



Brilliance Candida Selective Supplement

EN

REF SR0231E

*See additional IFUs for Brilliance Candida Agar Base product codes CM1002B

Intended Use

Brilliance™ Candida Selective Supplement (SR0231E) is a vial containing chloramphenicol, which is sold separately and used to supplement Brilliance Candida Agar Base (CM1002B) for the isolation and identification of clinically important *Candida* spp. from clinical samples, and for identifying clinical isolates. Brilliance Candida Agar Base (CM1002B) with Brilliance Candida Selective Supplement (SR0231E) added can be used with a variety of sample types; the main sample types are sputum and urine, as well as bronchial secretion, genital, nasal, ear, throat, wound, skin, gastrostomy and central venous line site samples.

Brilliance™ Candida Selective Supplement (SR0231E) is used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having candidiasis. The device is for professional use only, is not automated, nor is it a companion diagnostic.

Summary and Explanation

Candida spp. are commensal yeasts that are found normally as part of the skin, oral, gut and vaginal flora of humans¹. *Candida* spp. are the causative agents of Candidiasis, a fungal infection which typically occurs in immunocompromised groups such as children or individuals with HIV¹⁻¹². *Candida* spp. are also nosocomial pathogens, with invasive medical interventions such as catheterisation or immunosuppressant treatment contributes to the incidence of nosocomial candidiasis, such as urinary tract infections (UTIs) and bloodstream infections (candidaemia)⁸⁻¹³. Moreover, the emergence of antifungal resistance in *Candida* spp. complicates treatment and impacts patient outcomes, especially in immunocompromised or hospitalised individuals¹⁴⁻¹⁸.

Principle of Method

Differentiation of clinically important *Candida* spp. is achieved through the inclusion of two chromogens that are targeted by specific enzymes hexosaminidase and alkaline phosphatase. The action of these enzymes on the chromogens causes release of the coloured component inside the fungal cell, resulting in coloured colonies. The colour produced depends on which enzymes the organisms produce. The presence of hexosaminidase in *C. albicans*, and *Candida dubliniensis* results in green/blue colonies. The presence of hexosaminidase in *C. tropicalis*, and other metabolic reactions that cause localised drop in pH, results in dark blue colonies. The presence of alkaline phosphatase in *Candida krusei* results in brown or pink colonies. The presence of alkaline phosphatase in *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* and *Candida lusitanae* results in a variety of beige/brown/yellow colours due to the mixture of natural pigmentation and some alkaline phosphatase activity. Experienced users may be able to differentiate these species by colour and colony morphology. The opaque background allows identification of *Candida* spp., especially when mixed infections are present. The medium contains chloramphenicol, which inhibits bacterial growth.

Typical Formula

Chloramphenicol 250.0mg

Materials Provided

SR0231E: 10x freeze dried vials each for 500ml of medium

Materials Required but Not Supplied

- Brilliance Candida Agar Base (dehydrated) product code:CM1002B

Storage

- Store product in its original packaging between 2°C and 8°C.
- The product may be used until the expiry date stated on the label.
- Protect from moisture.
- Store away from light.
- Allow reconstituted product to equilibrate to room temperature before use.

Warnings and Precautions



Signal Word: Danger

Hazard Statements
H350 - May cause cancer

Precautionary Statements

P280 - Wear protective gloves/protective clothing
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P201 - Obtain special instructions before use
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

Each vial is for single use. Do not re-use.

For in vitro diagnostic use only.

For professional use only.

Inspect the product packaging before first use.

Do not use the product if there is any visible damage to the packaging or vials.

Do not use the product beyond the stated expiry date.

Do not use the device if signs of contamination are present.

Do not use the device if the colour has changed or there are other signs of deterioration.

It is the responsibility of each laboratory to manage waste produced according to their nature and degree of hazard and to have them treated or disposed of in accordance with any federal, state and local applicable regulations. Directions should be read and followed carefully. This includes the disposal of used or unused reagents as well as any other contaminated disposable material following procedures for infectious or potentially infectious products.

Refer to the Safety Data Sheet (SDS) for safe handling and disposal of the product (www.thermofisher.com).

Serious Incidents

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.

Specimen Collection, Handling and Storage

Specimen should be collected and handled following local recommended guidelines, such as the UK Standards for Microbiology Investigations (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 and S 6.

Procedure
















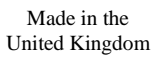



Aseptically add 5ml of 70% ethanol to one vial and mix gently to dissolve the contents completely. Add the vial contents to 500ml of *Brilliance*[™] Candida Agar Base (CM1002B) as directed. Mix well and bring to the boil with frequent agitation. DO NOT AUTOCLAVE. Cool to 45°C and pour into sterile containers.

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Symbol Legend

Symbol	Definition
	Catalogue number
	In Vitro Diagnostic Medical Device
	Batch code
	Temperature limit
	Use-by date
	Keep away from sunlight
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Contains sufficient for <n> tests
	Do not use if packaging damaged and consult instructions for use
	Manufacturer
	Authorized representative in the European Community/ European Union
	European Conformity Assessment
	UK Conformity Assessment
	Unique device identifier
	Made in the United Kingdom
	Importer - To indicate the entity importing the medical device into the locale. Applicable to the European Union
	Hazard to health
	Keep Dry



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2797

For technical assistance please contact your local distributor.

Revision information

Version	Date of issue and modifications introduced
3.0	2024-10-28 Minor formatting changes Warnings and Precautions corrected to match SDS Addition of the Keep Dry symbol



Selektivní doplněk Brilliance Candida

CZ

REF SR0231E

*Viz další návody k použití pro agarovou bázi Brilliance Candida s kódy produktu CM1002B

Účel použití

Selektivní doplněk Brilliance™ Candida (SR0231E) je injekční lahvička obsahující chloramfenikol, který se prodává samostatně a používá se jako doplněk agarové báze Brilliance Candida (CM1002B) pro izolaci a identifikaci klinicky významných *Candida* spp. z klinických vzorků a pro identifikaci klinických izolátů. Agarová báze Brilliance Candida (CM1002B) s přidaným selektivním doplňkem Brilliance Candida (SR0231E) lze použít s různými typy vzorků; hlavními typy vzorků jsou sputum a moč, dále vzorky bronchiálních sekretů, genitálií, nosních dutin, ušních, krčních, vzorků z rány, kůže, gastrostomie a z centra centrální žilní cesty.

Selektivní doplněk Brilliance™ Candida (SR0231E) se používá v diagnostickém pracovním postupu, aby pomohl lékařům při určování potenciálních možností léčby pacientů s podezřením na kandidózu. Prostředek je určen pouze pro profesionální použití, není automatizovaný a není určen pro doprovodnou diagnostiku.

Souhrn a vysvětlení

Candida spp. jsou kmenzální kvasinky, které se normálně vyskytují jako součást lidské kůže, úst, střev a pochvy¹. *Candida* spp. jsou původci kandidózy, plísňové infekce, která se obvykle vyskytuje u imunokompromitovaných skupin, jako jsou děti nebo jedinci s HIV¹⁻¹². *Candida* spp. jsou také nozokomiálními patogeny, přičemž invazivní lékařské intervence, jako je katetrizace nebo imunosupresivní léčba, přispívají k výskytu nozokomiální kandidózy, jako jsou infekce močových cest (UTI) a infekce krevního řečiště (kandidémie)⁸⁻¹³. Léčbu navíc komplikuje vznik antimykotické rezistence u *Candida* spp., která ovlivňuje výsledky pacientů, zejména u imunokompromitovaných nebo hospitalizovaných jedinců¹⁴⁻¹⁸.

Princip metody

Diferenciace klinicky významných *Candida* spp. je dosažena zahrnutím dvou chromogenů, na které cílí specifické enzymy hexosaminidáza a alkalická fosfatáza. Působením těchto enzymů na chromogeny dochází k uvolnění barevné složky uvnitř buňky kvasinky, což vede k barevným koloniím. Jejich barva závisí na tom, které enzymy tyto organismy produkují. Přítomnost hexosaminidázy u *C. albicans* a *Candida dubliniensis* má za následek tvorbu zelenomodrých kolonií. Přítomnost hexosaminidázy u *C. tropicalis* a další metabolické reakce, které způsobují lokalizovaný pokles pH, mají za následek tvorbu tmavě modrých kolonií. Přítomnost alkalické fosfatázy u *Candida krusei* má za následek tvorbu hnědých nebo růžových kolonií. Přítomnost alkalické fosfatázy u *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* a *Candida lusitanae* má za následek tvorbu různých béžových/hnědých/žlutých barev díky směsi přirozené pigmentace a určité aktivity alkalické fosfatázy. Zkušenosti uživatelé mohou být schopni rozlišit tyto druhy podle barvy a morfologie kolonií. Neprůhledné pozadí umožňuje identifikaci *Candida* spp., zejména pokud jsou přítomny smíšené infekce. Médium obsahuje chloramfenikol, který inhibuje růst bakterií.

Typické složení

Chloramfenikol 250,0 mg

Dodávané materiály

SR0231E: 10x lyofilizované lahvičky na 500 ml média

Potřebný materiál, který není součástí dodávky

- Agarová báze Brilliance Candida (dehydratovaná) kód produktu: CM1002B

Skladování

- Výrobek skladujte v původním obalu při teplotě od 2 °C do 8 °C.
- Produkt lze používat do data použitelnosti uvedeného na štítku.
- Chraňte před vlhkostí.
- Chraňte před světlem.
- Před použitím nechte rekonstituovaný výrobek vytemperovat na pokojovou teplotu.

Upozornění a opatření



Signální slovo: Nebezpečí

Prohlášení o riziku

H350 – Může způsobovat rakovinu

Preventivní opatření

P280 – Používejte ochranné rukavice/ochranný oděv

P302 + P352 – PŘI STYKU S KŮŽÍ: Omyjte velkým množstvím vody a mýdla

P342 + P311 – Při respiračních příznacích: Volejte TOXIKOLOGICKÉ INFORMAČNÍ STŘEDISKO nebo lékaře

P201 – Před použitím si obstarejte speciální instrukce

P308 + P313 - PŘI expozici nebo podezření na ni: Vyhledejte lékařskou pomoc/ošetření

P304 + P340 - PŘI VDECHNUTÍ: Přeneste osobu na čerstvý vzduch a udržujte ji v poloze usnadňující dýchání

Každá lahvička je určena k jednorázovému použití. Nepoužívejte opakovaně.

Určeno pouze pro diagnostické použití in vitro.

Pouze pro odborné použití.

Před prvním použitím zkontrolujte obal výrobku.

Produkt nepoužívejte, pokud je obal viditelně poškozen, případně pokud jsou poškozeny lahvičky.

Produkt nepoužívejte po uplynutí uvedeného data použitelnosti.

Prostředek nepoužívejte, pokud jsou přítomny známky kontaminace.

Prostředek nepoužívejte, pokud se změnila jeho barva nebo se objevují jiné známky zhoršení kvality.

Je odpovědností každé laboratoře nakládat s vyprodukovaným odpadem podle jeho povahy a stupně nebezpečí a nechat jej zpracovat nebo zlikvidovat v souladu s veškerými federálními, státními a místními platnými předpisy. Pozorně si přečtěte všechny pokyny a pečlivě je dodržujte. To zahrnuje likvidaci použitých nebo nepoužitých činidel i jakéhokoli jiného kontaminovaného jednorázového materiálu v souladu s postupy pro infekční nebo potenciálně infekční výrobky.

Informace o bezpečné manipulaci a likvidaci produktu naleznete v bezpečnostním listu (SDS) (www.thermofisher.com).

Závažné události

Každá závažná událost, ke které došlo v souvislosti s prostředkem, se musí nahlásit výrobci a příslušnému správnému orgánu v místě, kde se uživatel a/nebo pacient nachází.

Odběr vzorků, manipulace a skladování

Odběr a zacházení se vzorky musí probíhat podle místních doporučených pokynů, jako jsou normy pro mikrobiologická vyšetření platné ve Spojeném království (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 and S 6.

Postup

Do jedné lahvičky asepticky přidejte 5 ml 70% ethanolu a jemně promíchejte, aby se úplně rozpustil. Přidejte obsah injekční lahvičky do 500 ml agarové báze *Brilliance™* Candida (CM1002B) podle pokynů. Dobře promíchejte a za časté agitace přiveďte k varu. NEPROVÁDĚJTE AUTOKLÁVOVÁNÍ. Zchladte na 45 °C. Dobře promíchejte a nalijte do sterilních nádob.



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Symbol, legenda

Symbol	Definice
	Katalogové číslo
	Diagnostický zdravotnický prostředek in vitro
	Kód dávky
	Teplotní limit
	Datum použitelnosti
	Uchovávejte mimo dosah slunečního světla
	Nepoužívejte opakovaně
	Seznamte se s návodem k použití nebo s návodem k použití v elektronické podobě
	Obsah postačuje pro <n> testů
	Nepoužívejte, pokud je obal poškozen, a seznamte se s návodem k použití
	Výrobce
	Autorizovaný zástupce v Evropském společenství/ Evropské unii
	Posouzení shody v Evropě
	Posouzení shody ve Spojeném království
	Jedinečný identifikátor prostředku
	Vyrobeno ve Spojeném království
	Dovozce – označení subjektu, který dováží zdravotnický prostředek do dané lokality. Platí pro Evropskou unii

	Riziko ohrožení zdraví
	Chraňte před vlhkem



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Spojené království



2797

Technickou pomoc poskytně váš místní prodejce.

Informace o revizi

Verze	Datum vydání a provedené změny
3.0	28. 10. 2024 Drobné změny formátování Výstrahy a preventivní opatření byly opraveny tak, aby odpovídaly bezpečnostnímu listu Přidání symbolu „Chraňte před vlhkem“



www.thermofisher.com

Brilliance Candida-Selektiv-Supplement

DE

REF SR0231E

*Siehe zusätzliche IFUs für Brilliance Candida-Agar-Basis, Produktcodes CM1002B

Verwendungszweck

Brilliance™ Candida-Selektiv-Supplement (SR0231E) ist ein Fläschchen mit Chloramphenicol, das separat erhältlich ist und als Zusatz zu Brilliance Candida-Agar-Basis (CM1002B) zur Isolierung und Identifizierung von klinisch relevanten *Candida* spp. aus klinischen Proben und zur Identifizierung klinischer Isolate verwendet wird. Brilliance Candida-Agar-Basis (CM1002B) mit hinzugefügtem Brilliance Candida-Selektiv-Supplement (SR0231E) kann mit einer Vielzahl von Probentypen verwendet werden; Die Haupt Probenarten sind Sputum, Urin und Blut sowie Proben aus Bronchialsekret, Genitalien, Nase, Ohr, Rachen, Wunde, Haut, Gastrostomie und zentralen Venenkathetern.

Brilliance™ Candida-Selektiv-Supplement (SR0231E) wird in einem diagnostischen Arbeitsablauf verwendet, um Ärzte bei der Bestimmung potenzieller Behandlungsoptionen für Patienten mit Verdacht auf Candidose zu unterstützen. Das Produkt ist nur für den professionellen Gebrauch bestimmt; es ist weder automatisiert noch ein Begleitdiagnostikum.

Zusammenfassung und Erläuterung

Candida spp. sind kommensale Hefen, die normalerweise als Teil der Haut-, Mund-, Darm- und Vaginalflora des Menschen vorkommen¹. *Candida* spp. sind die Erreger von Candidose, einer Pilzinfektion, die typischerweise bei immungeschwächten Gruppen wie Kindern oder Personen mit HIV⁺¹⁻¹² auftritt. *Candida* spp. sind auch nosokomiale Krankheitserreger, wobei invasive medizinische Eingriffe wie Katheterisierung oder immunsuppressive Behandlung zur Inzidenz nosokomialer Candidose beitragen, wie Harnwegsinfektionen (HWI) und Blutbahninfektionen (Candidämie)⁸⁻¹³. Darüber hinaus erschwert das Auftreten von Antimykotika-Resistenzen bei *Candida* spp. die Behandlung und wirkt sich auf den Behandlungserfolg aus, insbesondere bei immungeschwächten oder hospitalisierten Personen¹⁴⁻¹⁸.

