the other alpha-haemolytic streptococci.

CONTENT OF THE PACKAGES
Each package contains:
- 2 cartridges with 50 discs each, packaged in a heat-sealed container.
- Dryer.

PRINCIPLE OF THE METHOD
Optochin is an agent specifically active against *Streptococcus pneumoniae*, the other alpha-haemolytic streptococci are resistant. The disc is placed onto the surface of a culture medium that is suitable for the growth of streptococci, inoculated with a pure liquid culture of the microorganism under examination. After the incubation all the plates are examined for the presence or absence of an inhibition halo around the disc of Optochin.

COMPOSITION
Each disc contains 5 µg of Optochin.

PREPARATION OF THE SPECIMEN
1. Mixed cultures or clinical specimens must not be used to determine susceptibility to Optochin.
2. Inoculate a tube of Brain Heart Infusion Broth (ref. 20104) with pure colonies of the microorganism under examination.
3. Incubate at 36 ± 1°C overnight.

TEST PROCEDURE
1. Take the cartriges container from the refrigerator and leave it on the test bench until it reaches room temperature (about 30 minutes). This will prevent humidity being deposited on the discs when the package is opened, which could prejudice their long-term stability.
2. Using a sterile swab, evenly inoculate the surface of a plate of blood agar such as Tryptic Soy Blood Agar (ref. 11037), Columbia Blood Agar (ref. 11025) or other blood medium, with the suspension of the streptococcus under examination.
3. Using sterile tools, gently press one disc of Optochin on the inoculated surface.
4. Turn the plate upside down and incubate at 36 ± 1°C for 18-24 hours in atmosphere containing 5% of CO_2.
5. Check for presence or absence of an inhibition halo around the disc of Optochin.

INTERPRETATION OF THE RESULTS
The test organism is considered sensitive to Optochin and presumptively *Streptococcus pneumoniae* if the inhibition zone is ≥ 14 mm diameter. The presumptive identification must be confirmed by serological tests.

QUALITY CONTROL
Each batch of Optochine Test is tested for susceptibility to Optochin by using *Streptococcus pneumoniae* ATCC® 6305 for positive control, and *Streptococcus pyogenes* ATCC® 19615 for negative control, inoculated on Columbia Blood Agar with 5% of defibrinated sheep blood.

PRECAUTIONS
Optochine Test cannot be classified as being hazardous according to the current legislation. Optochine Test is a disposable device to be used only for diagnostic use *in vitro*. It must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE
Store Optochine Test at -20°C/+8°C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions, the product will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL
After use, Optochine Test and material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

BIBLIOGRAPHY

- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/394193/TP_25i3.pdf
- J. Lab. Clin. Med., 49: 641, 1957.
- J. Clin. Path., 8: 58, 1955.
- Serological Studies on Pneumococci, Munksgaard, Copenhagen, Oxford University Press, London, 1943.
- J. Exp. Med. 22: 269, 1915.

PRESENTATION

Product	Ref.	Test
Optochine Test	9501	100

TABLE OF SYMBOLS

IVD	*In Vitro* Diagnostic Medical Device		Do not reuse
REF	Catalogue number		Fragile,handle with care
	Manufacturer	Σ	Contains sufficient for <n> tests
	Use by		Caution, consult accompanying documents
	Temperature limitation	LOT	Batch code

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CE IVD F00010

Optochine Test

DEUTSCH

Diagnostische Discs für Pneumokokken Identifikation.

BESCHREIBUNG

Der Optochine Test besteht aus Papier-Discs, mit je 5 µg Optochin (Ethylhydrocupreinhydrochlorid), die zur Differenzierung von *Streptococcus pneumoniae* von anderen alpha-hämolysierenden Streptokokken verwendet wird.

PACKUNGSINHALT

Jede Packung enthält:

- 2 Patronen mit 50 Discs, verpackt in hitzeversiegelten Beuteln.
- Trockenmittel.

METHODENPRINZIP

Optochin ist ein Reagenz, das spezifisch gegen *Streptococcus pneumoniae* wirksam ist. Andere alpha-hämolysierende Streptokokken sind resistent. Die Disc wird auf die Oberfläche eines Kulturmediums gelegt, die für das Wachstum von Streptokokken geeignet ist und mit einer reinen Flüssigkultur inokuliert. Nach Inkubation müssen alle Platten auf die An- oder Abwesenheit von Hemmhöfen um die Optochin Disc untersucht werden.

ZUSAMMENSETZUNG

Jede Disc enthält 5 µg Optochin.

VORBEREITUNG DER PROBE

1. Mischkulturen von klinischen Proben dürfen nicht verwendet werden, um die Empfindlichkeit gegen Optochin zu bestimmen.
2. Beimpfen eines Röhrchens Brain Heart Broth (ref. 20104) mit geprüften, reinen Kolonien von Mikroorganismen.
3. Über Nacht bei 36 ±1°C inkubieren.

TESTDURCHFÜHRUNG

1. Kartuschenpackung aus dem Kühlschrank nehmen und auf der Laborbank so lange liegen lassen, bis diese Raumtemperatur angenommen hat (ca. 30 Minuten). Das verhindert, dass sich Flüssigkeit auf der Disk bei geöffneter Packung ablagert und dadurch die langfristige Stabilität beeinträchtigt wird.
2. Die Oberfläche einer Blutagarplatte, z.B. Tryptic Soy Blood Agar (ref. 11037), Columbia Blood Agar (ref. 11025) oder einem anderem Blutmedium gleichmäßig mit der Streptokokkenlösung unter Verwendung einer sterilen Impföse animpfen.
3. Mit sterilen Hilfsmitteln die Optochin Disc vorsichtig auf die beimpfte Oberfläche drücken.
4. Platten umdrehen und bei 36 ±1°C für 18-24 Stunden in einer 5% CO_2 Atmosphäre inkubieren.
5. Überprüfen auf An- oder Abwesenheit eines Hemmhofs um die Optochin Disc.

INTERPRETATION DER ERGEBNISSE

Der Testorganismus ist gegen Optochin empfindlich und vermutlich auch gegen *Streptococcus pneumoniae* im falle der Durchmesser der Inhibition Zone ≥ 14 mm ist. Die vermutliche Identifikation muss danach mit einem Serologischen Test bestaetigt werden.

QUALITÄTSKONTROLLE

Jede Charge des Optochine Test wird auf die Empfindlichkeit für Optochin von *Streptococcus pneumoniae* ATCC® 6305 als Positivkontrolle und *Streptococcus pyogenes* ATCC® 19615 als Negativkontrolle geprüft. Diese Stämme werden auf ein Columbia Blood Agar mit 5% defibriniertem Schafblut inokuliert.

VORSICHTSMAßNAHMEN

Optochine Test wird aufgrund der aktuellen Gesetzgebung als nicht-gefährlich eingestuft. Optochine Test ist ein Einwegprodukt und ausschließlich für den Gebrauch in der In-Vitro Diagnostik bestimmt. Er darf nur in einem geeigneten Labor von qualifiziertem Personal durchgeführt werden, wobei anerkannte, sterile und sichere Methoden im Umgang mit pathogenen Erregern angewendet werden

LAGERUNG

Den Optochine Test bei -20°C/+8°C in der Originalverpackung lagern. Von Hitzequellen fernhalten und extreme Temperaturunterschiede vermeiden. Unter diesen Bedingungen ist der Test bis zu dem auf der Packung angegebenen Verfallsdatum gültig. Test nicht nach Ablauf des Verfalldatums benutzen. Bei Anzeichen von Schäden Test beseitigen und nicht verwenden.

BESEITIGUNG VERWENDETER MATERIALIEN

Nach Gebrauch Optochine Test und alle Materialien, die mit der Probe in Berührung gekommen sind, dekontaminieren und nach den im Labor üblichen Methoden der Dekontamination und Beseitigung von potenziell infektiösem Material entsorgen.