Methodenprinzip

Die Differenzierung klinisch wichtiger *Candida* spp. wird durch die Zugabe von zwei Chromogenen erreicht, auf die die spezifischen Enzyme Hexosaminidase und alkalische Phosphatase abzielen. Die Wirkung dieser Enzyme auf die Chromogene bewirkt die Freisetzung der gefärbten Komponente innerhalb der Hefezelle, was zu gefärbten Kolonien führt. Welche Farbe erzeugt wird, hängt davon ab, welche Enzyme die Organismen produzieren. Das Vorhandensein von Hexosaminidase bei *C. albicans* und *Candida dubliniensis* führt zu grünen/blauen Kolonien. Das Vorhandensein von Hexosaminidase bei *C. tropicalis*, sowie andere metabolische Reaktionen, die einen örtlich begrenzten pH-Abfall verursachen, führt zu dunkelblauen Kolonien. Das Vorhandensein von alkalischer Phosphatase bei *Candida krusei* führt zu braunen oder rosafarbenen Kolonien. Das Vorhandensein von alkalischer Phosphatase bei *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* und *Candida lusitanae* führt zu einer Vielzahl von beigen/braunen/gelben Farben aufgrund der Mischung aus natürlicher Pigmentierung und einer gewissen Aktivität der alkalischen Phosphatase. Erfahrene Anwender können diese Arten möglicherweise anhand der Farbe und Morphologie der Kolonie unterscheiden. Der undurchsichtige Hintergrund ermöglicht die Identifizierung von *Candida* spp., insbesondere wenn Mischinfektionen vorliegen. Das Medium enthält Chloramphenicol, das das Bakterienwachstum hemmt.

Typische Formulierung

Chloramphenicol 250,0 mg

Im Lieferumfang erhaltene Materialien

SR0231E: 10 x gefriergetrocknete Fläschchen für jeweils 500 ml Medium

Zusätzlich erforderliche, nicht im Lieferumfang enthaltene Materialien

- Brilliance Candida-Agar-Basis (dehydriert) Produktcode: CM1002B

Lagerung

- Produkt in der Originalverpackung zwischen 2 °C und 8 °C lagern.
- Das Produkt darf bis zum auf dem Etikett angegebenen Verfallsdatum verwendet werden.
- Vor Feuchtigkeit schützen.
- Vor Licht geschützt aufbewahren.
- Das rekonstituierte Produkt vor dem Gebrauch auf Raumtemperatur bringen.

Warnungen und Sicherheitsmaßnahmen



Signalwort: Gefahr

Gefahrenhinweise

H350 - Kann Krebs verursachen

Sicherheitshinweise

P280 - Schutzhandschuhe/Schutzkleidung tragen

P302 + P352 – BEI KONTAKT MIT DER HAUT: Mit viel Wasser und Seife waschen

P342 + P311 - Bei Symptomen der Atemwege: GIFTNOTRUFZENTRUM oder Arzt rufen

P201 - Vor Gebrauch besondere Anweisungen einholen

P308 + P313 – BEI Exposition oder falls betroffen: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen

P304 + P340 – BEI EINATMEN: Betroffene Person an die frische Luft bringen, um die Atmung zu erleichtern

Jedes Fläschchen ist zum einmaligen Gebrauch bestimmt. Nicht erneut verwenden.

Nur zur In-vitro-Diagnostik.

Nur für den professionellen Gebrauch.

Vor dem Öffnen die Produktverpackung untersuchen.

Das Produkt nicht verwenden, falls die Verpackung oder die Fläschchen sichtbare Beschädigungen aufweisen.

Das Produkt nicht über das Verfallsdatum hinaus verwenden.

Das Produkt nicht verwenden, falls Anzeichen für eine Kontamination vorliegen.

Das Produkt nicht verwenden, wenn sich die Farbe verändert hat oder andere Anzeichen für eine Produktverschlechterung vorliegen.

Es liegt in der Verantwortung jedes Labors, die anfallenden Abfälle entsprechend ihrer Art und ihres Gefährlichkeitsgrades zu behandeln und sie in Übereinstimmung mit den auf Bundes-, Landes- und lokaler Ebene geltenden Vorschriften zu behandeln oder zu entsorgen. Die Anweisungen müssen gelesen und genau befolgt werden. Dazu gehört auch die Entsorgung gebrauchter oder unbenutzter Reagenzien sowie anderer kontaminierter Einwegmaterialien gemäß den Verfahren für infektiöse oder potenziell infektiöse Produkte.

Informationen zur sicheren Handhabung und Entsorgung des Produkts finden Sie im Sicherheitsdatenblatt (SDB) (www.thermofisher.com).

Schwerwiegende Vorkommnisse

Alle schwerwiegenden Vorkommnisse, die im Zusammenhang mit dem Produkt aufgetreten sind, müssen dem Hersteller sowie der zuständigen Aufsichtsbehörde, in dem der Anwender und/oder Patient ansässig ist, gemeldet werden.

Entnahme, Handhabung und Lagerung von Proben

Proben sollten gemäß den lokalen empfohlenen Richtlinien entnommen und behandelt werden, wie die UK Standards for Microbiology Investigations (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 und S 6.

Verfahren
















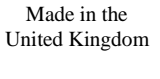
Geben Sie aseptisch 5 ml 70 %iges Ethanol in ein Fläschchen und mischen Sie vorsichtig, um den Inhalt vollständig aufzulösen. Geben Sie den Inhalt des Fläschchens wie angegeben zu 500 ml *Brilliance*™ Candida-Agar-basis (CM1002A/B) hinzu. Gut mischen und unter häufigem Rühren zum Kochen bringen. NICHT AUTOKLAVIEREN. Auf 45 °C abkühlen und in sterile Behälter füllen.




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Symbol-Legende

Symbol	Bedeutung
	Bestellnummer
	In-vitro-Diagnostikum
	Chargencode
	Temperaturgrenze
	Verwendbar bis
	Vor Sonnenlicht schützen
	Nicht wiederverwenden
	Gebrauchsanweisung beachten oder elektronische Anleitung zum Gebrauch konsultieren
	Inhalt ausreichend für <n> Tests
	Bei beschädigter Verpackung nicht verwenden und die Gebrauchsanweisung beachten
	Hersteller
	Bevollmächtigter in der Europäischen Gemeinschaft/ Europäische Union
	Europäische Konformitätsbewertung
	Britische Konformitätsbewertung
	Eindeutige Produktkennung
	Hergestellt im Vereinigten Königreich

	Importeur – Zur Angabe des Unternehmens, welches das Medizinprodukt in die Region einführt. Anwendbar auf die Europäische Union
	Gesundheitsgefährdung
	Trocken halten



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Vereinigtes Königreich



2797

Technische Unterstützung erhalten Sie von Ihrem Händler vor Ort.

Informationen zur Revision

Ausgabe-Nr.	Ausstellungsdatum und Änderungen eingefügt
3,0	28.10.2024 Kleinere Formatierungsänderungen Warnhinweise und Vorsichtsmaßnahmen wurden korrigiert, um dem Sicherheitsdatenblatt zu entsprechen Hinzufügung des Trockenhalten-Symbols



Εκλεκτικό συμπλήρωμα *Candida Brilliance*

EL

REF SR0231E

*Βλ. πρόσθετες οδηγίες χρήσης (IFU) για τους κωδικούς προϊόντος CM1002B βάσης άγαρ *Brilliance Candida Agar Base*

Προβλεπόμενη χρήση

Το εκλεκτικό συμπλήρωμα *Candida Brilliance™* (SR0231E) είναι ένα φιαλίδιο που περιέχει χλωραμφαινικόλη, το οποίο πωλείται χωριστά και χρησιμοποιείται ως συμπλήρωμα της βάσης άγαρ *Brilliance Candida Agar Base* (CM1002B) για την απομόνωση και την ταυτοποίηση κλινικά σημαντικών *Candida* spp. από κλινικά δείγματα και για την ταυτοποίηση κλινικών απομονωμένων στελεχών. Η βάση άγαρ *Brilliance Candida Agar Base* (CM1002B) με προσθήκη του εκλεκτικού συμπληρώματος *Candida Brilliance* (SR0231E) μπορεί να χρησιμοποιηθεί με διάφορους τύπους δειγμάτων. Οι κύριοι τύποι δειγμάτων περιλαμβάνουν δείγματα πτυέλων και ούρων, καθώς και δείγματα βρογχικών εκκρίσεων, γεννητικών οργάνων, ρινικών εκκρίσεων, ωτικού υγρού, τραχήλου, τραυμάτων, δέρματος, γαστροστομίας και κεντρικής φλεβικής γραμμής.

Το εκλεκτικό συμπλήρωμα *Candida Brilliance™* (SR0231E) χρησιμοποιείται σε μια διαγνωστική ροή εργασίας για να βοηθήσει τους κλινικούς ιατρούς στον καθορισμό πιθανών θεραπευτικών επιλογών για ασθενείς για τους οποίους υπάρχει υποψία καντινίασης. Το τεχνολογικό προϊόν προορίζεται αποκλειστικά για επαγγελματική χρήση, δεν είναι αυτοματοποιημένο και δεν αποτελεί συνοδευτικό διαγνωστικό μέσο.

Περίληψη και επεξήγηση

Οι *Candida* spp. είναι συμβιωτικοί ζυμομύκητες που αποτελούν φυσιολογικά μέρος της χλωρίδας του δέρματος, του στόματος, του εντέρου και του κόλπου του ανθρώπου¹. Οι *Candida* spp. είναι οι αιτιολογικοί παράγοντες της καντινίασης, μιας μυκητίασης που εμφανίζεται συνήθως σε ανοσοκατεσταλμένες ομάδες, όπως παιδιά ή άτομα με HIV¹⁻¹². Οι *Candida* spp. αποτελούν επίσης νοσοκομειακά παθογόνα, καθώς επεμβατικές ιατρικές παρεμβάσεις, όπως ο καθετηριασμός ή η ανοσοκατασταλτική θεραπεία, συμβάλλουν στην επίπτωση της νοσοκομειακής καντινίασης, όπως οι λοιμώξεις του ουροποιητικού συστήματος (UTI) και οι λοιμώξεις της κυκλοφορίας του αίματος (καντιναιμία)⁸⁻¹³. Επιπλέον, η εμφάνιση αντιμυκητιασικής ανθεκτικότητας στον *Candida* spp. περιπλέκει τη θεραπεία και επηρεάζει τις εκβάσεις των ασθενών, ειδικά σε ανοσοκατεσταλμένα άτομα ή άτομα που νοσηλεύονται¹⁴⁻¹⁸.

Αρχή της μεθόδου

Η διαφοροποίηση των κλινικά σημαντικών *Candida* spp. επιτυγχάνεται μέσω της συμπερίληψης δύο χρωμογόνων που στοχεύονται από τα ειδικά ένζυμα εξοζαμινιδάση και αλκαλική φωσφατάση. Η δράση αυτών των ενζύμων στα χρωμογόνα προκαλεί την απελευθέρωση του έγχρωμου συστατικού στο εσωτερικό του κυττάρου του μύκητα, με αποτέλεσμα τη δημιουργία έγχρωμων αποικιών. Το χρώμα που παράγεται εξαρτάται από τα ένζυμα που παράγουν οι μικροοργανισμοί. Η παρουσία εξοζαμινιδάσης στα είδη *C. albicans* και *Candida dubliniensis* οδηγεί σε πράσινες/μπλε αποικίες. Η παρουσία εξοζαμινιδάσης στο είδος *C. tropicalis* και άλλες μεταβολικές αντιδράσεις που προκαλούν τοπική πτώση του pH οδηγεί σε σκούρες μπλε αποικίες. Η παρουσία αλκαλικής φωσφατάσης στο είδος *Candida krusei* οδηγεί σε καφέ ή ροζ αποικίες. Η παρουσία αλκαλικής φωσφατάσης στα είδη *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* και *Candida lusitanae* οδηγεί σε μια ποικιλία μπλε/καφέ/κίτρινων χρωμάτων λόγω του μείγματος φυσικής μελάγχρωσης και κάποιας δραστηριότητας αλκαλικής φωσφατάσης. Οι έμπειροι χρήστες μπορεί να είναι σε θέση να διακρίνουν αυτά τα είδη από το χρώμα και τη μορφολογία των αποικιών. Το αδιαφανές υπόβαθρο επιτρέπει την ταυτοποίηση του *Candida* spp., ιδίως σε περιπτώσεις μικτών λοιμώξεων. Το μέσο περιέχει χλωραμφαινικόλη, η οποία αναστέλλει τη βακτηριακή ανάπτυξη.

Τυπική σύνθεση

Χλωραμφαινικόλη 250,0 mg

Υλικά που παρέχονται

SR0231E: 10x φιαλίδια ξηράς ψύξης, το καθένα επαρκεί για 500 ml μέσου

Υλικά που απαιτούνται αλλά δεν παρέχονται

- Βάση άγαρ *Brilliance Candida Agar Base* (αφυδατωμένο) κωδικός προϊόντος:CM1002B

Φύλαξη

- Φυλάσσετε το προϊόν στην αρχική του συσκευασία σε θερμοκρασία μεταξύ 2 °C και 8 °C.
- Το προϊόν μπορεί να χρησιμοποιηθεί μέχρι την ημερομηνία λήξης που αναγράφεται στην επισήμανση.
- Προστατεύετε από την υγρασία.
- Φυλάσσετε μακριά από το φως.
- Αφήστε το ανασταθέν προϊόν να ισορροπήσει σε θερμοκρασία δωματίου πριν από τη χρήση.

Προειδοποιήσεις και προφυλάξεις



Προειδοποιητική λέξη: Κίνδυνος

Δηλώσεις επικινδυνότητας
H350 - Μπορεί να προκαλέσει καρκίνο

Δηλώσεις προφύλαξης

P280 - Να φοράτε προστατευτικά γάντια/προστατευτικά ενδύματα

P302 + P352 - ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΠΑΦΗΣ ΜΕ ΤΟ ΔΕΡΜΑ: Πλύνετε με άφθονο νερό και σαπούνι

P342 + P311 - Εάν παρουσιάζονται αναπνευστικά συμπτώματα: Καλέστε το ΚΕΝΤΡΟ ΔΗΛΗΤΗΡΙΑΣΕΩΝ ή γιατρό

P201 - Εφοδιαστείτε με τις ειδικές οδηγίες πριν από τη χρήση

P308 + P313 - ΣΕ ΠΕΡΙΠΤΩΣΗ έκθεσης ή πιθανής έκθεσης: Συμβουλευθείτε/Επισκεφθείτε γιατρό

P304 + P340 - ΣΕ ΠΕΡΙΠΤΩΣΗ ΕΙΣΠΝΟΗΣ: Μεταφέρετε τον παθόντα στον καθαρό αέρα και αφήστε τον να ξεκουραστεί σε

στάση που διευκολύνει την αναπνοή

Κάθε φιαλίδιο προορίζεται για μία χρήση. Μην επαναχρησιμοποιείτε.

Μόνο για in vitro διαγνωστική χρήση.

Μόνο για επαγγελματική χρήση.

Επιθεωρήστε τη συσκευασία του προϊόντος πριν από την πρώτη χρήση.

Μη χρησιμοποιείτε το προϊόν εάν υπάρχει ορατή ζημιά στη συσκευασία ή στα φιαλίδια.

Μη χρησιμοποιείτε το προϊόν πέρα από την αναγραφόμενη ημερομηνία λήξης.

Μη χρησιμοποιείτε το προϊόν εάν υπάρχουν ενδείξεις επιμόλυνσης.

Μη χρησιμοποιείτε το προϊόν εάν έχει αλλάξει το χρώμα ή υπάρχουν άλλες ενδείξεις αλλοίωσης.

Αποτελεί ευθύνη κάθε εργαστηρίου να διαχειρίζεται τα απόβλητα που παράγονται σύμφωνα με τη φύση και τον βαθμό επικινδυνότητάς τους και να τα επεξεργάζεται ή να τα απορρίπτει σύμφωνα με τους ισχύοντες ομοσπονδιακούς, πολιτειακούς και τοπικούς κανονισμούς. Οι οδηγίες πρέπει να διαβάζονται και να ακολουθούνται προσεκτικά. Αυτό περιλαμβάνει την απόρριψη χρησιμοποιημένων ή αχρησιμοποίητων αντιδραστηρίων καθώς και οποιουδήποτε άλλου επιμολυσμένου υλικού μίας χρήσης, ακολουθώντας διαδικασίες για μολυσματικά ή δυνητικά μολυσματικά προϊόντα.

Ανατρέξτε στο Δελτίο Δεδομένων Ασφάλειας (SDS) για ασφαλή χειρισμό και απόρριψη του προϊόντος (www.thermofisher.com).

Σοβαρά συμβάντα

Κάθε σοβαρό συμβάν που έχει προκύψει σε σχέση με το ιατροτεχνολογικό προϊόν θα πρέπει να αναφέρεται στον κατασκευαστή και στη σχετική ρυθμιστική αρχή του κράτους στο οποίο είναι εγκατεστημένος ο χρήστης ή/και ο ασθενής.

Συλλογή, χειρισμός και φύλαξη δειγμάτων

Η συλλογή και ο χειρισμός των δειγμάτων θα πρέπει να πραγματοποιείται σύμφωνα με τις τοπικές συνιστώμενες κατευθυντήριες οδηγίες, όπως τα Πρότυπα του HB για Μικροβιολογικές Έρευνες (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 και S 6.

Διαδικασία

Προσθέστε με άσηπτη τεχνική 5 ml αιθανόλης 70 % σε ένα φιαλίδιο και ανακινήστε ήπια για να διαλυθεί εντελώς. Προσθέστε το περιεχόμενο του φιαλιδίου σε 500 ml βάσης άγαρ *Brilliance™* Candida Agar Base (CM1002B) σύμφωνα με τις οδηγίες.

Ανακινήστε καλά και φέρτε το σε σημείο βρασμού με συχνή ανάδευση. ΜΗΝ ΑΠΟΣΤΕΙΡΩΝΕΤΕ ΣΕ ΑΥΤΟΚΑΥΣΤΟ. Ψύξτε στους 45 °C και αδειάστε σε αποστειρωμένους περιέκτες.

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Επεξήγηση συμβόλων

Σύμβολο	Ορισμός
	Αριθμός καταλόγου
	In vitro διαγνωστικό ιατροτεχνολογικό προϊόν
	Κωδικός παρτίδας
	Όριο θερμοκρασίας
	Ημερομηνία λήξης
	Να φυλάσσεται μακριά από το ηλιακό φως
	Μην επαναχρησιμοποιείτε
	Συμβουλευτείτε τις οδηγίες χρήσης ή τις ηλεκτρονικές οδηγίες χρήσης
	Περιέχει επαρκή αντιδραστήρια για <n> δοκιμές
	Μην το χρησιμοποιείτε εάν η συσκευασία είναι κατεστραμμένη και συμβουλευτείτε τις οδηγίες χρήσης
	Κατασκευαστής
	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα/ Ευρωπαϊκή Ένωση
	Αξιολόγηση της Συμμόρφωσης στην Ευρώπη
	Αξιολόγηση της Συμμόρφωσης στο Ηνωμένο Βασίλειο
	Μοναδικό αναγνωριστικό ιατροτεχνολογικού προϊόντος

Made in the United Kingdom	Κατασκευάζεται στο Ηνωμένο Βασίλειο
	Εισαγωγέας - Υποδεικνύει την οντότητα που εισάγει το ιατροτεχνολογικό προϊόν στην περιοχή. Ισχύει για την Ευρωπαϊκή Ένωση
	Κίνδυνος για την υγεία
	Διατηρείτε στεγνό



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Ηνωμένο Βασίλειο



2797

Για τεχνική υποστήριξη, επικοινωνήστε με τον τοπικό διανομέα σας.

Πληροφορίες αναθεώρησης

Έκδοση	Ημερομηνία έκδοσης και τροποποιήσεις που εισηγήθηκαν
3.0	28-10-2024 Αλλαγές ήσσονος σημασίας στη μορφοποίηση Οι προειδοποιήσεις και οι προφυλάξεις διορθώθηκαν για να αντιστοιχούν στο SDS Προσθήκη του συμβόλου «Διατηρείτε στεγνό»



Suplemento selectivo Candida Brilliance

ES

REF SR0231E

*Véanse las instrucciones de uso adicionales para los códigos de producto CM1002B de la base de agar Candida Brilliance

Uso previsto

El suplemento selectivo Candida Brilliance™ (SR0231E) es un vial que contiene cloranfenicol, que se vende por separado y se utiliza para complementar la base de agar Candida Brilliance (CM1002B) para aislar e identificar especies de Candida clínicamente importantes tomadas de muestras clínicas y para identificar cepas aisladas clínicas. La base de agar Candida Brilliance (CM1002B) con el suplemento selectivo Candida Brilliance (SR0231E) agregado se puede usar con distintos tipos de muestras. Los principales tipos de muestras son esputo y orina, así como muestras de secreciones bronquiales, genitales, nasales, de oído, de garganta, de heridas, de piel, de gastrostomía y muestras tomadas de sitios de vías venosas centrales.

El suplemento selectivo para Candida Brilliance™ (SR0231E) se utiliza en un flujo de trabajo de diagnóstico para ayudar a los médicos a determinar posibles opciones de tratamiento para pacientes con sospecha de candidiasis. El producto es exclusivamente para uso profesional, no está automatizado y no es una prueba diagnóstica complementaria.

Resumen y explicación

Las especies del género Candida son levaduras comensales que se encuentran normalmente como parte de la flora cutánea, oral, intestinal y vaginal de los seres humanos¹. Las especies del género Candida son los agentes causales de la candidiasis, una infección fúngica que suele presentarse en grupos inmunodeficientes como niños o personas con VIH¹⁻¹². Asimismo, las especies de Candida también son patógenos nosocomiales en intervenciones médicas invasivas como el cateterismo o el tratamiento inmunosupresor y contribuyen a la incidencia de candidiasis nosocomiales, como infecciones de las vías urinarias (IVU) e infecciones del torrente sanguíneo (candidemia)⁸⁻¹³. Por otra parte, la aparición de resistencia antifúngica en especies de Candida complica el tratamiento y afecta a los resultados de los pacientes, especialmente en personas inmunodeficientes u hospitalizadas¹⁴⁻¹⁸.

Principio del método

La diferenciación de especies de Candida importantes desde el punto de vista clínico se logra mediante la inclusión de dos cromógenos que son el objetivo de las enzimas específicas hexosaminidasa y fosfatasa alcalina. La acción de estas enzimas en los cromógenos provoca la liberación del componente de color en el interior de la célula fúngica, lo que da lugar a colonias de colores. El color producido depende de las enzimas que generan los organismos. La presencia de hexosaminidasa en *C. albicans* y *Candida dubliniensis* da como resultado colonias de color verde/azul. La presencia de hexosaminidasa en *C. tropicalis* y otras reacciones metabólicas que provocan un descenso localizado del pH dan como resultado colonias de color azul oscuro. La presencia de fosfatasa alcalina en *Candida glabrata*, *Candida kefir*, *Candida parapsilosis* y *Candida lusitanae* da como resultado una serie de colores beige/marrón/amarillo debido a la mezcla de la pigmentación natural y a cierta actividad de la fosfatasa alcalina. Los usuarios con experiencia deben ser capaces de diferenciar estas especies por el color y la morfología de las colonias. El fondo opaco permite la identificación de especies del género *Candida*, especialmente cuando hay infecciones mixtas. El medio contiene cloranfenicol, que inhibe el crecimiento bacteriano.

Fórmula clásica

Cloranfenicol 250,0 mg

Materiales suministrados

SR0231E: 10 viales liofilizados para 500 ml de medio cada uno

Materiales necesarios, pero no suministrados

- Base de agar Candida Brilliance (deshidratada), código del producto: CM1002B

Almacenamiento

- Conserve el producto en su embalaje original a una temperatura de entre 2 °C y 8 °C.
- El producto se puede utilizar hasta la fecha de caducidad indicada en la etiqueta.
- Proteja el producto de la humedad.
- Conserve el producto protegido de la luz.
- Deje que el producto preparado se estabilice a temperatura ambiente antes de usarlo.

Advertencias y precauciones



Palabra de advertencia: peligro

Frases de peligro

H350: Puede causar cáncer

Consejos de prudencia

P280: Use guantes y ropa protectores

P302 + P352 - EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes

P342 + P311: Si presenta síntomas respiratorios: llame a un CENTRO DE INFORMACIÓN TOXICOLÓGICA o a un médico
P201: Obtenga instrucciones específicas antes del uso
P308 + P313 - En caso de exposición o sospecha de exposición: obtenga asesoramiento/atención médica
P304 + P340: SI SE INHALA: Llevar a la persona a una zona de aire fresco y mantenerla cómoda para que pueda respirar
Cada vial es para un solo uso. No reutilizar.
Solo para uso diagnóstico *in vitro*.

Solo para uso profesional.

Inspeccione el embalaje del producto antes de usarlo por primera vez.

No utilice el producto si presenta daños visibles en el embalaje o los viales.

No utilice el producto más allá de la fecha de caducidad indicada.

No utilice el producto si presenta signos de contaminación.

No utilice el producto si el color ha cambiado o hay otros signos de deterioro.

Es responsabilidad de cada laboratorio gestionar los residuos generados de acuerdo con su naturaleza y el grado de peligrosidad, y tratarlos o eliminarlos según las normativas federales, estatales y nacionales vigentes. Es necesario leer las instrucciones y seguirlas atentamente. Esto incluye la eliminación de reactivos usados o sin usar, así como cualquier otro material desechable contaminado según los procedimientos para productos infecciosos o potencialmente infecciosos.

Para manipular y eliminar el producto de manera segura, consulte la ficha de datos de seguridad (FDS) (www.thermofisher.com).

Incidentes graves

Cualquier incidente grave que se haya producido en relación con el producto deberá notificarse al fabricante y a las autoridades sanitarias pertinentes en las que esté establecido el usuario y/o paciente.

Obtención, manipulación y conservación de las muestras

La muestra debe obtenerse y manipularse conforme a las directrices locales recomendadas, como las Normas del Reino Unido para las Investigaciones Microbiológicas (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 y S 6.

Procedimiento

Añada asépticamente 5 ml de etanol al 70 % a un vial y mezcle suavemente para disolver completamente el contenido. Añada el contenido del vial a 500 ml de la base de agar Candida Brilliance™ (CM1002B) según las indicaciones. Mezcle bien y póngalo a hervir mientras se agita con frecuencia. NO TRATAR EN AUTOCLAVE. Refrigere a 45 °C y vierta el contenido en recipientes esterilizados.



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Leyenda de los símbolos

Símbolo	Definición
	Número de catálogo
	Producto sanitario para diagnóstico <i>in vitro</i>
	Código de lote
	Límite de temperatura
	Fecha de caducidad
	Mantener alejado de la luz solar
	No reutilizar
	Consulte las instrucciones de uso en papel o en formato electrónico
	Contiene la cantidad suficiente para <n> pruebas
	No utilice el producto si presenta daños en el embalaje y consulte las instrucciones de uso
	Fabricante
	Representante autorizado en la Comunidad Europea/ Unión Europea
	Declaración de conformidad europea
	Declaración de conformidad del Reino Unido
	Identificador único de producto
	Fabricado en el Reino Unido
	Importador: indicar la entidad que importa el producto sanitario a la localidad. Aplicable en la Unión Europea

	Peligro para la salud
	Mantener seco



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Reino Unido



2797

Para obtener asistencia técnica, póngase en contacto con su distribuidor local.

Información sobre revisiones

Versión	Fecha de publicación y modificaciones introducidas
3.0	28/10/2024 Pequeños cambios de formato Se corrigieron las advertencias y precauciones para que coincidieran con la SDS Adición del símbolo de «Mantener seco»



Brilliance Candida selektiivne lisand

ET

REF SR0231E

* Vaadake Brilliance Candida agarsöötme täiendavatest kasutusjuhenditest toote koode CM1002B

Sihtotstarve

Brilliance™ Candida selektiivne lisand (SR0231E) on klooramfenikooli sisaldav vial, mida müüakse eraldi ja kasutatakse Brilliance Candida agarsöötme (CM1002B) lisandina kliiniliselt olulise *Candida* spp. isoleerimiseks ja tuvastamiseks ning kliiniliste isolaatide tuvastamiseks. Brilliance Candida agarsöödet (CM1002B) koos Brilliance Candida selektiivse lisandiga (SR0231E) saab kasutada koos erinevate proovituüpidega; peamised proovituübid on röga ja uriin, samuti bronhisekreedi, suguelundite, nina-, kõrva-, kurgu-, haava-, naha-, gastrostoomi- ja tsentraalveenide piirkonna proovid.

Brilliance™ Candida selektiivset lisandit (SR0231E) kasutatakse diagnostilises töövoos, et aidata arstidel määrata võimalikke ravivõimalusi patsientidele, kellel kahtlustatakse kandidoosi. Seade on mõeldud ainult professionaalseks kasutamiseks, see pole automatiseeritud ega sobivusdiagnostikaseade.

Kokkuvõtte ja selgitus

Candida spp. on kommensaalsed pärmsened, mida leidub tavaliselt inimeste naha-, suu-, soole- ja tupefloora osana¹. *Candida* spp. on kandidoosi tekitavad agendid, see on seennakkus, mis esineb tavaliselt immuunpuudulikkusega rühmadel, nagu lapsed või HIV+ nakatunud isikud¹⁻¹². *Candida* spp. on ka nosokomiaalne patogeen, mille puhul on näidustatud invasiivne meditsiiniline sekkumine, nt kateteriseerimine või immunosuppressioonravi, mis soodustavad nosokomiaalset kandidoosi, nagu kuseteede infektsioonid (UTI) ja vereringeinfektsioonid (kandideemia)⁸⁻¹³. Lisaks raskendab *Candida* spp. pärmsenevastase resistentsuse tekkimine ravi ja mõjutab patsiendi tulemusi, eriti immuunpuudulikkusega või haiglaravil olevatel isikutel¹⁴⁻¹⁸.

Meetodi põhimõte

Kliiniliselt olulise *Candida* spp. eristamine saavutatakse kahe kromogeeni kaasamisega, millele on suunatud spetsiifilised ensüümid heksosaminidaas ja aluseline fosfataas. Nende ensüümide toime kromogeenidele põhjustab värvilise komponendi vabanemise pärmseneeraku sees, mille tulemusel tekivad värvilised kolooniad. Tekkiv värv sõltub sellest, milliseid ensüüme organismid toodavad. Heksosaminidaasi olemasolu *C. albicans*'is ja *Candida dubliniensis*'es tulemuseks on rohelised/sinised kolooniad. Heksosaminidaasi olemasolu *C. tropicalis*'es ja muud metaboolsed reaktsioonid, mis põhjustavad lokaalset pH langust, tekitavad tumesiniseid kolooniaid. Aluselise fosfataasi olemasolu *Candida krusei*'s tulemuseks on pruunid või roosad kolooniad. Aluselise fosfataasi olemasolu *Candida glabrata*'s, *Candida kefyr*'is, *Candida parapsilosis*'es ja *Candida lusitanae*'s tulemuseks on erinevad beežid/pruunid/kollased värvid tänu loodusliku pigmentatsiooni ja mõningase aluselise fosfataasi aktiivsuse segunemisele. Kogenud kasutajad võivad eristada neid liike värvi ja koloonia morfoloogia alusel. Läbipaistmatu taust võimaldab *Candida* spp. tuvastamist, eriti kui esinevad segainfektsioonid. Sööde sisaldab klooramfenikooli, mis pärsib bakterite kasvu.

Tüüpiline valem

Klooramfenikool 250,0 mg

Komplektis olevad materjalid

SR0231E: 10 külmuivatatud vialit, igas vialis 500 ml söödet

Vajalikud materjalid, mis ei kuulu komplekti

- Brilliance Candida agarsööde (dehüdreeritud) tootekood: CM1002B

Säilitamine

- Säilitada toodet originaalpakendis temperatuuril 2...8 °C.
- Toodet võib kasutada kuni etiketil näidatud aegumiskuupäevani.
- Kaitske niiskuse eest.
- Hoidke eemal valgusest.
- Enne kasutamist laske valmissegatud tootel toatemperatuurini soojeneda.