BIBLIOGRAPHIE

- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/394193/TP_25i3.pdf
- J. Lab. Clin. Med., 49: 641, 1957.
- J. Clin. Path., 8: 58, 1955.
- Serological Studies on Pneumococci, Munksgaard, Copenhagen, Oxford University Press, London, 1943.
- J. Exp. Med. 22: 269, 1915.

PRÄSENTATION

Produkt	Ref.	Test
Optochine Test	9501	100

SYMBOLTABELLE

IVD	*In Vitro Diagnostikum*		Nicht zur Wiederverwendung
REF	Katalognummer		Zerbrechlich, vorsichtig behandeln
	Hersteller	Σ	Ausreichend für <n> Tests
	Zu verbrauchen bis		Achtung, Packungsbeilage beachten
	Lagerung zwischen	LOT	Chargennummer

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CE IVD F00010

X FACTOR TEST
V FACTOR TEST
V+X FACTOR TEST

ITALIANO

DESCRIZIONE
X FACTOR TEST, V FACTOR TEST e V+X FACTOR TEST sono costituiti da dischi di carta bibula, contenenti i relativi fattori della coagulazione, utilizzati per la differenziazione di Haemophilus spp.

CONTENUTO DELLE CONFEZIONI
Ciascuna confezione contiene:
- 2 cartucce con 50 dischi ciascuna, confezionate in un contenitore termosaldato
- 1 essiccatore
- 1 foglio di istruzioni

PRINCIPIO DEL METODO
Le diverse specie di Haemophilus crescono su terreno di coltura solo in presenza del fattore o dei fattori della coagulazione (X, V o entrambi) di cui hanno bisogno. Questo costituisce un fattore differenziale per l'identificazione di Haemophilus spp.

COMPOSIZIONE
- Ciascun disco di X FACTOR TEST contiene Emina.
- Ciascun disco di V FACTOR TEST contiene NAD (Nicotinammide-Adenin-Dinucleotide).
- Ciascun disco di V+X FACTOR TEST contiene Emina e NAD (Nicotinammide-Adenin-Dinucleotide).

PROCEDURA DEL TEST
1. Prelevare il contenitore delle cartucce dal frigorifero e lasciarlo sul banco di lavoro fino al raggiungimento della temperatura ambiente (circa 30 minuti). In tal modo si evita che all'apertura della confezione si depositi umidità di condensa sui dischi, pregiudicandone la stabilità nel tempo.
2. Utilizzando un tampone sterile, inoculare uniformemente la superficie di una piastra di Tryptic Soy Agar (ref. 10037) o Mueller Hinton Agar (ref. 10031) con una sospensione pura del microrganismo da saggiare.
3. Utilizzando strumenti sterili, depositare, esercitando una lieve pressione, un disco di X FACTOR TEST, V FACTOR TEST e V+X FACTOR TEST sulla superficie inoculata, ad una distanza di circa 120° l'uno dall'altro e di 1-2 cm dal bordo della piastra. Incubare 24-48 ore a 36±1°C in atmosfera con il 5-10% di anidride carbonica.

INTERPRETAZIONE DEI RISULTATI
Se il microrganismo richiede solo il Fattore X, esso crescerà solo attorno ai dischi X FACTOR TEST e V+X FACTOR TEST; se richiede solo il Fattore V, il microrganismo crescerà solo attorno ai dischi V FACTOR TEST e V+X FACTOR TEST; se richiede entrambi i fattori X e V, il microrganismo crescerà solo attorno al disco V+X FACTOR TEST.
Nella seguente tabella vengono riportati alcuni esempi:

	Senza Fattori	Fattore X	Fattore V	Fattori V+X
Haemophilus influenzae	-	-	-	+
Haemophilus aegyptius	-	-	-	+
Haemophilus parainfluenzae	-	-	+	+
Haemophilus ducreyi	-	+	-	+
Bordetella pertussis	+	+	+	+

CONTROLLO QUALITA'
Ogni lotto di X FACTOR TEST, V FACTOR TEST e V+X FACTOR TEST viene sottoposto a controllo microbiologico, inoculando sospensioni pure di Haemophilus influenzae ATCC 19418 ed Haemophilus parainfluenzae ATCC 7901 su piastre di Tryptic Soy Agar.

PRECAUZIONI
I prodotti X FACTOR TEST, V FACTOR TEST e V+X FACTOR TEST non sono classificabili come pericolosi ai sensi della legislazione vigente.
X FACTOR TEST, V FACTOR TEST e V+X FACTOR TEST sono dispositivi monouso, da usare solo per uso diagnostico in vitro, destinati ad un ambito professionale e devono essere usati in laboratorio da personale adeguatamente addestrato, con metodi approvati di asepsi e sicurezza nei confronti di agenti patogeni.

CONSERVAZIONE
Conservare X FACTOR TEST, V FACTOR TEST e V+X FACTOR TEST a 2-8°C nella confezione originale. Non conservare vicino a fonti di calore ed evitare eccessive variazioni di temperatura. In queste condizioni X FACTOR TEST, V FACTOR TEST e V+X FACTOR TEST mantengono la validità fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento.

ELIMINAZIONE DEL MATERIALE USATO
Dopo l'utilizzo, X FACTOR TEST, V FACTOR TEST e V+X FACTOR TEST ed il materiale venuto a contatto con il campione devono essere decontaminati e smaltiti in accordo con le tecniche in uso in laboratorio per la decontaminazione e lo smaltimento di materiale potenzialmente infetto.

BIBLIOGRAFIA

- Kilian M. (1980) Haemophilus. in Manual of Clinical Microbiology. Eds. Lennette et al. Amer. Soc. for Microbiol. 3rd edn. Washington.

PRESENTAZIONE

Prodotto	REF	µg	Σ
X FACTOR TEST	9503	5	100
V FACTOR TEST	9504	4	100
V+X FACTOR TEST	9505	4+5	100

TABELLA DEI SIMBOLI

IVD	Dispositivo medico diagnostico in vitro		Non riutilizzare
REF	Numero di catalogo		Fragile, maneggiare con cura
	Fabbricante	Σ	Contenuto sufficiente per <n> saggi
	Utilizzare entro		Attenzione, vedere le istruzioni per l'uso
	Limiti di temperatura	LOT	Codice del lotto

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CE IVD F00005 Rev. 1/ 28.03.2013

X FACTOR TEST
V FACTOR TEST
V+X FACTOR TEST

ENGLISH

DESCRIPTION
X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST are constituted by paper discs with special features, containing the respective coagulation factors, used for differentiating Haemophilus spp.

CONTENT OF THE PACKAGES
Each package contains:
- 2 cartridges with 50 discs each, packaged in a heat-sealed container
- 1 dryer
- 1 instruction sheet

PRINCIPLE OF THE METHOD
Different strains of Haemophilus grow on a culture medium only in presence of the coagulation factor or factors (X, V, or both) which they need. These different requirements allow the differentiation and the identification of Haemophilus spp.

COMPOSITION
- Each disc of X FACTOR TEST contains Hemin.
- Each disc of V FACTOR TEST contains NAD (Nicotinamide-Adenine-Dinucleotide).
- Each disc of V+X FACTOR TEST contains Hemin and NAD (Nicotinamide-Adenine-Dinucleotide).

TEST PROCEDURE
1. Take the cartriges container from the refrigerator and leave it on the test bench until it reaches room temperature (about 30 minutes). This will prevent humidity being deposited on the discs when the package is opened, which could prejudice their long-term stability.
2. Using a sterile swab, evenly inoculate the surface of a plate of Tryptic Soy Agar (ref. 10037) or Mueller Hinton Agar (ref. 10031) with a pure suspension of the microorganism to test.
3. Using sterile tools, press one disc of X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST on the inoculated surface, at a distance of 120° from one to another and at 1-2 cm from the edge of the plate. Incubate at 36±1°C for 24-48 in 5-10% carbon dioxide atmosphere.