Hoiatused ja ettevaatusabinõud



Tunnussõna: Oht

Ohulaused

H350 – võib põhjustada vähki

Hoiatuslaused

P280 – kanda kaitsekindaid/kaitserõivastust

P302 + P352 – NAHALE SATTUMISE KORRAL: pesta rohke vee ja seebiga

P342 + P311 – hingamisteede sümptomite ilmnemisel: helistada mürgistuskeskusesse või arstile

P201 – enne kasutamist tutvuda erijuhistega

P308 + P313 – kokkupuute või kokkupuutekahtluse korral: pöörduda arsti poole

P304 + P340 – SISSEHINGAMISE KORRAL: viia kannatanu värske õhu kätte ja tagada hingamiseks mugav asend

Iga vial on ühekordseks kasutamiseks. Mitte korduskasutada.
Kasutamiseks ainult in vitro diagnostikas.
Üksnes kutsealaseks kasutamiseks.
Enne esmakordset kasutamist kontrollige toote pakendit.
Toodet mitte kasutada, kui pakendil või vialidel on nähtavaid kahjustusi.
Mitte kasutada toodet pärast märgitud kõlblikkusaja möödumist.
Ärge kasutage seadet, kui esineb saastumismärke.
Ärge kasutage seadet, kui värv on muutunud või esineb muid riknemise märke.
Iga labor vastutab tekkivate jäätmete käitlemise eest vastavalt nende liigile ja ohuastmele ning nende töötlemise või kõrvaldamise eest vastavalt riigi või kohalikele kehtivatele eeskirjadele. Juhiseid tuleb hoolikalt lugeda ja järgida. See hõlmab kasutatud või kasutamata reaktiivide ning muude saastunud ühekordselt kasutatavate materjalide kõrvaldamist pärast protseduure, mis on tehtud nakkusohutike või potentsiaalselt nakkusohutike toodetega.

Toote ohutu käitlemise ja kõrvaldamise kohta vaadake ohutuskaarti (Safety Data Sheet, SDS) (www.thermofisher.com).

Ohujuhtumid

Kõigist seadmega seotud ohujuhtumitest tuleb teavitada tootjat ja kasutaja ja/või patsiendi asukohariigi asjaomast järelevalveasutust.

Proovide kogumine, käsitsemine ja säilitamine

Proovide kogumisel ja käsitsemisel tuleb järgida kohalikke soovituslikke suuniseid, nt standardikogu UK Standards for Microbiology Investigations (UK SMI) dokumente ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 ja S 6.

Protseduur

Lisage ühte viali aseptiliselt 5 ml 70% etanooli, segage ettevaatlikult, et lahustada sisu täielikult. Lisage viali sisu 500 ml Brilliance™ *Candida* agarsöötmesse (CM1002B) vastavalt juhisele. Segage korralikult läbi ja kuumutage sagedase segamisega keemiseni. ÄRGE AUTOKLAAVIGE. Jahutage temperatuurini 45 °C.

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Sümbolite kirjeldus

Sümbol	Kirjeldus
	Katalooginumber
	<i>In vitro</i> diagnostikameditsiiniseade
	Partii kood
	Temperatuuripiirang
	Aegumiskuupäev
	Hoida päikesevalguse eest
	Ei ole korduskasutatav
	Lugeda kasutusjuhendit või elektroonilist kasutusjuhendit
	Sisaldab piisavalt <n> testi jaoks
	Mitte kasutada, kui pakend on kahjustunud, ja lugeda kasutusjuhendit
	Tootja
	Volitatud esindaja Euroopa Ühenduses / Euroopa Liidus
	Euroopa vastavushindamine
	Ühendkuningriigi vastavushindamine
	Seadme kordumatu identifitseerimistunnus
	Valmistatud Ühendkuningriigis
	Importija – tähistab meditsiiniseadme kohalikku importijat. Kehtib Euroopa Liidus
	Oht tervisele
	Hoida kuivas



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Ühendkuningriik



2797

Tehnilise abi saamiseks võtke ühendust kohaliku edasimüüjaga.

Muudatuste teave

Versioon	Väljaandmiskuupäev ja tehtud muudatused
3.0	28.10.2024 Väikesed vormingumuudatused Jaotist „Hoiatused ja ettevaatusabinõud“ parandati, et need vastaksid ohutuskaardile Kuivas hoidmise sümboli lisamine

**Supplément sélectif pour gélose Candida Brilliance™**

FR

REF SR0231E

*Voir les notices d'utilisation supplémentaires pour la base de gélose pour Candida Brilliance, code de produit CM1002B

Utilisation prévue

Le supplément sélectif pour Candida Brilliance™ (SR0231E) est un flacon contenant du chloramphénicol, qui est vendu séparément et utilisé afin de compléter la base de gélose pour Candida Brilliance (CM1002B) qui permet d'identifier et d'isoler des *Candida* spp. cliniquement importants à partir d'échantillons cliniques et d'identifier les isolats cliniques. La base de gélose pour Candida Brilliance (CM1002) avec le supplément sélectif pour Candida Brilliance (SR0231E) ajouté peut être utilisée avec différents types d'échantillons ; les principaux types d'échantillons sont les expectorations et les échantillons d'urine, ainsi que les échantillons provenant de sécrétions bronchiques, les échantillons génitaux, nasaux, auriculaires, oropharyngés, les échantillons provenant de plaies, cutanés, les échantillons provenant de gastrostomie et de site de voie veineuse centrale.

Le supplément sélectif pour Candida Brilliance™ (SR0231E) est utilisé dans le processus diagnostique afin d'aider les cliniciens à déterminer d'éventuelles options thérapeutiques chez les patients présumés atteints d'une infection à candidose. Le produit est destiné à un usage professionnel uniquement, n'est pas automatisé et n'est pas un diagnostic compagnon.

Résumé et explications

Les *Candida* spp. sont des levures commensales que l'on trouve normalement dans la flore cutanée, buccale, intestinale et vaginale chez l'être humain¹. Les *Candida* spp. sont les agents responsables de la candidose, une infection fongique qui survient généralement chez les groupes immunodéprimés tels que les enfants ou les personnes atteintes du VIH¹⁻¹². Les *Candida* spp. sont également des agents pathogènes nosocomiaux, et certaines interventions médicales invasives telles que le cathétérisme ou les traitements immunosuppresseurs contribuent à l'incidence de la candidose nosocomiale, comme dans le cas des infections des voies urinaires (IVU) et des infections du sang (candidémie)⁹⁻¹³. De plus, l'émergence d'une résistance antifongique dans les *Candida* spp. complique le traitement et a un impact sur l'évolution de l'état de santé des patients, en particulier chez les personnes immunodéprimées ou hospitalisées¹⁴⁻¹⁸.

Principe de la méthode

La différenciation cliniquement importante des *Candida* spp. est obtenue grâce à l'inclusion de deux chromogènes ciblés par des enzymes spécifiques, l'hexosaminidase et la phosphatase alcaline. L'action de ces enzymes sur les chromogènes provoque la libération du composant coloré à l'intérieur de la cellule fongique, donnant naissance à des colonies colorées. La couleur obtenue dépend des enzymes produites par les organismes. La présence d'hexosaminidase dans *C. albicans* et *Candida dubliniensis* donne des colonies vertes/bleues. La présence d'hexosaminidase dans *C. tropicalis* et d'autres réactions métaboliques qui provoquent une baisse localisée du pH entraîne la formation de colonies bleu foncé. La présence de phosphatase alcaline dans *Candida krusei* donne des colonies brunes ou roses. La présence de phosphatase alcaline dans *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* et *Candida lusitanae* entraîne une variété de couleurs beige/brun/jaune en raison du mélange de pigmentation naturelle et d'une certaine activité de la phosphatase alcaline. Les utilisateurs expérimentés peuvent être capables de différencier ces espèces par la couleur et la morphologie de la colonie. Le fond opaque permet l'identification des *Candida* spp., en particulier lorsque des infections mixtes sont présentes. Le milieu contient du chloramphénicol, qui inhibe la croissance bactérienne.

Formule classique

Chloramphénicol 250,0 mg

Matériel fourni

SR0231E : 10 flacons lyophilisés chacun pour 500 ml de milieu

Matériel requis, mais non fourni

- Base de gélose pour Candida Brilliance, code de produit :CM1002B

Stockage

- Conserver le produit dans son emballage d'origine entre 2°C et 8°C.
- Le produit peut être utilisé jusqu'à la date limite d'utilisation mentionnée sur l'étiquette.
- Protéger de l'humidité.
- Conserver à l'abri de la lumière.
- Laisser le produit reconstitué revenir à température ambiante avant utilisation.

Avertissements et précautions**Mot indicateur : Danger**

Mentions de danger

H350 — Peut provoquer le cancer

Consignes de prudence

P280 — Porter des gants de protection/des vêtements de protection

P302 + P352 — EN CAS DE CONTACT AVEC LA PEAU : Laver abondamment à l'eau et au savon
P342 + P311 — En cas de symptômes respiratoires : Appeler un CENTRE ANTIPOISON ou un médecin
P201 — Se procurer les instructions spécifiques avant utilisation
P308 + P313 — EN CAS D'EXPOSITION OU D'INQUIÉTUDE : obtenir des conseils/une attention médicale
P304 + P340 — EN CAS D'INHALATION : transporter la personne à l'extérieur et la maintenir dans une position où elle peut confortablement respirer
Chaque flacon est réservé à un usage unique. Ne pas réutiliser.
Réservé à un usage diagnostique in vitro.
Réservé à un usage professionnel.
Vérifier l'emballage du produit avant la première utilisation.
Ne pas utiliser le produit si l'emballage ou les flacons présentent des dommages visibles.
Ne pas utiliser le produit au-delà de la date limite d'utilisation indiquée.
Ne pas utiliser le dispositif en cas de signes de contamination.
Ne pas utiliser le dispositif si la couleur a changé ou si d'autres signes de détérioration apparaissent.
Il incombe à chaque laboratoire de gérer les déchets produits conformément à leur nature et à leur degré de dangerosité et de les traiter ou de les éliminer conformément aux réglementations fédérales, nationales et locales applicables. Ces instructions doivent être lues attentivement et appliquées avec soin. Cela inclut l'élimination des réactifs utilisés ou non ainsi que de tout autre matériel jetable contaminé, conformément aux procédures relatives aux produits infectieux ou potentiellement infectieux.

Pour en savoir plus sur la manipulation et l'élimination sans danger du produit, consulter la fiche de données de sécurité (FDS) (www.thermofisher.com).

Incidents graves

Il convient de signaler tout incident grave survenu en lien avec le dispositif au fabricant et à l'autorité de régulation concernée dans le pays où l'utilisateur et/ou le patient sont établis.

Prélèvement, manipulation et stockage des échantillons

Les échantillons doivent être prélevés et manipulés conformément aux directives locales recommandées, telles que les UK Standards for Microbiology Investigations (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 et S 6.

Procédure
















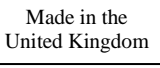

De façon aseptique, ajouter 5 ml d'éthanol à 70 % dans un flacon et mélanger délicatement pour dissoudre entièrement le contenu. Ajouter le contenu du flacon à 500 ml de base de gélose pour *Candida Brilliance*[™] (CM1002B) conformément aux instructions. Bien mélanger et porter à ébullition en remuant fréquemment. NE PAS AUTOCLAVER. Refroidir jusqu'à 45°C, bien mélanger et verser dans des contenants stériles.



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Légende des symboles

Symbole	Définition
	Référence catalogue
	Dispositif médical de diagnostic in vitro
	Code de lot
	Limite de température
	Date de péremption
	Tenir à l'abri de la lumière directe du soleil
	Ne pas réutiliser
	Consulter le mode d'emploi ou consulter la version électronique du mode d'emploi
	Contenu suffisant pour <n> tests
	Ne pas utiliser si l'emballage est endommagé et consulter le mode d'emploi
	Fabricant
	Représentant autorisé au sein de la Communauté européenne/ Union européenne
	Système européen d'évaluation de la conformité
	Système d'évaluation de la conformité du Royaume-Uni
	Identifiant unique du dispositif
	Fabriqué au Royaume-Uni
	Importateur – Pour indiquer l'entité qui importe le dispositif médical

	localement. Applicable à l'Union européenne
	Risques pour la santé
	Garder au sec



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2797

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Informations concernant les révisions

Version	Date de publication et des modifications apportées
3.0	28-10-2024 Modifications mineures apportées à la mise en page Avertissements et précautions corrigées pour correspondre à la FDS Ajout du symbole Garder au sec

**Selektivni dodatak Candida Brilliance**

HR

REF SR0231E

*Pogledajte dodatne upute za uporabu za agar bazu *Brilliance* Candida sa šifrom proizvoda CM1002B**Namjena**

Selektivni dodatak *Candida Brilliance*TM (SR0231E) bočica je koja sadrži kloramfenikol, koja se prodaje zasebno i koristi se kao dodatak agar bazi *Candida Brilliance* (CM1002B) za izolaciju i identifikaciju klinički važnih *Candida* spp. iz kliničkih uzoraka, kao i za identifikaciju kliničkih izolata. *Agar baza Candida Brilliance* (CM1002B) sa selektivnim dodatkom *Candida Brilliance* (SR0231E) može se koristiti s različitim vrstama uzoraka; glavne su vrste uzoraka sputum i urin, kao i uzorci bronhijalnog sekreta, uzorci s genitalija, nosa, uha, grla, rana, kože, gastrostome i sa središnjeg venskog katetera.

Selektivni dodatak *Candida Brilliance*TM (SR0231E) koristi se u dijagnostičkom tijeku rada kao pomoć kliničarima u određivanju potencijalnih mogućnosti liječenja pacijenata kod kojih postoji sumnja na kandidijazu. Proizvod je namijenjen samo za profesionalnu uporabu, nije automatiziran niti je nadopuna dijagnostičkim postupcima.

Sažetak i objašnjenje

Candida spp. kmenzalne su kvasnice koje se nalaze kao dio normalne ljudske flore kože, usne šupljine, crijeva i vagine¹. *Candida* spp. uzročnik je kandidijaze, gljivične infekcije koja se obično javlja kod imunokompromitiranih skupina poput djece ili osoba pozitivnih na virus HIV-a¹⁻¹². *Candida* spp. također je nozokomijalni patogen, pri čemu invazivne medicinske intervencije, poput kateterizacije ili imunosupresivnog liječenja, doprinose učestalosti nozokomijalne kandidijaze, poput infekcija mokraćnog sustava (IMS) i infekcija krvotoka (kandidemija)⁸⁻¹³. Štoviše, pojava antifungalne rezistencije kod *Candida* spp. komplicira liječenje i utječe na ishode pacijenata, posebno kod imunokompromitiranih ili hospitaliziranih osoba¹⁴⁻¹⁸.

Načelo metode

Diferencijacija klinički važnih *Candida* spp. postiže se uključivanjem dvaju kromogena koja ciljaju specifični enzimi heksozaminidaza i alkalna fosfatasa. Djelovanje tih enzima na kromogene uzrokuje oslobađanje obojene komponente unutar stanica gljivice, što za posljedicu ima obojene kolonije. Boja koja se razvije ovisi o tome koje enzime organizmi proizvode. Prisutnost heksozaminidaze u gljivicama *C. albicans* i *Candida dubliniensis* rezultira zelenim/plavim kolonijama. Prisutnost heksozaminidaze u gljivici *C. tropicalis* i druge metaboličke reakcije koje uzrokuju lokalizirani pad pH vrijednosti rezultiraju tamnoplavim kolonijama. Prisutnost alkalne fosfatase u gljivici *Candida krusei* rezultira smeđim ili ružičastim kolonijama. Prisutnost alkalne fosfatase u gljivicama *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* i *Candida lusitanae* rezultira raznim bež/smeđim/žutim bojama zbog mješavine prirodne pigmentacije i određene aktivnosti alkalne fosfatase. Iskusni korisnici mogu razlikovati ove vrste prema boji i morfologiji kolonije. Neprozirna pozadina omogućuje identifikaciju *Candida* spp., posebno kada su prisutne mješovite infekcije. Medij sadrži kloramfenikol, koji inhibira rast bakterija.

Uobičajena formula

Kloramfenikol 250,0 mg

Isporučeni materijali

SR0231E: 10 liofiliziranih bočica, svaka za 500 ml medija

Potrebni materijali koji nisu isporučeni

- *Agar baza Candida Brilliance* (dehidrirana) sa šifrom proizvoda: CM1002B

Skladištenje

- Čuvajte proizvod u originalnom pakiranju na temperaturi od 2 °C do 8 °C.
- Proizvod se može koristiti do isteka roka valjanosti navedenog na naljepnici.
- Zaštitite od vlage.
- Čuvajte podalje od svjetla.
- Prije uporabe pustite da rekonstituirani proizvod postigne sobnu temperaturu.

Upozorenja i mjere opreza**Signalna riječ: opasnost**Izjave o opasnosti
H350 – može izazvati rak

Izjave o predostrožnosti

P280 – nositi zaštitne rukavice / zaštitnu odjeću

P302 + P352 – U SLUČAJU DODIRA S KOŽOM: obilno isprati sapunom i vodom

P342 + P311 – ako osjetite respiratorne simptome, nazovite CENTAR ZA KONTROLU OTROVANJA ili liječnika

P201 – prije uporabe pribaviti posebne upute

P308 + P313 – U SLUČAJU izloženosti ili zabrinutosti: zatražiti savjet/pomoć liječnika

P304 + P340 – AKO SE UDAHNE: premjestiti osobu na svjež zrak i postaviti je u položaj koji olakšava disanje

Svaka je bočica namijenjena za jednokratnu uporabu. Nemojte ponovno upotrebljavati.

Samo za *in vitro* dijagnostičku uporabu.

Samo za profesionalnu uporabu.

Pregledajte pakiranje proizvoda prije prve uporabe.

Nemojte upotrebljavati proizvod ako ima vidljivih oštećenja na pakiranju ili bočicama.

Ne upotrebljavajte proizvod nakon isteka navedenog roka valjanosti.

Nemojte upotrebljavati proizvod ako su prisutni znakovi kontaminacije.

Nemojte upotrebljavati proizvod ako je došlo do promjene boje ili su prisutni drugi znakovi narušenja kvalitete.

Svaki je laboratorij odgovoran za upravljanje nastalim otpadom u skladu s prirodom i stupnjem opasnosti otpada te za njegovu obradu ili zbrinjavanje u skladu s primjenjivim saveznim, državnim i lokalnim propisima. Potrebno je pročitati upute i pažljivo ih se pridržavati. To uključuje odlaganje iskorištenih ili neiskorištenih reagensa, kao i bilo kojeg drugog kontaminiranog materijala za jednokratnu uporabu, uz pridržavanje postupaka za zarazne ili potencijalno zarazne proizvode.

Proučite Sigurnosno-tehnički list (engl. *Safety Data Sheet*, SDS), koji sadržava informacije za sigurno rukovanje proizvodom i njegovo odlaganje (www.thermofisher.com).

Ozbiljni štetni događaji

Svi ozbiljni štetni događaji do kojih dođe u vezi s proizvodom moraju se prijaviti proizvođaču i nadležnom regulatornom tijelu u zemlji u kojoj korisnik i/ili bolesnik živi.

Prikupljanje uzoraka, rukovanje i skladištenje

Uzorak treba prikupiti i s njim postupati u skladu s lokalnim preporučenim smjernicama, kao što su Standardi za mikrobiološka istraživanja u Ujedinjenom Kraljevstvu (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 i S 6.

Postupak

U jednu bočicu aseptično dodajte 5 ml 70 %-tnog etanola i lagano promiješajte sadržaj da se potpuno rastopi. Sadržaj bočice dodajte u 500 ml agar baze *Candida Brilliance™* (CM1002B) prema uputama. Dobro promiješajte i uz često miješanje dovedite suspenziju do vrenja. NEMOJTE AUTOKLAVIRATI. Ohladite na 45 °C i ulijte u sterilne spremnike.

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Kazalo simbola

Simbol	Definicija
	Kataloški broj
	<i>In vitro</i> dijagnostički medicinski proizvod
	Šifra serije
	Ograničenje temperature
	Upotrijebiti do
	Zaštite od sunčeve svjetlosti
	Nemojte ponovno upotrebljavati
	Proučite upute za uporabu ili pogledajte elektroničke upute za uporabu
	Sadrži dovoljnu količinu za <n> testova
	Ne upotrebljavati ako je pakiranje oštećeno; proučite upute za uporabu
	Proizvođač
	Ovlašteni zastupnik u Europskoj zajednici / Europskoj uniji
	Europska procjena sukladnosti
	Procjena sukladnosti u Ujedinjenom Kraljevstvu
	Jedinstvena identifikacija proizvoda
	Proizvedeno u Ujedinjenom Kraljevstvu
	Uvoznik – za označivanje subjekta koji uvozi medicinski proizvod na lokalno tržište. Primjenjuje se na Europsku uniju
	Opasnost za zdravlje
	Čuvati na suhom



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2797

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Informacije o reviziji

Inačica	Datum izdavanja i uvedene izmjene
3.0	28. listopada 2024. Manje izmjene formatiranja Podaci iz upozorenja i mjera opreza ispravljani kako bi odgovarali onima iz sigurnosno-tehničkog lista (STL) Dodavanje simbola „Čuvati na suhom”



Brilliance Candida Selective Supplement**IT****REF SR0231E***Consultare le ulteriori Istruzioni per l'uso relative ai codici prodotto CM1002B di *Brilliance Candida Agar Base***Uso previsto**

Brilliance™ Candida Selective Supplement (SR0231E) è una fiala contenente cloramfenicolo, venduto separatamente, che si utilizza per arricchire *Brilliance Candida Agar Base (CM1002B)* per l'isolamento e l'identificazione di specie di *Candida* clinicamente rilevanti da campioni clinici, nonché per l'identificazione di isolati clinici. *Brilliance Candida Agar Base (CM1002B)* arricchito con *Brilliance Candida Selective Supplement (SR0231E)* può essere utilizzato con campioni provenienti da varie fonti, in particolare da espettorato e urine, nonché campioni di secrezione bronchiale, genitale, nasale, dell'orecchio, della gola, della ferita, della pelle, della gastrostomia e della linea venosa centrale.

Brilliance™ Candida Selective Supplement (SR0231E) si utilizza in un flusso di lavoro diagnostico per orientare i medici nella scelta di potenziali opzioni terapeutiche per il trattamento di pazienti con sospetta candidosi. Il dispositivo è esclusivamente per uso professionale, non è automatizzato e non è adatto per la diagnostica di accompagnamento.

Riepilogo e spiegazione

Le specie del genere *Candida* sono lieviti commensali normalmente presenti nell'uomo nella flora cutanea, orale, intestinale e vaginale¹. Sono responsabili della candidosi, un'infezione fungina che interessa in genere i soggetti immunocompromessi, ad esempio bambini o individui con HIV+¹⁻¹². Le specie di *Candida* sono inoltre patogeni nosocomiali; le procedure mediche invasive, come la cateterizzazione o il trattamento immunosoppressivo, hanno un impatto significativo sull'incidenza delle candidosi nosocomiali, quali infezioni delle vie urinarie (*Urinary Tract Infection*, [UTI]) e del torrente ematico (candidemia)⁸⁻¹³. Inoltre, lo sviluppo di una resistenza agli antimicotici nelle specie di *Candida* complica il trattamento e ha un impatto sugli esiti dei pazienti, specialmente in individui immunocompromessi o ospedalizzati¹⁴⁻¹⁸.

Principio del metodo

La differenziazione delle specie di *Candida* clinicamente rilevanti si ottiene con la concomitante presenza di due cromogeni target degli enzimi esosaminidasi e fosfatasi alcalina. L'azione di questi enzimi sui cromogeni causa il rilascio di un cromoforo all'interno della cellula fungina, che conferisce un tipico colore alle colonie. Il colore dipende dagli enzimi che il microorganismo produce. La presenza di esosaminidasi nelle colonie di *C. albicans* e *Candida dubliniensis* dà origine a colonie verde/blu. La presenza di esosaminidasi nelle colonie di *C. tropicalis*, insieme ad altre reazioni metaboliche che causano un abbassamento localizzato del pH, produce colonie di colore blu scuro. La presenza di fosfatasi alcalina nelle colonie di *Candida krusei* dà origine a colonie di colore marrone o rosa. La presenza di fosfatasi alcalina nelle colonie di *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* e *Candida lusitanae* dà origine a una varietà di colori beige, marrone o giallo, dovuti alla combinazione tra pigmentazione naturale e una certa attività della fosfatasi alcalina. L'esperienza dell'utilizzatore può aiutare a differenziare tali specie in base alle caratteristiche cromatiche e morfologiche delle colonie. Lo sfondo opaco consente l'identificazione di *Candida* spp., soprattutto in presenza di infezioni miste. Il terreno contiene cloramfenicolo, che inibisce la crescita batterica.

Formula tipica

Cloramfenicolo 250,0 mg

Materiali forniti

SR0231E: 10 fiale di liofilizzato, ciascuna per 500 mL di terreno

Materiali necessari ma non forniti

- *Brilliance Candida Agar Base* (disidratato) codice prodotto:CM1002B

Conservazione

- Conservare il prodotto nella sua confezione originale a una temperatura compresa tra 2 °C e 8 °C.
- Il prodotto può essere utilizzato fino alla data di scadenza indicata sull'etichetta.
- Proteggere dall'umidità.
- Conservare al riparo dalla luce.
- Attendere che il prodotto ricostituito raggiunga la temperatura ambiente prima dell'uso.

Avvertenze e precauzioni**Parola di segnalazione: pericolo**

Frase di rischio

H350 - Può provocare il cancro

Consigli di prudenza

P280 - Indossare guanti/indumenti protettivi

P302 + P352 - IN CASO DI CONTATTO CON LA PELLE: lavare abbondantemente con acqua e sapone

P342 + P311 - In caso di sintomi respiratori: contattare un CENTRO ANTIVELENI o un medico

P201 - Procurarsi istruzioni specifiche prima dell'uso

P308 + P313 - IN CASO di esposizione o di possibile esposizione, consultare un medico
P304 + P340 - IN CASO DI INALAZIONE: trasportare l'infortunato all'aria aperta e mantenerlo a riposo in posizione che favorisca la respirazione
Ogni fiala è monouso. Non riutilizzare.
Esclusivamente per uso diagnostico in vitro.
Solo per uso professionale.
Ispezionare la confezione del prodotto prima del primo utilizzo.
Non utilizzare il prodotto se sono presenti danni visibili all'imballaggio o alle fiale.
Non utilizzare il prodotto oltre la data di scadenza indicata sull'etichetta.
Non utilizzare il dispositivo in presenza di tracce di contaminazione.
Non utilizzare il dispositivo se ha cambiato colore o se sono presenti altri segni di deterioramento.
Ogni laboratorio è tenuto a gestire i rifiuti prodotti in base alla loro natura e al grado di rischio e a far sì che siano trattati o smaltiti in conformità alle normative statali, regionali e locali applicabili. Leggere e seguire attentamente le indicazioni. Ciò include lo smaltimento dei reagenti utilizzati o inutilizzati, nonché di qualsiasi altro materiale contaminato monouso, secondo le procedure per i prodotti infettivi o potenzialmente infettivi.

Per un utilizzo e uno smaltimento sicuri del prodotto, fare riferimento alla scheda dei dati di sicurezza (*Safety Data Sheet*, [SDS]) (www.thermofisher.com).

Incidenti gravi

Qualsiasi incidente grave verificatosi in relazione al dispositivo deve essere segnalato al fabbricante e all'autorità normativa competente del Paese in cui risiede l'utilizzatore e/o il paziente.

Prelievo, manipolazione e conservazione dei campioni

Il campione deve essere prelevato e manipolato in conformità con le linee guida locali raccomandate, come le Procedure standard del Regno Unito per le ricerche microbiologiche (*UK Standards for Microbiology Investigations*, [UK SMI]) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 e S 6.

Procedura

Versare asepticamente 5 mL di etanolo al 70% in un flaconcino e mescolare delicatamente fino a completa dissoluzione del contenuto. Aggiungere il contenuto della fiala a 500 mL di *Brilliance™* Candida Agar Base (CM1002B) come indicato. Mescolare bene e portare a ebollizione, agitando frequentemente. NON STERILIZZARE IN AUTOCLAVE. Raffreddare a 45 °C e versare in contenitori sterili.



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Legenda dei simboli

Simbolo	Definizione
	Numero di catalogo
	Dispositivo medico-diagnostico <i>in vitro</i>
	Codice lotto
	Limite di temperatura
	Utilizzare entro
	Tenere lontano dalla luce diretta del sole
	Non riutilizzare
	Consultare le istruzioni per l'uso in formato cartaceo o elettronico
	Sufficiente per <n> test
	Non utilizzare se la confezione è danneggiata e consultare le istruzioni per l'uso
	Fabbricante
	Rappresentante autorizzato per la Comunità Europea/ Unione Europea
	Valutazione di conformità per l'Europa
	Valutazione di conformità per il Regno Unito
	Identificativo unico del dispositivo
	Fabbricato nel Regno Unito
	Importatore: indicare l'entità che importa il dispositivo medico nel mercato locale. Applicabile all'Unione Europea

	Pericolo per la salute
	Conservare in luogo asciutto



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, UK



2797

Per assistenza tecnica, rivolgersi al distributore locale.

Informazioni sulla revisione

Versione	Data di pubblicazione e modifiche apportate
3.0	28-10-2024 Piccole modifiche di formattazione Avvertenze e precauzioni corrette per corrispondere alla SDS Aggiunto il simbolo Conservare in luogo asciutto



Brilliance Candida Selective Supplement

NO

REF SR0231E

*Se ytterligere bruksanvisninger for produktkodene CM1002B for Brilliance Candida Agar Base.

Tiltenkt bruk

Brilliance™ Candida Selective Supplement (SR0231E) er et hetteglass som inneholder kloramfenikol, som selges separat og brukes som supplement til Brilliance Candida Agar Base (CM1002B) for isolering og identifisering av klinisk viktige *Candida*spp. fra kliniske prøver, og for identifisering av kliniske isolater. Brilliance Candida Agar Base (CM1002B) med tilsatt Brilliance Candida Selective Supplement (SR0231E) kan brukes med en rekke prøvetyper. De viktigste prøvetyperne er sputum og urin, samt prøver fra bronkial sekresjon, genitalprøver, neseprøver, øreprøver, halsprøver, sårprøver, hudprøver, prøver fra gastrotomi og prøver fra sentrale venekatetre.

Brilliance™ Candida Selective Supplement (SR0231E) brukes i en diagnostisk arbeidsflyt for å hjelpe klinikere med å bestemme potensielle behandlingsalternativer for pasienter som mistenkes å ha candidiasis. Enheten skal kun brukes av fagpersoner, er ikke automatisert og er heller ikke beregnet som behandlingsveiledende diagnostikk.

Sammendrag og forklaring

Candida spp. er kommensale sopparter som normalt finnes i huden, munnen, tarmen og den vaginale floraen hos mennesker¹. *Candida* spp. er organismene som forårsaker Candidiasis, en soppinfeksjon som vanligvis oppstår hos grupper som har svekket immunforsvar, som barn eller personer med HIV¹⁻¹². *Candida* spp. er også nosokomale patogener, der invasive medisinske intervensjoner som kateterisering eller behandling mot svekket immunforsvar bidrar til forekomsten av nosokomial candidiasis, som urinveisinfeksjoner (UTI-er) og infeksjoner i blodbanen (candidemi)⁸⁻¹³. Utvikling av resistens mot soppdrepende midler hos *Candida* spp. vanskeliggjør behandling og påvirker pasientutfall, spesielt hos personer med svekket immunforsvar eller pasienter innlagt på sykehus¹⁴⁻¹⁸.