INTERPRETATION OF THE RESULTS
If the organism requires X Factor alone, it will grow only at the edge of the X and the X+V FACTOR TEST discs; if it requires V Factor alone, it will grow only at the edge of the V and the X+V FACTOR TEST discs; if both X and V Factors are required, it will grow only at the vicinity of the X+V FACTOR TEST discs.
Some examples are indicated in the following table:

	Without Factors	Factor X	Factor V	Factors V+X
Haemophilus influenzae	-	-	-	+
Haemophilus aegyptius	-	-	-	+
Haemophilus parainfluenzae	-	-	+	+
Haemophilus ducreyi	-	+	-	+
Bordetella pertussis	+	+	+	+

QUALITY CONTROL
Each batch of X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST is subjected to microbial control, inoculating pure suspensions of Haemophilus influenzae ATCC 19418 and Haemophilus parainfluenzae ATCC 7901 on plates of Tryptic Soy Agar.

PRECAUTIONS
X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST cannot be classified as being hazardous according to the current legislation.
X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST is a disposable device to be used only for diagnostic use in vitro. It must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE
Store X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST at 2-8°C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions, X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL
After use, X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST and material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

BIBLIOGRAPHY

- Kilian M. (1980) Haemophilus. in Manual of Clinical Microbiology. Eds. Lennette et al. Amer. Soc. for Microbiol. 3rd edn. Washington.

PRESENTATION

Product	REF	µg	Σ
X FACTOR TEST	9503	5	100
V FACTOR TEST	9504	4	100
V+X FACTOR TEST	9505	4+5	100

TABLE OF SYMBOLS

IVD	In Vitro Diagnostic Medical Device		Do not reuse
REF	Catalogue number		Fragile,handle with care
	Manufacturer	Σ	Contains sufficient for <n> tests
	Use by		Caution, consult accompanying documents
	Temperature limitation	LOT	Batch code

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CE IVD F00005 Rev. 1/ 28.03.2013

ITALIANO

Bacitracin Test

DESCRIZIONE
Bacitracin Test sono dischi di carta, impregnati con 0,04 unità di Bacitracina, utilizzati per la differenziazione degli streptococchi del Gruppo A di Lancefield dagli altri streptococchi beta emolitici appartenenti a Gruppi diversi.

CONTENUTO DELLE CONFEZIONI
Ciascuna confezione contiene 2 cartucce con 50 dischi ciascuna, confezionate in un contenitore termosaldato, in presenza di un essiccatore e un foglio istruzioni.

PRINCIPIO DEL METODO
La Bacitracina, antibiotico polipeptidico, è attiva nei confronti degli streptococchi beta emolitici di Gruppo A. Gli streptocchi di Gruppo C e G sono meno sensibili e quelli di Gruppo B sono resistenti. Il disco viene applicato sulla superficie di un terreno di coltura, idoneo per la crescita degli streptococchi, inoculato con una brodocoltura allestita con colonie pure del microrganismo in esame. Dopo l'incubazione, vengono esaminate le piastre e verificata la presenza o l'assenza di un alone di inibizione intorno al disco di Bacitracina.

COMPOSIZIONE
Ciascun disco è impregnato con 0,04 UI di Bacitracina.

PROCEDURA DEL TEST
1. Prelevare il contenitore delle cartucce dal frigorifero e lasciarlo sul banco di lavoro fino al raggiungimento della temperatura ambiente (circa 30 minuti). In tal modo si evita che all'apertura della confezione si depositi umidità di condensa sui dischi, pregiudicandone la stabilità nel tempo.
2. Inoculare uniformemente la superficie di una piastra di agar-sangue quali Tryptic Soy Blood Agar, Columbia Blood Agar o altro terreno al sangue, con una coltura dello streptococco beta-emolitico da saggiare. Bacitracin Test può essere effettuato anche inoculando il materiale clinico in esame, come per esempio l'essudato rino-faringeo prelevato con un tampone, su una piastra di agar-sangue.
3. Depositare il disco di Bacitracina sulla superficie inoculata.
4. Incubare 18-24 ore a 36 ± 1 °C.
5. Verificare la presenza o l'assenza di un alone di inibizione intorno al disco di Bacitracina.

INTERPRETAZIONE DEI RISULTATI
Semina del ceppo precedentemente isolato
La presenza di un alone di inibizione di 10-18 mm, intorno al disco di Bacitracina, indica che lo streptococco è presumibilmente di Gruppo A. Altri streptococchi beta emolitici, non di Gruppo A, crescono fino ai bordi del disco.
I risultati del test della Bacitracina vanno confermati con l'identificazione sierologia di Gruppo.
Semina del materiale clinico
La presenza di un alone di inibizione intorno al disco di Bacitracina, se confermati dai dati della morfologia delle colonie e dell'emolisi, depongono a favore della presenza di Streptococchi di Gruppo A, da confermare mediante l'identificazione sierologica di Gruppo.

CONTROLLO QUALITA'
Ogni lotto di Bacitracin Test viene sottoposto al test di sensibilità alla Bacitracina, utilizzando una coltura di *Streptococcus pyogenes* ATCC® 19615 per il controllo positivo e di *Streptococcus agalactiae* ATCC® 13813 per il controllo negativo, seminati su Columbia Blood Agar con 5% di sangue defibrinato di montone.

PRECAUZIONI
Il prodotto Bacitracin Test non è classificabile come pericoloso ai sensi della legislazione vigente, ma rientra nello specifico campo di applicazione della normativa relativa all'obbligo di fornitura di scheda di sicurezza, perché può causare fenomeni di allergia in soggetti sensibili, in caso di contatto con la pelle. Bacitracin Test è un dispositivo monouso, da usare solo per uso diagnostico *in vitro*, è destinato ad un ambito professionale e deve essere usato in laboratorio da operatori adeguatamente addestrati, con metodi approvati di asepsi e di sicurezza nei confronti degli agenti patogeni.

CONSERVAZIONE
Conservare Bacitracin Test a 2-8°C nella sua confezione originale. Non conservare vicino a fonti di calore ed evitare eccessive variazioni di temperatura. In queste condizioni Bacitracin Test è valido fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento quali tracce di umidità.

ELIMINAZIONE DEL MATERIALE USATO
Dopo l'utilizzazione Bacitracin Test ed il materiale venuto a contatto con il campione devono essere decontaminati e smaltiti in accordo con le tecniche in uso in laboratorio per la decontaminazione e lo smaltimento di materiale potenzialmente infetto.

BIBLIOGRAFIA

- K.L. Ruoff, R.A. Whiley and D.Beighton.1999. *Streptococcus* . In P.R. Murray, E.J.Baron, M.A. Pfaller, F.C. Tenover, R.H.Yolken (ed) *Manual of Clinical Microbiology 7th* ed. American Society for Microbiology, Washington, D.C.
- W.R. Maxted. 1953 *The use of bacitracin for identifyng Group A haemolytic Streptococci*.J.Clin.Path.6 (3),224-226.

PRESENTAZIONE

Prodotto	REF	Σ
Bacitracin Test	9502	100

TABELLA DEI SIMBOLI

IVD	Dispositivo medico diagnostico *in vitro*		Non riutilizzare
REF	Numero di catalogo		Fragile, maneggiare con cura
	Fabbricante	Σ	Contenuto sufficiente per <n> saggi
	Utilizzare entro		Attenzione, vedere le istruzioni per l'uso
	Limiti di temperatura	LOT	Codice del lotto

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CE IVD

I13113
Rev.2 / 12.11.2015

ENGLISH

Bacitracin Test

DESCRIPTION
Bacitracin Test are paper discs impregnated with 0.04 units of Bacitracin that are used to distinguish Group A Lancefield streptococci from other beta haemolytic streptococci belonging to different Groups.