Metodeprinsipp

Differensiering av klinisk signifikant *Candida* spp. oppnås ved å inkludere to kromogener som er målrettet med de spesifikke enzymene heksosaminidase og alkalisk fosfatase. Disse enzymenes virkning på kromogenene fører til frigivelse av den fargede komponenten inne i bakteriecellen, noe som resulterer i fargede kolonier. Fargen som produseres, beror på hvilke enzymer som organismene produserer. Tilstedeværelse av heksosaminidase i *C. albicans* og *Candida dubliniensis* resulterer i grønne/blå kolonier. Tilstedeværelse av heksosaminidase i *C. tropicalis* og andre metabolske reaksjoner som forårsaker lokalt fall i pH, resulterer i mørkeblå kolonier. Tilstedeværelse av alkalisk fosfatase i *Candida krusei* resulterer i brune eller rosa kolonier. Tilstedeværelse av alkalisk fosfatase i *Candida glabrata*, *Candida kefyr*, *Candida parapsilose* og *Candida lusitanae* resulterer i en rekke beige/brune/gule farger på grunn av blandingen av naturlig pigmentering og noe alkalisk fosfataseaktivitet. Det kan være mulig for erfarne brukere å skille disse artene etter farge og kolonimorfologi. Den ugjennomsiktige bakgrunnen muliggjør identifisering av *Candida* spp., spesielt når blandede infeksjoner er til stede. Mediet inneholder kloramfenikol, som hemmer bakterievekst.

Vanlig formel

Kloramfenikol 250,0 mg

Materialer som følger med

SR0231E: 10 x frysetørkede hetteglass, hvert for 500 ml medium

Materialer som er nødvendige, men som ikke følger med

- Brilliance Candida Agar Base (dehydrert) produktkode: CM1002B

Oppbevaring

- Oppbevar produktet i originalemballasjen mellom 2 °C og 8 °C.
- Produktet kan brukes frem til utløpsdatoen som er oppgitt på etiketten.
- Beskyttes mot fuktighet.
- Oppbevares borte fra lys.
- La det rekonstituerte produktet nå romtemperatur før bruk.

Advarsler og forholdsregler



Signalord: Fare

Faresetninger

H350 – Kan forårsake kreft

Sikkerhetssetninger

P280 – Benytt vernehansker/verneklær

P302 + P352 – VED HUDKONTAKT: Vask med mye såpe og vann

P342 + P311 - Ved symptomer i luftveiene: Kontakt et GIFTINFORMASJONSSENTER eller lege

P201 - Innhent særskilt instruks før bruk

P308 + P313 – Ved eksponering eller mistanke om eksponering: Søk legehjelp

P304 + P340 – VED INNÅNDING: Flytt personen til frisk luft og sørg for at vedkommende hviler i en stilling som letter åndedrettet

Hvert hetteglass er til engangsbruk. Må ikke brukes flere ganger.

Kun for in vitro-diagnostisk bruk.

Kun til profesjonell bruk.

Inspiser produktemballasjen før første gangs bruk.

Ikke bruk produktet hvis det er synlig skade på emballasjen eller hetteglassene.

Produktet må ikke brukes etter den angitte utløpsdatoen.

Ikke bruk enheten hvis det er tegn på kontaminering.

Ikke bruk enheten hvis fargen har endret seg eller det er andre tegn på forringelse.

Det er hvert laboratoriums ansvar å håndtere avfallet i henhold til typen og faregrad og å få det behandlet eller kastet i samsvar med føderale, statlige og lokale forskrifter. Instruksjonene skal leses og følges nøye. Dette inkluderer avhending av brukte eller ubrukte reagenser, så vel som alt annet kontaminert engangsmateriale, i samsvar med prosedyrer for smittefarlige eller potensielt smittefarlige produkter.

Se sikkerhetsdatabladet (SDS) for sikker håndtering og kassering av produktet (www.thermofisher.com).

Alvorlige hendelser

Enhver alvorlig hendelse som har oppstått i forbindelse med enheten, skal rapporteres til produsenten og den relevante tilsynsmyndigheten der brukeren og/eller pasienten befinner seg.

Prøvetaking, håndtering og oppbevaring

Prøver skal tas og håndteres i henhold til lokale anbefalte retningslinjer, for eksempel UK Standards for Microbiology Investigations (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 og S 6.

Prosedyre


Tilsett aseptisk 5 ml av 70 % etanol til ett hetteglass og bland forsiktig slik at innholdet løser seg helt opp. Tilsett innholdet i hetteglasset til 500 ml *Brilliance*™ Candida Agar Base (CM1002B) som anvist. Bland godt og kok opp under hyppig omrøring. IKKE BRUK AUTOKLAV. Avkjøl til 45 °C og hell i sterile beholdere.

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Symbolforklaring

Symbol	Definisjon
	Katalognummer
	In vitro-diagnostisk medisinsk utstyr
	Batchkode
	Temperaturgrense
	Brukes før-dato
	Må ikke utsettes for sollys
	Må ikke brukes flere ganger
	Se bruksanvisningen eller den elektroniske bruksanvisningen
	Inneholder tilstrekkelig til <n> tester
	Må ikke brukes hvis emballasjen er skadet. Se bruksanvisningen.
	Produsent
	Autorisert representant i EF/EU
	Europeisk samsvarsvurdering
	Britisk samsvarsvurdering
	Unik enhetsidentifikator
	Produsert i Storbritannia
	Importør – Angir enheten som importerer det medisinske utstyret til stedet. Gjelder for EU
	Helsefare
	Må holdes tørr



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Storbritannia



2797

For teknisk støtte må du kontakte din lokale distributør.

Informasjon om revisjon

Versjon	Utstedelsesdato og introduserte endringer
3,0	2024-10-28 Mindre formateringsendringer Advarsler og forholdsregler rettet for å samsvare med sikkerhetsdatablad Tillegg av «Må holdes tørr»-symbol



Brilliance Candida Selective Supplement

PL

REF SR0231E

*Patrz dodatkowe instrukcje użycia wyrobów *Brilliance Candida Agar Base*, nr kat. CM1002B

Przeznaczenie

Selektywny suplement *Brilliance™ Candida Selective Supplement* (SR0231E) to fiołka zawierająca chloramfenikol stosowany do przygotowania podłoża *Brilliance Candida Agar Base* (CM1002B) do izolacji i identyfikacji klinicznie istotnych gatunków drożdżaków *Candida* w próbkach klinicznych oraz do identyfikacji izolatów klinicznych. *Pożywka agarowa Brilliance Candida Agar Base* (CM1002B) z dodatkiem suplementu *Brilliance Candida Selective Supplement* (SR0231E) może być używana z różnymi rodzajami próbek; główne rodzaje próbek to płwocina i mocz, a także wydzieliny z oskrzeli, próbki z narządów płciowych, nosa, uszu, gardła, ran, skóry, gastrostomii i z centralnej linii żyłnej.

Dodatek selektywny *Brilliance™ Candida Selective Supplement* (SR0231E) jest stosowany w procedurze diagnostycznej, aby pomóc klinicytom w określeniu potencjalnych opcji leczenia pacjentów z podejrzeniem kandydozy. Wyrób ten jest przeznaczony wyłącznie do użytku profesjonalnego, nie jest zautomatyzowany i nie stanowi narzędzia do diagnostyki towarzyszącej.

Podsumowanie i wyjaśnienie

Gatunki *Candida* to drożdżaki komensalne, które normalnie występują u ludzi jako część flory skóry, jamy ustnej, jelit i pochwy¹. Drożdżaki z rodzaju *Candida* są czynnikami wywołującymi kandydozę, zakażenie grzybicze, które zwykle występuje w grupach o obniżonej odporności, takich jak dzieci lub osoby z HIV¹⁻¹². Gatunki z rodzaju *Candida* są również patogenami szpitalnymi, a inwazyjne interwencje medyczne, takie jak cewnikowanie lub leczenie immunosupresyjne, przyczyniają się do występowania kandydozy szpitalnej, takiej jak zakażenia układu moczowego (ZUM) i zakażenia krwi (kandydemia)⁸⁻¹³. Ponadto pojawienie się oporności przeciwgrzybiczej u drożdżaków *Candida* komplikuje leczenie i wpływa na jego wyniki, zwłaszcza u osób z obniżoną odpornością lub hospitalizowanych¹⁴⁻¹⁸.

Zasada działania

Różnicowanie istotnych klinicznie gatunków *Candida* osiąga się poprzez włączenie dwóch chromogenów, na które działają swoiste enzymy heksozoaminidaza i fosfataza zasadowa. Działanie tych enzymów na chromogeny powoduje uwolnienie zabarwiającego składnika do wnętrza komórki grzyba, w wyniku czego powstają kolorowe kolonie. Wytwarzany kolor zależy od tego, jakie enzymy są wytwarzane przez drobnoustroje. Obecność heksozoaminidazy w *C. albicans* oraz *Candida dubliniensis* powoduje powstawanie zielonych/niebieskich kolonii. Obecność heksozoaminidazy w *C. tropicalis* oraz inne reakcje metaboliczne, które powodują miejscowy spadek pH, powodują powstawanie ciemnoniebieskich kolonii. Obecność fosfatazy zasadowej w *Candida krusei* prowadzi do powstawania brązowych lub różowych kolonii. Obecność fosfatazy zasadowej w *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* oraz *Candida lusitanae* skutkuje różnorodnymi, beżowo-brązowo-żółtymi kolorami kolonii ze względu na mieszankę naturalnej pigmentacji i pewnego stopnia aktywności fosfatazy zasadowej. Doświadczeni użytkownicy mogą być w stanie odróżnić te gatunki na podstawie koloru i morfologii kolonii. Nieprzezroczyste tło pozwala na identyfikację drożdżaków *Candida*, zwłaszcza w przypadku infekcji mieszanych. Pożywka zawiera chloramfenikol, który hamuje wzrost bakterii.

Typowa formuła

Chloramfenikol 250,0 mg

Dostarczone materiały

SR0231E: 10 liofilizowanych fiołek po 500 ml pożywki

Materiały wymagane, ale niedostarczone

- *Brilliance Candida Agar Base* (baza sucha) nr. kat.:CM1002B

Przechowywanie

- Produkt należy przechowywać w oryginalnym opakowaniu w temperaturze od 2°C do 8°C.
- Produkt nadaje się do użytku, jeśli nie upłynął termin jego przydatności do użycia podany na etykiecie.
- Chronić przed wilgocią.
- Przechowywać z dala od źródeł światła.
- Przed użyciem odczekać, aż produkt osiągnie temperaturę pokojową.

Ostrzeżenia i środki ostrożności



Hasło ostrzegawcze: niebezpieczeństwo

Zwroty dotyczące zagrożeń

H350 – Może wywoływać nowotwory złośliwe

Zwroty wskazujące środki ostrożności

P280 – Stosować rękawice ochronne/odzież ochronną

P302 + P352 – W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody z mydłem

P342 + P311 – W przypadku wystąpienia objawów ze strony układu oddechowego: Skontaktować się z OŚRODKIEM ZATRUCI lub z lekarzem

P201 – Przed użyciem zapoznać się ze specjalnymi środkami ostrożności

P308 + P313 – W PRZYPADKU narażenia lub jego podejrzenia: zasięgnąć porady/zgłosić się pod opiekę lekarza

P304 + P340 – W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: Wyprowadzić lub wynieść poszkodowaną osobę na świeże powietrze i zapewnić warunki do swobodnego oddychania

Każda fiolka jest przeznaczona do jednorazowego użytku. Nie używać ponownie.

Wyłącznie do stosowania w diagnostyce in vitro.

Wyłącznie do zastosowań profesjonalnych.

Przed pierwszym użyciem sprawdzić opakowanie produktu.

Nie używać produktu, jeśli widoczne jest jakiegokolwiek uszkodzenie opakowania lub fiolek.

Nie używać produktu po upływie podanego terminu ważności.

Nie używać wyrobu w przypadku widocznych oznak zanieczyszczenia.

Nie używać wyrobu, jeśli kolor uległ zmianie lub występują inne oznaki świadczące o pogorszeniu jego stanu.

Każde laboratorium odpowiada za gospodarowanie generowanymi odpadami zgodnie z ich charakterem i stopniem zagrożenia oraz za ich przetwarzanie lub usuwanie zgodnie z wszelkimi obowiązującymi przepisami federalnymi, stanowymi i lokalnymi.

Należy uważnie zapoznać się z wytycznymi i ściśle ich przestrzegać. Obejmuje to usuwanie zużytych lub niewykorzystanych odczynników, a także wszelkich innych skażonych materiałów jednorazowego użytku zgodnie z procedurami dotyczącymi produktów zakaźnych lub potencjalnie zakaźnych.

Wytyczne dotyczące bezpiecznego obchodzenia się z produktem oraz jego bezpiecznej utylizacji znajdują się w karcie charakterystyki bezpieczeństwa materiału (SDS) (www.thermofisher.com).

Poważne incydenty

Wszelkie poważne incydenty, które miały miejsce w związku z wyrobem, należy zgłaszać producentowi i właściwemu organowi regulacyjnemu w kraju zamieszkanym przez użytkownika i/lub pacjenta.

Pobieranie próbek, postępowanie z nimi oraz ich przechowywanie

Próbki należy pobierać i obchodzić się z nimi zgodnie z lokalnymi zalecanymi wytycznymi, takimi jak brytyjskie standardy badań mikrobiologicznych (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 i S 6.

Procedura

Aseptycznie dolać 5 ml etanolu 70% do jednej fiołki i delikatnie wymieszać, aby całkowicie rozpuścić zawartość. Dolać zawartość fiołki do 500 ml *Brilliance™* Candida Agar Base (CM1002B) zgodnie z zaleceniami. Dobrze wymieszać i doprowadzić do wrzenia z częstym mieszaniem. NIE STERYLIZOWAĆ W AUTOKLAWIE. Schłodzić do 45°C i przelać do sterylnych pojemników.




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Legenda symboli

Symbol	Definicja
	Numer katalogowy
	Wyrób medyczny do diagnostyki in vitro
	Kod partii
	Limit temperatur
	Data ważności
	Chronić przed światłem słonecznym
	Nie używać ponownie
	Zapoznać się z instrukcją użytkowania w formie papierowej lub elektronicznej
	Zawartość wystarcza do wykonania <n> testów
	Nie używać w przypadku uszkodzenia opakowania i zapoznać się z instrukcją użycia
	Producent
	Autoryzowany Przedstawiciel we Wspólnocie Europejskiej/Unii Europejskiej
	Ocena zgodności z wymaganiami europejskimi
	Brytyjska ocena zgodności
	Unikatowy identyfikator urządzenia
Made in the United Kingdom	Wyprodukowano w Zjednoczonym Królestwie

	Importer — aby wskazać podmiot importujący wyrób medyczny do danej lokalizacji. Dotyczy Unii Europejskiej
	Zagrożenie dla zdrowia
	Przechowywać w suchym miejscu



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Zjednoczone Królestwo



2797

Aby uzyskać pomoc techniczną, prosimy skontaktować się z lokalnym dystrybutorem.

Informacje o wersji

Wersja	Data wydania i wprowadzone zmiany
3.0	28 października 2024 r. Niewielkie zmiany formatowania Poprawiono ostrzeżenia i środki ostrożności w celu dostosowania ich do karty charakterystyki substancji niebezpiecznej Dodanie symbolu „przechowywać w suchym miejscu”

**Brilliance Candida Selective Supplement**

PT

REF SR0231E

*Consulte as instruções de utilização adicionais do *Brilliance Candida Agar Base* com o código de produto CM1002B**Utilização prevista**

O *Brilliance™ Candida Selective Supplement* (SR0231E) é um frasco com cloranfenicol utilizado na preparação de *Brilliance Candida Agar Base* (CM1002B) para o isolamento e a identificação de *Candida* spp. clinicamente importantes a partir de amostras clínicas, bem como para a identificação de isolados clínicos. O *Brilliance Candida Agar Base* (CM1002) com *Brilliance Candida Selective Supplement* (SR0231E) adicionado pode ser utilizado com vários tipos de amostras; os principais tipos de amostras são de expectoração e urina, bem como de secreção brônquica, genitais, de nariz, ouvido, garganta, feridas, pele, gastrostomia e veia venosa central.