CONTENT OF THE PACKAGES
Each package contains 2 cartridges with 50 discs each, packaged in a heat-sealed container in the presence of a dryer and a sheet of instructions.

PRINCIPLE OF THE METHOD
Bacitracin is a polypeptide antibiotic that acts against Group A beta haemolytic streptococci. Group C and G streptococci are less sensitive and Group B streptococci are resistant. The disc is applied to the surface of a culture medium that is suitable for growing streptococci and inoculated with a broth culture containing pure colonies of the micro-organism under examination. After incubation, all the plates are examined for the presence or absence of an inhibition halo around the disc of Bacitracin.

COMPOSITION
Each disc is impregnated with 0.04 IU of Bacitracin.

TEST PROCEDURE
1. Take the cartridges container from the refrigerator and leave it on the test bench until it reaches ambient temperature (about 30 minutes). This will prevent humidity being deposited on the discs when the package is opened, which could jeopardise their long-term stability.
2. Inoculate evenly the surface of a plate of blood agar such as Tryptic Soy Blood Agar, Columbia Blood Agar or another blood medium with a culture of the beta-haemolytic streptococci to be tested. The Bacitracin Test can also be carried out by inoculating the clinical material under examination, such as, for example, a swab of rhino-pharyngeal exudate on a blood agar plate.
3. Deposit the disc of Bacitracin on the inoculated surface.
4. Incubate for 18-24 hours at 36 ± 1 °C.
5. Check for presence or absence of an inhibition halo around the disc of Bacitracin.

INTERPRETATION OF THE RESULTS
Sowing previously isolated strain
The presence of a 10-18-mm inhibition halo around the bacitracin disc indicates that the streptococcus is presumably Group A. Other beta haemolytic streptococci that are not Group A grow right up to the edge of the disc. The results of the Bacitracin Test are confirmed by serological identification of the Group.
Sowing the clinical material
The presence of an inhibition halo around the Bacitracin disc, if confirmed by data on the morphology of the colonies and by haemolysis, indicates the presence of Group A streptococci, which must be confirmed by serological identification of the Group.

QUALITY CONTROL
Each Bacitracin Test batch is tested for sensitivity to Bacitracin by using Streptococcus pyogenes ATCC® 19615 culture for the positive control and Streptococcus agalactiae ATCC® 13813 culture for the negative control. The cultures are sown on Columbia Blood Agar with 5% defibrinated sheep's blood.

PRECAUTIONS
Bacitracin Test cannot be classified as being hazardous according to current legislation but fall within the specific field of application where a safety datasheet must be supplied because they can cause allergic phenomena in sensitive subjects if they come into contact with the skin. Bacitracin Test are disposable products. They are only for diagnostic *in vitro* professional use. They must be used in the laboratory by properly trained operators using approved aseptic and safety methods for pathogenic agents.

STORAGE
Bacitracin Test must be stored at 2-8°C in their original packaging. Do not store them near sources of heat and do not expose them to excessive temperature variations. In such conditions, Bacitracin Test can be used until the expiry date shown on the label. Do not use after this date. Dispose of if they show traces of humidity.

DISPOSAL OF USED MATERIAL
After use, Bacitracin Test and the material that comes into contact with the sample must be decontaminated and disposed of in accordance with current laboratory techniques for the decontamination and disposal of potentially infected material.

BIBLIOGRAPHY

- K.L. Ruoff, R.A. Whiley and D.Beighton.1999. *Streptococcus* . In P.R. Murray, E.J.Baron, M.A. Pfaller, F.C. Tenover, R.H.Yolken (ed) *Manual of Clinical Microbiology 7th* ed. American Society for Microbiology, Washington, D.C.
- W.R. Maxted. 1953 *The use of bacitracin for identifyng Group A haemolytic Streptococci*.J.Clin.Path.6 (3),224-226.

PRESENTATION

Product	REF	Σ
Bacitracin Test	9502	100

TABLE OF SYMBOLS

IVD	*In Vitro* Diagnostic Medical Device		Do not reuse
REF	Catalogue number		Fragile,handle with care
	Manufacturer	Σ	Contains sufficient for <n> tests
	Use by		Caution, consult accompanying documents
	Temperature limitation	LOT	Batch code

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CE IVD

I13113
Rev.2 / 12.11.2015

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ПАСПОРТ КАЧЕСТВА

Индикаторы контроля параметров паровой стерилизации химические одноразовые ТУ 9398-042-11764404-2003

Регистрационное удостоверение
№ РЗН 2013/40
от 08.02.2013 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н17796
от 21.06.2016 г.

Наименование продукта **«Стеритест-П-132/20-02»**

Партия 7014028 *Дата изготовления* Февраль 2018 г.

Гарантийный срок *3 года*
Условия эксплуатации и хранения в соответствии с инструкцией производителя
Код ОКП 93 9854

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-042-11764404-2003	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный
за контроль качества О.С.Громаковская

М.П. ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА

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Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

ПАСПОРТ КАЧЕСТВА

Индикаторы контроля параметров паровой стерилизации химические одноразовые ТУ 9398-027-11764404-2003

Регистрационное удостоверение
№ РЗН 2013/38
от 08.02.2013 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н17793
от 21.06.2016 г.

Наименование продукта **«МедИС-132/20-1»**

Партия *7173028* ***Дата изготовления*** *Февраль 2018 г.*

Гарантийный срок *3 года*
Условия эксплуатации и хранения *в соответствии с инструкцией производителя*
Код ОКП 93 9854

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-027-11764404-2003	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный
за контроль качества О.С.Громаковская

М.П.

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ПАСПОРТ КАЧЕСТВА

Индикаторы бумажные воздушной стерилизации химические многопараметрические одноразовые ТУ 9398-032-11764404-2004

Регистрационное удостоверение
№ ФСР 2009/05017
от 06.03.2013 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н17797
от 21.06.2016 г.

Наименование продукта **«МедИС-В-180/60-1»**

Партия *7178028* *Дата изготовления* *Февраль 2018 г.*

Гарантийный срок *3 года*
Условия эксплуатации и хранения в соответствии с инструкцией производителя
Код ОКП 93 9854

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-032-11764404-2004	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный
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СПРАВКА
ПРЕДПРИЯТИЯ-ИЗГОТОВИТЕЛЯ

Доводим до Вашего сведения, что химические индикаторы контроля соблюдения параметров паровой и воздушной стерилизации одноразового применения модификаций «МедИС», «МедИС-В», «Стериконт-П», «Стериконт-В», «Стеритест-П», «Стеритест-Вл», «Интест-П», «Фарматест», «СанИС», «ВИНАР-5 класс», «ВИНАР-ЭО-5Класс», «Дезиконт», Термоиндикатор контроля «холодовой цепи» электронный «ТестТЕРМ» «ВИНАР», выпускаемые нашей фирмой по ТУ 9398-027-11764404-2003, ТУ 9398-032-11764404-2004, ТУ 9398-007-11764404-2004, ТУ 9398-006-11764404-2004, ТУ 9398-042-11764404-2003, ТУ 9398-019-11764404-2003, ТУ 9398-041-11764404-2003, ТУ 9398-021-11764404-2003, ТУ 9398-029-11764404-2008, ТУ 9398-043-11764404-2004, ТУ 9398-086-11764404-2010, ТУ 9398-103-11764404-2014, ТУ 9398-038-11764404-2003, ТУ 9398-088-11764404-2010 соответственно, изготавливаются полностью из материалов, произведенных в Российской Федерации.