O *Brilliance™ Candida Selective Supplement* (SR0231E) é utilizado num fluxo de trabalho de diagnóstico para auxiliar os médicos na determinação de potenciais opções de tratamento de doentes suspeitos de terem candidíase. O dispositivo serve apenas para utilização profissional, não é automatizado nem é um diagnóstico complementar.

Resumo e explicação

As *Candida* spp. são leveduras comensais que se encontram, geralmente, na flora da pele, oral, intestinal e vaginal dos humanos¹. As *Candida* spp. são os agentes causadores da candidíase, uma infeção fúngica que ocorre geralmente em grupos imunocomprometidos, como é o caso das crianças ou de indivíduos com VIH¹⁻¹². As *Candida* spp. também são agentes patogénicos nosocomiais, com intervenções médicas invasivas, como a cateterização ou o tratamento imunossupressor, contribuem para a incidência de candidíase nosocomial, como as infeções do trato urinário (UTI) e as infeções da corrente sanguínea (candidemia)⁸⁻¹³. Além disso, a ocorrência de resistência antifúngica em *Candida* spp. complica o tratamento e influencia os resultados nos doentes, principalmente em indivíduos imunocomprometidos ou hospitalizados¹⁴⁻¹⁸.

Princípio do método

A diferenciação de *Candida* spp. clinicamente importante é alcançada através da inclusão de dois cromogénios que são alvo das enzimas específicas hexosaminidase e fosfatase alcalina. A ação destas enzimas nos cromogénios desencadeia a libertação do componente colorido no interior da célula fúngica, originando colónias coloridas. A cor produzida depende das enzimas produzidas pelos organismos. A presença de hexosaminidase em *C. albicans* e *Candida dubliniensis* resulta em colónias verdes/azuis. A presença de hexosaminidase em *C. tropicalis* e outras reações metabólicas que originam uma queda localizada no pH, resultam em colónias azul-escuras. A presença de fosfatase alcalina em *Candida krusei* resulta em colónias castanhas ou cor-de-rosa. A presença de fosfatase alcalina em *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* e *Candida lusitanae* resulta numa variedade de beges/castanhos/amarelos devido à mistura de pigmentação natural e de alguma atividade da fosfatase alcalina. Os utilizadores mais experientes podem ser capazes de diferenciar as espécies em função da cor e da morfologia da colónia. O fundo opaco permite a identificação de *Candida* spp., especialmente quando estão presentes infeções mistas. O meio contém cloranfenicol, que inibe o crescimento bacteriano.

Fórmula típica

Cloranfenicol 250,0 mg

Materiais fornecidos

SR0231E: 10 frascos liofilizados, cada um para 500 ml de meio

Materiais necessários, mas não fornecidos

- *Brilliance Candida Agar Base* (desidratado), códigos do produto: CM1002B

Armazenamento

- Armazene o produto na sua embalagem original a uma temperatura entre 2 °C e 8 °C.
- O produto pode ser utilizado até ao prazo de validade indicado no rótulo.
- Manter ao abrigo da humidade.
- Conserve ao abrigo da luz.
- Deixe o produto reconstituído atingir a temperatura ambiente antes da utilização.

Advertências e precauções**Palavra-sinal: Perigo**Advertências de perigo
H350 - Pode provocar cancro

Recomendações de prudência

P280 - Usar luvas/roupas de proteção

P302 + P352 - SE ENTRAR EM CONTACTO COM A PELE: lavar com sabonete e água abundantes

P342 + P311 - Em caso de sintomas respiratórios: Ligar para um CENTRO DE INFORMAÇÃO TOXICOLÓGICA ou um médico

P201 - Obter instruções específicas antes da utilização

P308 + P313 - EM CASO DE exposição ou preocupação: Procure assistência ou aconselhamento médico

P304 + P340 - EM CASO DE INALAÇÃO: retirar a pessoa para uma zona ao ar livre e mantê-la numa posição que não dificulte a respiração

Cada frasco destina-se a uma única utilização. Não reutilizar.

Apenas para diagnóstico *in vitro*.

Utilização exclusiva por profissionais.

Inspeccione a embalagem do produto antes da primeira utilização.

Não utilize o produto se existir qualquer dano visível na embalagem ou nos frascos para injetáveis.

Não utilize o produto para além do prazo de validade indicado.

Não utilize o dispositivo se apresentar sinais de contaminação.

Não utilize o dispositivo se a cor tiver mudado ou se apresentar outros sinais de deterioração.

É da responsabilidade de cada laboratório gerir os resíduos produzidos de acordo com a respetiva natureza e grau de perigo e tratá-los ou eliminá-los de acordo com quaisquer regulamentos federais, estatais e locais aplicáveis. As instruções devem ser lidas e devidamente cumpridas. Isto inclui a eliminação de reagentes utilizados ou não utilizados, bem como de qualquer outro material descartável contaminado seguindo os procedimentos para produtos infecciosos ou potencialmente infecciosos.

Consulte a Ficha de dados de segurança (FDS) para obter informações sobre o manuseamento e a eliminação seguros do produto (www.thermofisher.com).

Incidentes graves

Qualquer ocorrência de um incidente grave relacionado com o dispositivo deverá ser comunicada ao fabricante e à autoridade reguladora relevante no local em que o utilizador e/ou doente reside.

Colheita, manuseamento e armazenamento de amostras

As amostras devem ser colhidas e manuseadas de acordo com as diretrizes locais recomendadas, como as UK Standards for Microbiology Investigations (UK SMI, Normas em matéria de investigação microbiológica do Reino Unido) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 e S 6.

Procedimento

Adicione asseticamente 5 ml de etanol a 70% a um frasco e misture cuidadosamente para dissolver totalmente o conteúdo. Adicione o conteúdo do frasco a 500 ml de *Brilliance™* Candida Agar Base (CM1002B) conforme indicado. Misture bem e deixe ferver com uma agitação frequente. NÃO AUTOCLAVE. Arrefeça até aos 45 °C e verta em recipientes estéreis.



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Legenda dos símbolos

Símbolo	Definição
	Número de catálogo
	Dispositivo médico para diagnóstico <i>in vitro</i>
	Código do lote
	Limites de temperatura
	Data limite de utilização
	Proteger da luz do sol
	Não reutilizar
	Consultar instruções de utilização ou consultar instruções de utilização eletrónicas
	Contém o suficiente para <n> testes
	Não utilizar em caso de danos na embalagem e consultar instruções de utilização
	Fabricante
	Representante autorizado na Comunidade Europeia/ União Europeia
	Avaliação de Conformidade Europeia
	Avaliação de Conformidade do Reino Unido
	Identificador único do dispositivo
	Fabricado no Reino Unido
	Importador – Para indicar a entidade que importa o dispositivo médico para o local de destino. Aplicável à União Europeia

	Perigo para a saúde
	Manter seco



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Reino Unido



2797

Para obter assistência técnica, contacte o seu distribuidor local.

Informações de revisão

Versão	Data de publicação e modificações introduzidas
3.0	28-10-2024 Pequenas alterações de formatação Advertências e precauções corrigidas para corresponder à FDS Adição do símbolo Manter Seco



Brilliance Candida Selective Supplement

RO

REF SR0231E

*Consultați instrucțiunile de utilizare suplimentare pentru codurile de produs ale Brilliance Candida Agar Base

Utilizare prevăzută

Brilliance™ Candida Selective Supplement (SR0231E) este un flacon care conține cloramfenicol, care se vinde separat și este utilizat pentru a suplimenta Brilliance Candida Agar Base (CM1002B) pentru izolarea și identificarea speciilor de *Candida* importante din punct de vedere clinic din probe clinice și pentru identificarea izolatelor clinice. Brilliance Candida Agar Base (CM1002B) la care se adaugă Brilliance Candida Selective Supplement (SR0231E) poate fi utilizată cu o varietate de tipuri de probe; principalele tipuri de probe sunt sputa, urina și sângele, precum și probe de secreție bronșică, genitală, nazală, din ureche, gât, rană, piele, gastrostomie și linie venoasă centrală.

Brilliance™ Candida Selective Supplement (SR0231E) se folosește într-un flux de lucru de diagnosticare pentru a ajuta clinicienii să stabilească opțiunile posibile de tratament pentru pacienții suspecți de candidoză. Dispozitivul este prevăzut doar pentru uz profesional, nu este automatizat și nu reprezintă un dispozitiv de diagnostic companion.

Rezumat și explicație

Speciile de *Candida* sunt drozdii comensale care se găsesc, în mod normal, ca parte a florei pielii, bucale, intestinale și vaginale umane¹. Speciile de *Candida* sunt agenții cauzali ai candidozei, o infecție fungică care apare de obicei la grupurile imunodeprimite, cum ar fi copiii sau persoanele cu HIV+¹⁻¹². Speciile de *Candida* sunt, de asemenea, agenți patogeni nosocomiali prezente în intervenții medicale invazive precum cateterizarea sau tratamentul imunosupresor ce contribuie la incidența candidozei nosocomiale, cum ar fi infecțiile tractului urinar (ITU) și infecțiile ale fluxului sanguin (candidaemia)⁸⁻¹³. În plus, apariția rezistenței antifungice la speciile de *Candida* complică tratamentul și influențează rezultatele pacienților, în special la persoanele imunodeprimite sau spitalizate¹⁴⁻¹⁸.

Principiul metodei

Diferențierea speciilor de *Candida* importante clinic se realizează prin includerea a doi cromogeni care sunt vizați de enzimele specifice hexosaminidază și fosfatază alcalină. Acțiunea acestor enzime asupra cromogenilor determină eliberarea componentei colorate în interiorul celulei bacteriene, rezultând colonii colorate. Culoarea generată depinde de enzimele pe care le produc microorganismele. Prezența hexosaminidazei în *C. albicans* și *Candida dubliniensis* are ca rezultat colonii verzil/albastre. Prezența hexosaminidazei în *C. tropicalis* și a altor reacții metabolice care provoacă scăderea localizată a pH-ului are ca rezultat colonii de culoare albastru închis. Prezența fosfatazei alcaline în *Candida krusei* are ca rezultat colonii maro sau roz. *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* și *Candida lusitanae* apar ca o varietate de culori bej/maro/galben datorită amestecului de pigmentare naturală și o anumită activitate a fosfatazei alcaline. Utilizatorii experimentați pot fi capabili să diferențieze aceste specii după culoare și morfologia coloniilor. Fondul opac permite identificarea speciilor de *Candida*, mai ales când sunt prezente infecții mixte. Mediul conține cloramfenicol, care inhibă creșterea bacteriilor.

Formula tipică

Cloramfenicol 250,0 mg

Materiale furnizate

SR0231E: 10 flacoane liofilizate, fiecare pentru 500 ml de mediu

Materiale necesare, dar care nu sunt furnizate

- Brilliance Candida Agar Base (dehydrated) cod produs:CM1002B

Condiții de păstrare

- Depozitați produsul în ambalajul original, la temperaturi cuprinse între 2°C și 8°C.
- Produsul poate fi utilizat până la data de expirare înscrisă pe etichetă.
- A se proteja de umiditate.
- A se păstra ferit de lumina solară.
- Lăsați produsul reconstituit să ajungă la temperatura camerei înainte de utilizare.

Avertismente și măsuri de precauție



Cuvânt de semnalizare: Pericol

Fraze de pericol
H350 - Poate provoca cancer

Fraze de precauție

P280 - Purtați mănuși de protecție/îmbrăcăminte de protecție
P302 + P352 - ÎN CAZ DE CONTACT CU PIELEA: spălați cu multă apă și săpun
P342 + P311 - În caz de simptome respiratorii: Sunați la un CENTRU DE TOXICOLOGIE sau un medic
P201 - Solicitați instrucțiuni speciale înainte de utilizare

P308 + P313 - ÎN CAZ de expunere sau dacă aveți preocupări în acest sens: solicitați recomandări/asistență medicală
P304 + P340 - ÎN CAZ DE INHALARE: Scoateți persoana la aer curat și mențineți-o într-o poziție confortabilă pentru a respira
Fiecare flacon este de unică folosință. A nu se refolosi.

Numai pentru diagnostic in vitro.

Exclusiv pentru utilizare profesională.

Inspectați ambalajul produsului înainte de prima utilizare.

Nu utilizați produsul dacă ambalajul sau flacoanele prezintă deteriorări vizibile.

Nu utilizați produsul după data de expirare specificată.

Nu utilizați dispozitivul dacă sunt prezente semne de contaminare.

Nu utilizați dispozitivul dacă culoarea este modificată sau dacă există alte semne de deteriorare.

Este responsabilitatea fiecărui laborator să gestioneze deșeurile produse, în funcție de natura și gradul de pericol și să le trateze sau să le elimine în conformitate cu reglementările naționale, regionale și locale aplicabile. Instrucțiunile trebuie citite și respectate cu atenție. Acest lucru presupune eliminarea reactivilor utilizați sau neutilizați, precum și a oricărui alt material de unică folosință contaminat, urmând procedurile pentru produsele infecțioase sau potențial infecțioase.

Consultați Fișa cu date de securitate (FDS) pentru informații despre manipularea și eliminarea în siguranță a produsului (www.thermofisher.com).

Incidente grave

Orice incident grav care a avut loc în legătură cu dispozitivul va fi raportat producătorului și autorității de reglementare relevante din zona în care se află utilizatorul și/sau pacientul.

Recoltarea, manipularea și depozitarea probelor

Probele trebuie colectate și manipulate conform recomandărilor locale, precum UK Standards for Microbiology Investigations (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 și S 6.

Procedură
















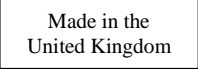

Adăugați aseptice 5 ml de etanol într-un flacon și amestecați ușor, pentru a dizolva complet conținutul. Adăugați conținutul fiolei la 500 ml de *Brilliance™* Candida Agar Base (CM1002B) conform instrucțiunilor. Se amestecă bine și se aduce la fierbere, agitând frecvent. NU AUTOCLAVAȚI. Se răcește la 45°C și se toarnă în vase sterile.



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Legenda simbolurilor

Simbol	Definiție
	Număr de catalog
	Dispozitiv medical pentru diagnostic in vitro
	Cod de lot
	Limită de temperatură
	Data expirării
	Ferți de lumina soarelui
	Nu reutilizați
	Consultați instrucțiunile de utilizare tipărite sau pe cele electronice
	Conține o cantitate suficientă pentru <n> teste
	Nu utilizați dacă ambalajul este deteriorat și consultați instrucțiunile de utilizare
	PRODUCĂTOR
	Reprezentant autorizat în Comunitatea Europeană/ Uniunea Europeană
	Evaluare de conformitate europeană
	Evaluare de conformitate în Regatul Unit
	Identificatorul unic al dispozitivului
	Fabricat în Regatul Unit
	Importator - Indicați entitatea care importă dispozitivul medical la nivel local. Aplicabil Uniunii Europene

	Pericol pentru sănătate
	A se păstra în stare uscată



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Regatul Unit



2797

Pentru asistență tehnică, vă rugăm să contactați distribuitorul local.

Informații despre revizuire

Versiune	Data emiterii și modificările introduse
3.0	28.10.2024 Modificări minore de formatare Avertismente și precauții corectate pentru a corespunde cu fișa cu date de securitate (FDS) Adăugarea simbolului „A se păstra uscat”



Selektívny suplement Candida *Brilliance* Selective Supplement

SK

REF SR0231E

*Pozrite si ďalšie návody na použitie pre kódy produktov agarovej bázy *Brilliance* Candida Agar Base CM1002B

Určené použitie

Selektívny suplement Brilliance™ Candida Selective Supplement (SR0231E) je liekovka obsahujúca chloramfenikol, ktorý sa predáva samostatne a používa sa ako suplement k agarovému základu *Brilliance* Candida Agar Base (CM1002B) na izoláciu a identifikáciu klinicky významných druhov *Candida* spp. z klinických vzoriek a na identifikáciu klinických izolátov. Agarová báza *Brilliance* Candida Agar Base (CM1002B) s pridaným selektívnym suplementom *Brilliance* Candida Selective Supplement (SR0231E) sa môže použiť s viacerými typmi vzoriek. Hlavné typy vzoriek sú spútum a moč, a tiež vzorky bronchiálneho sekrétu, genitálií, nosa, ucha, krku, rany, kože, gastrostómie a centrálnej žilovej línie.