Генеральный директор Андреев В.С.

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес:105094, Москва, ул.Госпитальный вал, д.5,стр.7А,пом.VIII
Для писем: 105094, г.Москва, а/я 26
тел/факс: (495) 963-7310, 988-76-67
http:\\www.vinar.ru e-mail: koltrade@vinar.ru

Исх № 1
от 16.01.13г

Индикаторы бумажные воздушной и паровой стерилизации химические одноразовые серии «МедИС» представляют собой прямоугольные полоски бумажного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полиэфира – 60%.
2. Пигмент – 40%, состоящий:

- оксалат железа 60-90%;
- натриевая соль уксусной кислоты 5-12,5%;
- краситель на основе бромфенолового синего 5-12,5%.

Индикаторы бумажные воздушной и пленочные паровой стерилизации химические одноразовые серии «Стеритест» представляют собой прямоугольные полоски с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полистирола – 60%.
2. Пигмент – 40%, состоящий:

- нитрат аммония 10-20%;
- сульфаминовой кислоты 5-10%;
- диоксида титана – 30-40%;
- краситель на основе бромфенолового синего 20-30%.

Индикаторы паровой стерилизации химические одноразовые серии «Интест» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полистирола – 50%.
2. Пигмент – 50%, состоящий:

- нитрат аммония 15-25%;
- сульфаминовой кислоты 5-10%;
- диоксида титана – 20-30%;
- краситель на основе бромфенолового синего 20-30%.

Индикаторы паровой стерилизации химические одноразовые серии «Фарматест» представляют собой прямоугольные полоски бумажно-пленочного

основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полистирола – 60%.
2. Пигмент – 40%, состоящий:

- щавелевой кислоты 20-40%;
- аммониевой соли щавелевой кислоты 10-20%;
- диоксида титана – 20-40%;
- краситель на основе бромфенолового синего 10-20%.

Индикаторы паровой стерилизации химические одноразовые «Винар-5класс» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полиэфирной связки – 72%.
2. Пигмент – 28%, состоящий:

- янтарной кислоты 20-40%;
- натриевой соли янтарной кислоты 10-20%;
- диоксида титана – 20-40%;
- краситель на основе бромкрезоловый зеленый 10-20%.

Индикаторы паровой стерилизации химические одноразовые серии «Винар-6 класс» представляют собой прямоугольные полоски бумажно-пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения.
Индикаторная композиция состоит из:

1. Полиэфирной связки – 65%.
2. Пигмент – 35%, состоящий:

- карбоновой (щавелевой) кислоты 20-50%;
- калиевой соли щавелевой кислоты 10-40%;
- диоксида титана – 5-20%;
- краситель на основе бромкрезоловый зеленый 10-20%.

Индикаторы парового обеззараживания химические одноразовые серии «СанИС» представляют собой прямоугольные полоски пленочного основания с нанесенным на него двумя цветными метками – индикаторной меткой и элементом сравнения, с тыльной стороны индикаторы имеют липкий слой, закрытый бумагой.
Индикаторная композиция состоит из:

1. Полимерной связки на основе полистирола – 55%.
2. Пигмент – 45%, состоящий:

- нитрат аммония 13-20%;
- сульфаминовой кислоты 25-35%;
- диоксида титана – 20-30%;
- краситель на основе бромфенолового синего 15-25%.

Генеральный директор
ООО «НПФ «ВИНАР» Андреев В.С.

sifin

EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity
CE
Nr./No. 105

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Salmonella O:2	**Anti-Salmonella O:19**	**Anti-Salmonella O:43**	**Anti-Salmonella O:58**
Anti-Salmonella O:4	**Anti-Salmonella O:20**	**Anti-Salmonella O:44**	**Anti-Salmonella O:59**
Anti-Salmonella O:5	**Anti-Salmonella O:21**	**Anti-Salmonella O:45**	**Anti-Salmonella O:60**
Anti-Salmonella O:6_1	**Anti-Salmonella O:25**	**Anti-Salmonella O:46**	**Anti-Salmonella O:61**
Anti-Salmonella O:7	**Anti-Salmonella O:27**	**Anti-Salmonella O:47**	**Anti-Salmonella O:62**
Anti-Salmonella O:8	**Anti-Salmonella O:28**	**Anti-Salmonella O:48**	**Anti-Salmonella O:63**
Anti-Salmonella O:9	**Anti-Salmonella O:30**	**Anti-Salmonella O:50**	**Anti-Salmonella O:65**
Anti-Salmonella O:10	**Anti-Salmonella O:34**	**Anti-Salmonella O:51**	**Anti-Salmonella O:66**
Anti-Salmonella O:11	**Anti-Salmonella O:35**	**Anti-Salmonella O:52**	**Anti-Salmonella O:67**
Anti-Salmonella O:13	**Anti-Salmonella O:38**	**Anti-Salmonella O:53**	**Anti-Salmonella Vi**
Anti-Salmonella O:14	**Anti-Salmonella O:39**	**Anti-Salmonella O:54**	
Anti-Salmonella O:15	**Anti-Salmonella O:40**	**Anti-Salmonella O:55**	
Anti-Salmonella O:16	**Anti-Salmonella O:41**	**Anti-Salmonella O:56**	
Anti-Salmonella O:17	**Anti-Salmonella O:42**	**Anti-Salmonella O:57**	

Sonstiges Produkt
Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen: Normes harmonisés appliqués: Applied harmonized standards:	DIN EN ISO 13485:2016, DIN EN 13612:2002, DIN EN 13641:2002, DIN EN ISO 14971:2013, DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013, DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015
Konformitätsbewertungsverfahren: Procèdure d'évaluation de la conformità: Conformity assessment procedure:	**Anhang III** Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz
Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer

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EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity
CE
Nr./No. 106

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sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Salmonella H:a
Anti-Salmonella H:b
Anti-Salmonella H:c
Anti-Salmonella H:d
Anti-Salmonella H:E
Anti-Salmonella H:f
Anti-Salmonella H:g
Anti-Salmonella H:g,m
Anti-Salmonella H:h
Anti-Salmonella H:i
Anti-Salmonella H:k
Anti-Salmonella H:L
Anti-Salmonella H:n
Anti-Salmonella H:r
Anti-Salmonella H:y
Anti-Salmonella H:z
Anti-Salmonella H:z_{10}
Anti-Salmonella H:z_{35}
Anti-Salmonella H:z_{38}
Anti-Salmonella H:z_{41}
Anti-Salmonella H:1
Anti-Salmonella H:2
Anti-Salmonella H:6

Sonstiges Produkt
Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

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Konformitätsbewertungsverfahren: Procèdure d'évaluation de la conformità: Conformity assessment procedure:	**Anhang III** Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer

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EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity

CE

Nr./No. 107

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sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Salmonella H:m
Anti-Salmonella H:p
Anti-Salmonella H:q
Anti-Salmonella H:s
Anti-Salmonella H:t
Anti-Salmonella H:u
Anti-Salmonella H:v
Anti-Salmonella H:w
Anti-Salmonella H:x

Anti-Salmonella H:z_4,z_{23}
Anti-Salmonella H:z_6
Anti-Salmonella H:z_{15}
Anti-Salmonella H:z_{24}
Anti-Salmonella H:z_{28}
Anti-Salmonella H:z_{29}
Anti-Salmonella H:z_{32}
Anti-Salmonella H:5
Anti-Salmonella H:7

Sonstiges Produkt
Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

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Gültig bis: Valable jusqu'au: Valid until:	2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer

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EG-Konformitätserklärung
CE-Declaration de Conformité / EC-Declaration of Conformity
CE
Nr./No. 111

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Shigella dysenteriae type 1
Anti-Shigella dysenteriae type 2
Anti-Shigella flexneri type 1
Anti-Shigella flexneri type 2
Anti-Shigella flexneri type 3
Anti-Shigella flexneri type 4
Anti-Shigella flexneri type 5
Anti-Shigella flexneri type 6
Anti-Shigella flexneri group 3,4 (y)
Anti-Shigella flexneri group 6
Anti-Shigella flexneri group 7,8 (x)
Anti-Shigella sonnei S-form (phase I)
Anti-Shigella sonnei F-form (phase II)
Anti-Shigella sonnei S- and F-form (phase I and II)

Sonstiges Produkt
Other device/Autre dispositif

allen Anforderungen der Richtlinie 98/79/EG entspricht.
remplit toutes les exigences de la Directive 98/79/EG qui le concernait.
meets all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes harmonisés appliqués:
Applied harmonized standards:

DIN EN ISO 13485:2016, DIN EN 13612:2002,
DIN EN 13641:2002, DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015

Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformità:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer

Zertifikat

mdc medical device certification GmbH
bescheinigt hiermit, dass das Unternehmen

sifin

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Deutschland

im Geltungsbereich

Entwicklung, Herstellung und Vertrieb von In-vitro-Diagnostika der Produktgruppen: Blutgruppenserologie, Bakteriologische Testreagenzien und Nährmedien sowie Produktion von Rohstoffen für die Herstellung von In-vitro-Diagnostika

ein

Qualitätsmanagementsystem

eingeführt hat und anwendet.

Ein Audit von mdc hat den Nachweis erbracht, dass dieses Qualitätsmanagementsystem die Forderungen der folgenden Norm erfüllt:

DIN EN ISO 13485

Medizinprodukte – Qualitätsmanagementsysteme – Anforderungen für regulatorische Zwecke

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

Gültig ab	2018-10-23
Gültig bis	2021-10-22
Registrier-Nr.	D1058700042
Bericht-Nr.	P18-00745-121758
Stuttgart, den	2018-07-16

Leiter Zertifizierungsstelle

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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Anti-Shigella

test reagent for slide agglutination

INFORMATION FOR PROFESSIONAL USE

CE IVD

RUO

Intended use

The test reagents are intended for use in the serological detection and the determination of the serovar of *Shigella* strains isolated from test material of human or other origin using the slide agglutination test

Principle of the test

If the *Shigella* strain possesses an antigen covered by the test reagent, this antigen becomes bound when mixed with the specific antibody. The antigen-antibody reaction results in clearly visible agglutination of the strain

Composition

The test reagents are absorbed sera from immunised rabbits, a mixture of absorbed sera from immunised rabbits and contain only monoclonal antibodies.
Preservative: sodium azide (NaN_3) 0.9 mg/ml

Available polyspecific specificities

Name	contains antibodies against
Anti-Shigella I	*S. flexneri* type 1 to 6 and group 3,4 (x), 6 and X (x), *S. sonnei* S- and R-form (phase I and II)
Anti-Shigella II	*S. dysenteriae* types 1 to 10
Anti-Shigella III	*S. boydii* type 1 to 15
Anti-Shigella flexneri	*S. flexneri* type 1 to 6 and group 3,4 (x), 6 and X (x)

Available monospecific specificities

Name	Name	Name
Anti-Shigella dysenteriae type 1	Anti-Shigella flexneri type 4	Anti-Shigella flexneri group 7,8 (x)
Anti-Shigella dysenteriae type 2	Anti-Shigella flexneri type 5	Anti-Shigella sonnei S-form (phase I)
Anti-Shigella flexneri type 1	Anti-Shigella flexneri type 6	Anti-Shigella sonnei R-form (phase II)
Anti-Shigella flexneri type 2	Anti-Shigella flexneri group 3,4 (x)	Anti-Shigella sonnei S- and R-form (phase I and II)
Anti-Shigella flexneri type 3	Anti-Shigella flexneri group X	

Form in which product is supplied, shelf life and storage

The test reagents which are lyophilized are ready for use once they have been rehydrated in 1 ml or 5 ml distilled water as stated on the label.
If stored unopened at 2...8 °C, they may be used up to the date given on the label. Once opened and rehydrated, they must be closed properly using the enclosed pipette. If stored at 2...8 °C, the polyspecific test reagent remain usable for at least 12 months, and the monospecific products for at least 18 months. However, they must not be used after the date given on the label.
Liquid test reagents may be used up to the date given on the label if stored at 2...8 °C both before and after opening. The reagents are ready to use.
The test reagent may sometimes show turbidity not caused by microbes. Such turbidity does not impair effectivity and the test reagents can be clarified by centrifugation or filtration. The test reagents must have their temperatures adjusted to room temperature (18 ...26 °C) before use

Warnings and precautions

The biotechnological manufacture of the monoclonal antibodies means that the risk of contamination by infectious agents can be virtually excluded. However, if the reagents contain animal materials (fetal calf serum, stabilizer), they should be treated as potentially infectious and handled accordingly.
Test reagents containing biological material in the form of rabbit serum should be treated as potentially infectious and handled accordingly.
As these products contain sodium azide, contact with the skin and mucous membranes must be avoided! In case of contact, rinse with plenty of water.
Since the performance of the slide agglutination test involves working with native pathogenic materials, all necessary work protection procedures must be adhered to (risk of infection!)

Materials and equipment not supplied

Glass slides, stirring rods, distilled water, physiological saline (NaCl 9 g/l), disposal containers for infectious material, pipettes, pipette tips

Test material and methodology

Transfer a small amount of bacterial mass from a suspicious colony onto a slide and mix with one drop of the test reagent (ca. 25 µl) so that a homogenous, slightly milky suspension results. Ensure that the slide is positioned on a dark surface. The result is read with the naked eye by holding the slide in front of a light source against a black background and rocking it (tilting it back and forth).
In exceptional cases, selective culture media may impair the agglutinability of the bacteria. This factor can be eliminated by removing the bacteria from the nutrient or blood agar or from the Kligler medium. To exclude the possibility of spontaneous agglutinations, a negative control (NC) with physiological saline must be tested in parallel.

Evaluation

The test can only be evaluated if the negative control (NC) remains milky-opaque.
Positive: visible agglutination after the sample has been tilted back and forth less than 20 times. In a strongly positive reaction (PP), agglutination coarsely or finely flocculent) appears as soon as the bacterial mass is mixed in. In a weakly positive result, agglutination only appears after the slide has been tilted back and forth 10-20 times.

Negative: If the suspension remains milky opaque, or a reaction occurs only when the sample has been tilted back and forth more than 20 times, the reaction is negative (NP).

Quality assurance during the testing procedure

For the quality control of serological determination by slide agglutination test, the good expression of the strain's cell-surface antigen is important. The use of strains from interlaboratory tests, field strains of defined origin that have been characterized by an external laboratory, or sifin Shigella control antigens for the slide agglutination test is therefore recommended for quality control

Limits of the procedure

The test reagents react with *Shigella* strains which contain antigens of the specificity declared on the label.
In exceptional cases, cross-reactions may occur with other genera of *Enterobacteriaceae* – especially with *E. coli* strains – due to antigen identities or related antigens.

Explanation of the symbols used

LOT	Batch code (Lot)		Use by YYYY-MM (MM = end of month)
REF	Catalogue number		Temperature limitation
IVD	In Vitro Diagnostic Medical Device		Consult instructions for use
TR	Test reagent		Slide agglutination
mTR	Monoclonal test reagent	LYO	lyophilized

Date of revision: 12/2022/03

Всем заинтересованным лицам

Авторизационное письмо

Настоящим, мы, компания «HELENA LABORATORIES (UK) Ltd», торгующая как «HELENA BIOSCIENCES EUROPE», с центральным офисом по адресу: Queensway South, Team Valley Trading Estate, Gateshead, Tyne & Wear, NEll OSD, Великобритания, подтверждает, что:

Компания "GBG-MLD" SRL, республика Молдова, г. Кишинёв, MD-2001, улица ChisinauTighina, дом 65, офис 607 являются уполномоченными дистрибьюторами всей продукции компании «HELENA BIOSCIENCES EUROPE» на территории Республики Молдова и авторизована принимать участие во всех тендерах.