Selektívny suplement Brilliance™ Candida Selective Supplement (SR0231E) sa používa v diagnostickom pracovnom postupe ako pomôcka pre lekárov pri určovaní potenciálnych možností liečby pacientov s podozrením na kandidózu. Pomôcka je určená len na profesionálne použitie, nie je automatizovaná a nie je ani sprievodná diagnostika.

Zhrnutie a vysvetlenie

Druhy rodu *Candida* spp. sú komenzálne kvasinky, ktoré sa bežne vyskytujú ako súčasť kožnej, ústnej, črevnej a vaginálnej flóry u ľudí. *Candida* spp. sú pôvodcami kandidózy, plesňovej infekcie, ktorá sa zvyčajne vyskytuje v skupinách s oslabenou imunitou, ako sú deti alebo HIV-pozitívni jedinci¹⁻¹². *Candida* spp. sú tiež nozokomiálne patogény, pričom invazívne zdravotnícke zákroky (napríklad katetrizácia alebo imunosupresívna liečba) prispievajú k výskytu nozokomiálnej kandidózy, ako sú infekcie močových ciest (UTI) a infekcie krvného obehu (kandidémia)⁸⁻¹³. Okrem toho, vznik rezistencie druhov rodu *Candida* spp. voči antimykotikám komplikuje liečbu a má dopad na výsledky pacientov, najmä v prípade jedincov s oslabenou imunitou alebo hospitalizovaných osôb¹⁴⁻¹⁸.

Princíp metódy

Diferenciácia klinicky významných druhov *Candida* spp. sa dosahuje zahrnutím dvoch chromogénov, na ktoré sa zameriavajú špecifické enzýmy hexozaminidáza a alkalická fosfatáza. Pôsobenie týchto enzýmov na chromogény spôsobuje uvoľnenie farebnej zložky vnútri bunky huby, čo vedie k tvorbe farebných kolónií. Produkovaná farba závisí od toho, ktoré enzýmy organizmy produkujú. Prítomnosť hexozaminidázy u *C. albicans* a *Candida dubliniensis* vedie k zeleným/modrým kolóniám. Prítomnosť hexozaminidázy v *C. tropicalis* a ďalšie metabolické reakcie, ktoré spôsobujú lokalizovaný pokles pH, majú za následok tmavomodré kolónie. Prítomnosť alkalického fosfatázy u *Candida krusei* vedie k hnedým alebo ružovým kolóniám. Prítomnosť alkalického fosfatázy u *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* a *Candida lusitanae* vedie k rôznym odtieňom béžovej/hnedej/žltej v dôsledku zmesi prirodzenej pigmentácie a určitej aktivity alkalického fosfatázy. Skúsení používatelia môžu byť schopní rozlíšiť tieto druhy podľa farby a morfológie kolónií. Nepriehľadné pozadie umožňuje identifikáciu *Candida* spp., najmä ak sú prítomné zmiešané infekcie. Médium obsahuje chloramfenikol, ktorý inhibuje rast baktérií.

Typické zloženie

Chloramfenikol 250,0 mg

Dodávané materiály

SR0231E: 10 × lyofilizovaná liekovka, každá na 500 ml média

Požadované materiály, ktoré sa nedodávajú

- *Brilliance*Candida Agar Base (dehydratovaná), kód produktu: CM1002B

Uchovávanie

- Produkt uchovávajte v pôvodnom obale pri teplote od 2 °C do 8 °C.
- Produkt je možné používať do dátumu expirácie uvedeného na štítku.
- Chráňte pred vlhkosťou.
- Uchovávajte chránené pred svetlom.
- Pred použitím nechajte rekonštituovaný produkt ustátiť na izbovú teplotu.

Varovania a preventívne opatrenia



Signálne slovo: Nebezpečenstvo

Výstražné upozornenia

H350 – Môže spôsobiť rakovinu

Bezpečnostné upozornenia

P280 – Noste ochranné rukavice/ochranný odev/ochranné okuliare

P302 + P352 – PRI KONTAKTE S POKOŽKOU: Umyte veľkým množstvom vody a mydlá

P342 + P311 – Pri sťaženom dýchaní: volajte TOXIKOLOGICKÉ INFORMAČNÉ CENTRUM alebo lekára

P201 – Pred použitím sa oboznáňte s osobitnými pokynmi

P308 + P313 – Po expozícii alebo podozrení z nej: Vyhľadajte lekársku pomoc/starostlivosť
P304 + P340 – PO VDYCHNUTÍ: Presuňte osobu na čerstvý vzduch a umožnite jej pohodlne dýchať
Každá liekovka je na jedno použitie. Nepoužívajte opakovane.

Len na diagnostické použitie in vitro.

Iba na odborné použitie.

Pred prvým použitím skontrolujte obal produktu.

Produkt nepoužívajte, ak sú liekovky alebo ich balenie viditeľne poškodené.

Po uplynutí uvedeného dátumu expirácie produkt nepoužívajte.

Ak sú prítomné známky kontaminácie, pomôcku nepoužívajte.

Pomôcku nepoužívajte, ak sa zmenila farba, alebo ak existujú iné známky poškodenia.

Je zodpovednosťou každého laboratória nakladať s vyprodukovaným odpadom v súlade s jeho povahou a stupňom nebezpečenstva a umožniť spracovanie alebo likvidáciu v súlade so všetkými platnými federálnymi, štátnymi a miestnymi predpismi. Je potrebné pozorne si prečítať a dodržiavať pokyny. To zahŕňa likvidáciu použitých alebo nepoužitých činidiel, a tiež iného kontaminovaného materiálu na jedno použitie podľa postupov pre infekčné alebo potenciálne infekčné produkty.

Pozrite si kartu bezpečnostných údajov (KBÚ) pre bezpečnú manipuláciu s produktom a jeho likvidáciu (www.thermofisher.com).

Závažné udalosti

Každý závažný incident, ktorý sa vyskytol v súvislosti s pomôckou, je nevyhnutné oznámiť výrobcovi a príslušnému regulačnému orgánu, pod pôsobnosť ktorého spadá používateľ a/alebo pacient.

Odber vzoriek, zaobchádzanie s nimi a ich uchovávanie

Vzorky je potrebné odberať a manipulovať s nimi podľa miestnych odporúčaných usmernení, ako sú UK Standards for Microbiology Investigations (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 a S 6.

Postup

Do jednej liekovky pridajte aseptickou technikou 5 ml 70 % etanolu a jemne premiešajte, aby sa obsah úplne rozpustil. Obsah liekovky pridajte do 500 ml agarovej bázy *Brilliance™* Candida Agar Base (CM1002B) podľa pokynov. Dobre premiešajte a za častého miešania privedte k varu. NESTERILIZUJTE V AUTOKLÁVE. Ochlaďte na teplotu 45 °C a nalejte do sterilných nádob.



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Vysvetlivky k symbolom

Symbol	Definícia
	Katalógové číslo
	Diagnostická zdravotnícka pomôcka in vitro
	Kód šarže
	Teplotný limit
	Spotrebujte do
	Chráňte pred slnečným žiarením
	Nepoužívajte opakovane
	Prečítajte si návod na použitie alebo elektronický návod na použitie
	Obsah postačuje na <n> testov
	Nepoužívajte, ak je obal poškodený, a prečítajte si návod na použitie
	Výrobca
	Autorizovaný zástupca v Európskom spoločenstve/ Európskej únii
	Posudzovanie zhody v EÚ
	Posudzovanie zhody v Spojenom kráľovstve
	Jedinečný identifikátor pomôcky
	Vyrobené v Spojenom kráľovstve
	Dovozca – označenie subjektu, ktorý dováža zdravotnícku pomôcku do danej oblasti. Vztahuje sa na Európsku úniu

	Nebezpečenstvo pre zdravie
	Uchovávajte v suchu



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Spojené kráľovstvo



2797

Ak potrebujete technickú pomoc, obráťte sa na miestneho distribútora.

Informácie o revíziách

Verzia	Dátum vydania a zavedené úpravy
3.0	28. 10. 2024 Drobné zmeny formátovania Varovania a bezpečnostné opatrenia opravené tak, aby zodpovedali KBÚ Pridanie symbolu Uchovávajte v suchu



Brilliance Candida Selective Supplement

SV

REF SR0231E

*Se ytterligare bruksanvisningar för Brilliance Candida Agar Base produktkoder CM1002B

Avsedd användning

Brilliance™ Candida Selective Supplement (SR0231E) är en injektionsflaska som innehåller kloramfenikol, som säljs separat och används som tillskott till Brilliance Candida Agar Base (CM1002B) för isolering och identifiering av kliniskt viktiga *Candida* spp. från kliniska prover samt för identifiering av kliniska isolat. Brilliance Candida Agar Base (CM1002B) med tillsatt Brilliance Candida Selective Supplement (SR0231E) kan användas med en mängd olika provtyper. De huvudsakliga provtyperna är sputum och urin, såväl som bronkial sekretion, genitala prover, näsprover, öronprover, halsprover, sårprover, hudprover, gastrostomiprover och prover från centrala venkatetrar.

Brilliance™ Candida Selective Supplement (SR0231E) används i ett diagnostiskt arbetsflöde för att hjälpa kliniker att fastställa potentiella behandlingsalternativ för patienter som misstänks ha kandidos. Produkten är endast avsedd för professionellt bruk, den är inte automatiserad och utgör heller ingen kompletterande diagnostik.

Sammanfattning och förklaring

Candida spp. är kommensala jästsvampar som normalt finns som en del av hud-, mun-, tarm- och vaginalfloran hos människor¹. *Candida* spp. är orsakerna till kandidos, en svampinfektion som vanligtvis förekommer i immunsupprimerade grupper som barn eller personer med HIV⁺¹⁻¹². *Candida* spp. är också nosokomiala patogener, där invasiva medicinska ingrepp som kateterisering eller immunsuppressiv behandling bidrar till förekomsten av nosokomial kandidos, såsom urinvägsinfektioner (UVI) och blodomloppsinfektioner (candidemi)⁸⁻¹³. Dessutom komplicerar uppkomsten av antifungal resistens hos *Candida* spp. behandlingen och påverkar patientutfall, särskilt hos immunförsvagade personer eller personer som är inlagda på sjukhus¹⁴⁻¹⁸.

Metodprincip

Differentiering av kliniskt viktiga *Candida* spp. uppnås genom införandet av två kromogener som riktar mot specifika enzymer, hexosaminidas och alkaliskt fosfatas. De här enzymernas påverkan på kromogenerna orsakar frisättning av den färgade komponenten inuti svampcellen, vilket resulterar i färgade kolonier. Vilken färg som produceras beror på vilka enzymer organismerna producerar. Närvaro av hexosaminidas i *C. albicans* och *Candida dubliniensis* resulterar i gröna/blåa kolonier. Närvaro av hexosaminidas i *C. tropicalis*, samt andra metaboliska reaktioner som orsakar lokal sänkning av pH-värdet, resulterar i mörkblå kolonier. Närvaro av alkalinfosfatas i *Candida krusei* resulterar i bruna eller rosa kolonier. Närvaro av alkaliskt fosfatas i *Candida glabrata*, *Candida kefyr*, *Candida parapsilosis* och *Candida lusitanae* resulterar i en mängd olika beige/bruna/gula färger på grund av blandningen av naturlig pigmentering och viss alkalisk fosfatasaktivitet. Erfarna användare kan eventuellt skilja dessa arter åt efter färg och kolonimorfologi. Den ogenomskinliga bakgrunden medger identifiering av *Candida* spp., särskilt när blandade infektioner förekommer. Mediet innehåller kloramfenikol, som hämmar bakterietillväxt.

Vanlig formel

Kloramfenikol 250,0mg

Material som medföljer

SR0231E: 10 st frystorkade flaskor för 500ml medium vardera

Material som krävs men som inte medföljer

- Brilliance Candida Agar Base (dehydrerad) produktkod: CM1002B

Förvaring

- Förvara produkten i originalförpackningen mellan 2 °C och 8 °C.
- Produkten får användas fram till det utgångsdatum som anges på etiketten.
- Skyddas mot fukt.
- Förvaras skyddat från ljus.
- Låt den rekonstituerade produkten anta rumstemperatur före användning.

Varningar och försiktighetsåtgärder



Signalord: Fara

Faroangivelser
H350 – Kan orsaka cancer

Skyddsangivelser

P280 - Använd skyddshandskar/skyddskläder
P302 + P352 - VID HUDKONTAKT: Tvätta med mycket tvål och vatten
P342 + P311 - Vid besvär i luftvägarna: Kontakta GIFTINFORMATIONSCENTRAL eller läkare
P201 - Inhämta särskilda instruktioner före användning
P308 + P313 - VID exponering eller misstanke om exponering: Sök läkarhjälp
P304 + P340 – VID INANDNING: Flytta personen till frisk luft, och se till att andningen underlättas

Varje flaska är för engångsbruk. Får inte återanvändas.

Endast för in vitro-diagnostik.

Endast för professionellt bruk.

Inspektera produktens förpackning före första användningen.

Använd inte produkten om det finns synliga skador på förpackningen eller injektionsflaskorna.

Använd inte produkten efter det angivna utgångsdatumet.

Använd inte produkten om det finns tecken på kontaminering.

Använd inte produkten om färgen har ändrats eller om det finns andra tecken på försämring.

Det är varje laboratoriums ansvar att hantera avfall som produceras i enlighet med avfallets typ och riskgrad samt att behandla eller bortskafla det i enlighet med eventuella nationella, statliga och lokala tillämpliga bestämmelser. Anvisningarna ska läsas och följas noggrant. Detta omfattar bortskaflande av använda eller oanvända reagenser samt alla andra förorenade engångsmaterial i enlighet med rutiner för smittsamma eller potentiellt smittsamma produkter.

Se säkerhetsdatabladet (SDS) för information om säker hantering och kassering av produkten (www.thermofisher.com).

Allvarliga tillbud

Eventuella allvarliga tillbud som inträffar i samband med produkten ska anmälas till tillverkaren och relevant tillsynsmyndighet där användaren och/eller patienten befinner sig.

Insamling, hantering och förvaring av prover

Prover ska samlas in och hanteras enligt lokala rekommenderade riktlinjer, såsom UK Standards for Microbiology Investigations (UK SMI) ID 1, B 1, B 5, B 9, B 11, B 20, B 28, B 39, B 41, B 57 och S 6.

Förfarande


Tillsätt med aseptisk teknik 5ml 70 % etanol till en injektionsflaska och blanda försiktigt så att innehållet löses upp helt. Tillsätt innehållet i flaskan till 500ml *Brilliance™* Candida Agar Base (CM1002B) enligt anvisningarna. Blanda väl och koka upp under ständig omrörning. AUTOKLAVERA INTE. Kyl ner till 45 °C, blanda väl och håll i sterila behållare.



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Symbolförklaring

Symbol	Definition
	Katalognummer
	Medicinteknisk produkt för in vitro-diagnostik
	Batchkod
	Temperaturgräns
	Utgångsdatum
	Håll borta från solljus
	Får inte återanvändas
	Se bruksanvisningen eller den elektroniska bruksanvisningen
	Innehåller tillräckligt med material för <n> tester
	Använd inte produkten om förpackningen är skadad och se bruksanvisningen
	Tillverkare
	Auktoriserad representant i Europeiska gemenskapen/ EU
	Europeisk bedömning av överensstämmelse
	Brittisk bedömning av överensstämmelse
	Unik produktidentifierare
	Tillverkad i Storbritannien
	Importör – anger vilken instans som importerar den medicintekniska produkten till platsen. Gäller Europeiska unionen

	Hälsofara
	Förvaras torrt



Oxoid Limited, Wade Road, Basingstoke, Hampshire, RG24 8PW, Storbritannien



2797

Kontakta den lokala distributören för teknisk hjälp.

Revisionsinformation

Version	Utgivningsdatum och införda ändringar
3.0	2024-10-28 Mindre formateringsändringar Varningar och försiktighetsåtgärder korrigerade för överensstämmelse med SDS Tillägg av symbolen "Förvaras torrt"