Компании **"GBG-MLD" SRL** имеет право импорта, продвижения и продажи выше перечисленной продукции на территории Республики Молдова.

Настоящее письмо действительно до 31 декабря 2020 года.

Дата: 22/01/2020

Дмитрий Александров

Директор по развитию бизнеса в странах СНГ, Европы и Азии.

Helena Biosciences Europe
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bsi.

By Royal Charter

Certificate of Registration

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

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United Kingdom

Holds Certificate Number: **MD 69326**

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

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

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14
Expiry Date: 2021-04-13

...making excellence a habit.

Certificate No: **MD 69326**

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

Original Registration Date: 2002-10-25
Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14
Expiry Date: 2021-04-13

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Declaration of Conformity

HL-7-DC-0654 Rev. 6

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

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

Product Code	Description	GMDN Classification Code
5265L	Thromboplastin L	55983
5265HL	Thromboplastin L	55983
5267L	Thromboplastin L	55983
5562SLQ	APTT Si L Minus	55981
5558SLQ	APTT Si L Minus	55981
5559SLQ	APTT Si L Minus	55981
5560SLQ	APTT Si L Minus	55981
5386	Calcium Chloride	30593
5376/35R	Clauss Fibrinogen 35	55997
5556	Clauss Fibrinogen 50	55997
5556R	Clauss Fibrinogen 50	55997
5376	Clauss Fibrinogen 100	55997
5376R	Clauss Fibrinogen 100	55997
5374	Clauss Fibrinogen (Thrombin Only)	56000
5378	Clauss Fibrinogen (Thrombin Only)	56000
5375	Owren's Buffer	58237
5375R	Imidazole Buffer	58237
53765	Kaolin Suspension	56000
5377	Thrombin Time	55987
5380	Thrombin Time	55987
5392	Thrombin Time	55987
5790	Factor II Deficient Plasma (Immunodepleted)	56003
5791	Factor V Deficient Plasma (Immunodepleted)	56013
5792	Factor VII Deficient Plasma (Immunodepleted)	56247
5795	Factor X Deficient Plasma (Immunodepleted)	56037
5793	Factor VIII Deficient Plasma (Immunodepleted)	56025
5794	Factor IX Deficient Plasma (Immunodepleted)	56250
5796	Factor XI Deficient Plasma (Immunodepleted)	56042
5797	Factor XII Deficient Plasma (Immunodepleted)	56047

Declaration of Conformity

HL-7-DC-0654 Rev. 6

Product Code	Description	GMDN Classification Code
5191	Factor V Deficient Plasma (Congenital)	56013
5192	Factor VII Deficient Plasma (Congenital)	56247
5195	Factor X Deficient Plasma (Congenital)	56037
5193	Factor VIII Deficient Plasma (Congenital)	56025
5194	Factor IX Deficient Plasma (Congenital)	56250
5196	Factor XI Deficient Plasma (Congenital)	56042
5197	Factor XII Deficient Plasma (Congenital)	56047
5502	Antithrombin Xa (Chromogenic)	56155
5507	Antithrombin Xa (Chromogenic)	56155
5543	Protein C (Chromogenic)	47388
5552	Auto Blue D-Dimer 400	47346
5553IL	Auto Blue D-Dimer 400	47346
5501	Auto Red D-Dimer 700	47346
5250	Manual D-Dimer	47346
5250H	Manual D-Dimer	47346
5546	PCA Ratio	56221
5511	Protein S (Clot)	56208
5525	Free Protein S	60497
5484	DRVVT Screen	56202
5485	DRVVT Confirm	56202
5185	Calibration Plasma	55995
5185IL	Calibration Plasma	55995
5504R	Calibration Plasma	55995
5379	Fibrinogen Calibrator	55999
5186	Routine Control N	30590
5187	Routine Control A	30590
5183	Routine Control SA	30590
5301	Speciality Assayed Control N	30590
5301IL	Speciality Assayed Control N	30590
5302	Speciality Assayed Control A	30590
5302IL	Speciality Assayed Control A	30590
5486	LA Positive Control S	46029
5509	D-Dimer Control H/L	47347
5490	INR Reference Set	55995
5364	Arachidonic Acid	56092

Declaration of Conformity

HL-7-DC-0654 Rev. 6

Product Code	Description	GMDN Classification Code
5366	Adenosine Diphosphate	56092
5367	Epinephrine	56092
5368	Collagen	56092
5199	Ristocetin	56092
5372	Ristocetin	56081
5371	Lyophilised Platelets	56081
5373	Ristocetin Cofactor Abnormal Control	56080
5365	Tris-Buffered Saline	58208
5370	Ristocetin Cofactor Kit	56078
1479	Platelet Scale Set	58048

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

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 20 Oct 2019

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

ELITechGroup
VITAL
SCIENTIFIC

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

Spankeren, 18 July 2013

Letter of Authorization

To whom it may concern:

Vital Scientific B.V., manufacturers of clinical chemistry analyzers having headquarters and factory at:
Van Rensselaerweg 4
6956 AV Spankeren/Dieren
The Netherlands
and being a company of the ELITech Group, hereby confirms that the company

GBG-Moldova SRL company
Tighina str.65,office 607
MD-2001,Chisinau, Republic of Moldova

is authorized to market, offer, sell and support the following products in Moldova:

Selectra line: Selectra ProXS, Selectra Junior, Selectra ProS, Selectra ProM, Selectra XL
Microlab line: Microlab 300 and Microlab 300 LX
And older and newer type of products related to these lines (or of the Flexor line).

Vital Scientific B.V.

i/a

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

A. Altink
Managing Director

ISO 9001 -NF EN ISO 13485

ELITechGroup SEPPIM REAGENTS

Zone Industrielle – 61500 SEES – France
Tél. : + 33 (0)2 33 81 21 00 / Fax : + 33 (0)2 33 28 77 51

TO WHOM TO BE CONCERNED

We, Seppim S.A.S., manufacturers of Elitech Clinical Systems reagents, having our factory at Zone Industrielle, 61500 Sées - France, confirm that our clinical reagents have been validated on Vital Scientific equipment. As such available Elitech Clinical Systems reagent applications for Vital Scientific instruments are CE-IVD compliant.

Reagents, other than Elitech Clinical Systems reagents, are not validated on Vital Scientific equipments, and we also can't know the impact of other reagents on Vital Scientifc equipments.

May 22nd, 2012

Noi, subsemnații Seppim S.A.S., compania producătoare a regenților Elitech Clinical Systems, având fabrica de producere în Zone Industrielle, 61500, Franța, confirmăm, că reagenții au fost testați si validați pe echipamentele Vital Scientific. Pentru acești reagenți existând şi protocoale specializate pentru analizatoarele produse de Vital Scientific. Atât reagenții cât şi echipamentele sunt certificate CE-IVD.

Alți reagenți înafara de Elitech Clinical Systems, nu au fost testați şi validați la echipamentele Vital Scientific şi noi nu cunoaştem compatibilitatea şi impactul lor asupra analizatoarelor Vital Scientific.

22 mai 2012

Signed on behalf of the manufacturer
Valérie GOURDON
Regulatory Affairs Manager
COMPANY SEPPIM S.A.S

SEPPIM S.A.S
4 rue Auguste Mottin
Zone Industrielle
61500 SEES - FRANCE
Tél. +33 (0)2 33 81 21 00 - Fax +33 (0)2 33 28 77 51
SIRET : 318 365 228 00036

Declaration of Conformity

We: **ELITechGroup B.V.**
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

Declare under sole responsibility that the product indicated below (including all accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE marking.

Product	**Clinical chemistry analyzer, automated**
Model	**Selectra ProM**
Reference numbers	**6003-400**
GMDN code	**56678**
Accessories	**See separate document 'Regulatory status of parts & accessories'**

Product classification
As per Article 9, section 1 the products are categorized as other devices ("self declaration").

Conformity assessment procedure
In accordance with Annex III of the IVDD 98/79/EC

The product (including all accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL);
- All other member states of the European Union (EU);
- All member states of the European Free Trade Association (EFTA) and Switzerland.

Spankeren, August 2015

A. Altink

Managing Director

Declaration of Conformity

List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
	IEC 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2005	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	DEKRA
	IEC 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	

Instrument Training

ELITechGroup VITAL SCIENTIFIC

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

Participant: Mr. A. Legun

Company: Global Biomarketing Group-Moldova SRL Moldova

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

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

System Support Manager:

Jan Oostendorp

System Support Engineer:

Frank v.d. Korput

KABE LABORTECHNIK

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY

Name und Adresse des Herstellers: Name and address of the manufacturer:	**KABE LABORTECHNIK GmbH** **Jägerhofstraße 17** **51588 Nümbrecht-Elsenroth** Deutschland / Germany

Wir erklären in alleiniger Verantwortung, dass die In-Vitro-Diagnostika der Produktgruppe /
We declare under our sole responsibility that the in-vitro-diagnostica of product group

kapillare Blutentnahmesysteme
 	
• **Kapillarblutentnahmesystem (GK)**
• **kapillare Probenbehältnisse**
  • Blutgaskapillaren (BK)
  • Hämatokritkapillaren (HK)
  • end-to-end Kapillaren (EK)
	capillary blood collection systems
	
	• **capillary blood collection system (GK)**
	• **capillary sample containers**
	  • blood gas capillaries (BK)
	  • haematocrit capillaries (HK)
	  • end-to-end capillaries (EK)

der Klasse / of class	**Andere IVD-Produkte** **Other IVD-devices**

den einschlägigen Bestimmungen der IVD-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Konformitätserklärung gilt für die durch die KABE LABORTECHNIK GmbH freigegebenen Chargen.

meets the provisions of the directive 98/79/EEC and its transpositions in national laws which apply to it. This declaration is valid for the batches released by KABE LABORTECHNIK GmbH.

Konformitätsbewertungsverfahren: Conformity assessment procedure:	**Richtlinie 98/79/EWG Anhang III** **Directive 98/79/EEC Annex III**

Nümbrecht-Elsenroth, 21.03.2013

KABE LABORTECHNIK GmbH
Jägerhofstraße 17
D-51588 Nümbrecht-Elsenroth
☎ +49 (0) 2293 / 596

André Kolpe, Geschäftsführer / Managing director

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

KABE LABORTECHNIK GmbH
Jägerhofstr. 17
51588 Nümbrecht
Deutschland

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

Design and development, production and distribution of in vitro diagnostic devices and consumption materials for sample withdrawal, preparation and storage as well as single-use medical devices

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date:	2018-10-16
Certificate Registration No.:	SX 60133221 0001
An audit was performed. Report No.:	21234760 009
This Certificate is valid until:	2021-10-15

Certification Body

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

Date 2018-10-12

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. I. Munkler

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

APTACA S.p.A.
Regione Monforte, 30 - 14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com
www.aptaca.com - www.vacuaplaca.it
P.IVA: 00862050960 - Cod.Fisc.: 07520900155 - R.E.A. MB 1167248

TO WHOM IT MAY CONCERN

Letter of Authorization

We APTACA SPA , with head offices and plant located in :

Regione Monforte nr 30

14053 Canelli (At) Italy

Confirm that the below Company :

"GBG-MLD" S.R.L.
Tighina str.65, office 607
MD-2001,Chisinau,
Republic of Moldova

Web: www.gbg.md
Ph. +373 22 54 91 20
+373 22 54 91 21

Is authorized to prepare price quotations, advertising activities, warranty service, offers, to partecipate in tenders and to sell our whole range of product on exclusive basis in the territory of MOLDAVIA. This letter is valid until 31/12/2020 and may be prolonged by mutual agreement.

ON BEHALF OF NUOVA APTACA S.R.L.

Veronica FERRARI

Export Manager

APTACA SPA
Reg. Monforte n. 30
Tel. 0141/835075 r.a. - Fax 0141/835292
14053 CANELLI (AT)
C.F. 07520900155 - P.I. 00862050960
Cod. Univoco: SUBM70N

Canelli 25/11/2019

ITALCERT

CERTIFICATO N° 505SGQ03

CERTIFICATE N° 505SGQ03

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

NUOVA APTACA S.r.l.

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 ed 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. Commercializzazione di dispositivi medici 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. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dal Regolamento 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*
1998-07-23	2011-10-30	2017-10-30	2020-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A PRD N° 122D
SGA N° 020D ISP N° 075E
PAS N° 092C
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

KIMA

articoli per laboratorio analisi
disposable labware

www.kima.it

Messrs

"GBG-MLD" SRL
STR. TIGHINA 65
2001 CHISINAU
MOLDOVA

Piove di Sacco, 25/02/2019

DISTRIBUTOR AGREEMENT

To whom it may concern, we hereby declare that:

KIMA sas – Via Leonardo Da Vinci 22 – 35028 piove di Sacco - (PD) - ITALY

appoints "GBG-MLD" SRL – STR. TIGHINA 65. - 2001 CHISINAU –MOLDOVA

as authorized distributor of KIMA plastic labware products in the territory of MOLDOVA

GBG MLD has the right to import and distribute KIMA plastic labware products.

This Agreement is valid one (2) years from the present date.

The Distributor does not have any possibility to oblige the company KIMA sas with quantities or delivery time as well as prices without prior written authorization from KIMA sas.

KIMA sas keeps the right to modify the prices according to the market of the raw materials.

Renzo Chiarin
Managing Director

KIMA S.R.L.
Via Leonardo Da Vinci, 22
35028 PIOVE DI SACCO (PD)
Partita IVA 01466290283

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4/C**

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

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

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

UNI EN ISO 9001:2015

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

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

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

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

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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

FEDERAZIONE CISQ
www.cisq.com

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

0449CM_03_IT

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4265/4/C**

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

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

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

UNI CEI EN ISO 13485:2016

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento;
Refer to the documentation of the Quality Management System for details of application to reference standard requirements;
Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current Issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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

FEDERAZIONE CISQ
www.cisq.com

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

0360CIM_CIZ_IT

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www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4265/4/D**

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

VACUTEST KIMA S.r.l.

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

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

UNI CEI EN ISO 13485:2016

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

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 14 - 29

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

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

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.
Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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

FEDERAZIONE CISQ
www.cisq.com

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

0860CM_02_IT

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
21 июня 2018 - 31 августа 2021

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация, 196240

была признана соответствующей стандарту:
ISO 9001:2015

Настоящий сертификат действителен для следующей области:
ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.

Место и дата:
Москва, 21 июня 2018

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
IAF

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

От выпускающего офиса:
DNV GL – Business Assurance
Трехпрудный переулок 9, стр. 2, Москва,
Российская Федерация

S. Groubine

Сергей Грубин
Представитель руководства

Невыполнение условий Договора на сертификацию делает данный Сертификат недействительным.
Аккредитованный офис: DNV GL BUSINESS ASSURANCE FINLAND OY AB, Kellosatama 5, 02150 Espoo, Finland. TEL:+358 10 292 4200.
assurance.dnvgl.com