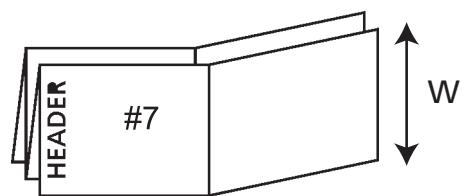
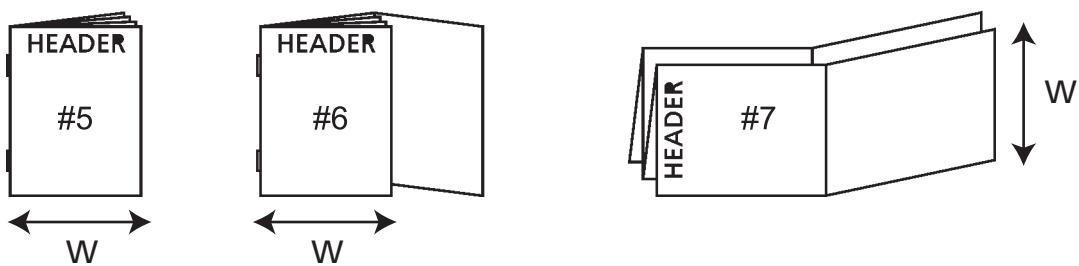
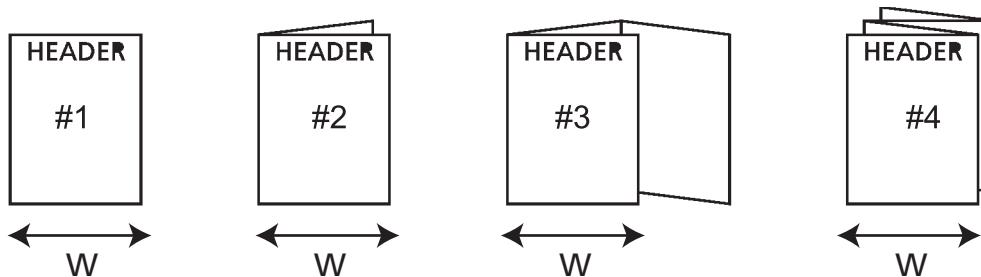


Rev from	Rev to	JOB #
02	03	8408-16

NOTES:

1. BD Catalog Number: 220093, 220097, 220099, 220105, 220109, 220115, 220116, 220129, 220130, 220132, 220133, 220134, 220135, 220146, 220147, 220148, 220149
2. Blank (Sheet) Size: Length: 23 5/8" Width: 3 15/32"
3. Number of Pages: 2 Number of Sheets: 1
4. Page Size: Length: N/A Width: N/A Final Folded Size: N/A
5. Ink Colors: No. of Colors: 1 PMS#: 2755 Blue
6. Printed two sides: Yes No *Peel-off insert / Label. Insert perforated 3/8" from bottom with 3/16" notch for easy peel-off. Top insert size 4 3/16" x 3 15/32" includes 3/8" bottom portion of glued area. Insert is folded under with an horizontal fold and followed by two parallel folds to form the size of 3 1/4" x 3 15/32". Insert to be glued on top 5/16" and bottom 3/8" to roll label, size 3 15/32" (web) x 4 3/8".
7. Style (see illustrations below): N/A



8. Vendor Printed Online/In House Printed Web
9. Material specification controled by Copan.
10. Graphics are approved by Becton, Dickinson and Company. Supplier has the responsibility for using the most current approved revision level.

Label Design	REVISED BY By Sonia Thompson at 9:49 am, Aug 24, 2016	COMPANY CONFIDENTIAL. THIS DOCUMENT IS THE PROPERTY OF BECTON, DICKINSON AND COMPANY AND IS NOT TO BE USED OUTSIDE THE COMPANY WITHOUT WRITTEN PERMISSION.	 Becton, Dickinson and Company 7 Loveton Circle Sparks, MD 21152 USA
Proofer	PROOFING APPROVED BY By Nichole Graham at 1:43 pm, Aug 24, 2016		
Checked By	THIRD EYE BY By Mary Schmidt at 1:40 pm, Aug 25, 2016		
Part Number:	L000021	Category and Description Peel-Off Insert / Label, CultureSwab	Sheet: 1 of 3 Scale: N/A

A

Contact your local BD representative for instructions. / Сържете се с местния представител на BD за инструкции. / Pokyny vám poskytne místní zástupce společnosti BD. / Kontakt den lokale BD-repräsentant for at få instruktioner. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / Kasutusjuhiste suhtes kontaktege oma kohaliku BD esindajaga. / Ota yhteys lähiimpiin BD:n edustajaan ohjeiden saamiseksi. / Kontaktiraj lokalnog predstavnika BD za upute. / A használati utasítást kérje a BD helyi képviselőtől. / Нүсекүарал шынын хөтөлбөрийн BD експлимент хабарласысыз. / Lai saņemtu norādījumus, sazinieties ar vietējo BD pārstāvi. / Naudojimmo instrukciju teikraukēties vietas BD igaliotojo astovo. / Neem contact op met uw plaatselijke BD-vertegenwoordiger voor instructies. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcję użytkowania, skontaktuj się z lokalnym przedstawicielem BD. / Contacte o representante local da BD para instruções. / Pentru instrucțiuni, contactați reprezentantul local BD. / Для получения указаний обратитесь к местному представителю компании BD. / Instrukcie získate u miestneho zástupcu spoločnosti BD. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Kontakt a národného BD-representanta pre anvisningar. / Talimatlar için yerel BD temsilcinizle temasla geçin. / За инструкциями зверніться до місцевого представника компанії BD.

INTENDED USE

BD BBL™ CultureSwab™ devices are sterile ready-to-use systems intended for the collection, transport and preservation of clinical specimens for bacteriological examination.

SUMMARY AND PRINCIPLES

One of the routine procedures in the diagnosis of bacterial infections involves the collection and safe transportation of a clinical specimen from the patient to the laboratory. This can be accomplished using the BD BBL CultureSwab collection and transport device. Each BD BBL CultureSwab unit is comprised of a sterile peel pouch containing a rayon- or polyester-tipped swab applicator used to collect the sample and a tube containing transport medium into which the swab applicator is placed after sampling.

The BD BBL CultureSwab transport media (Amies Liquid Medium, Liquid Stuart Medium and Cary-Blair Transport Medium) are non-nutritious, buffered with phosphate and provide a reduced environment due to their formulation with sodium thioglycollate.¹ Organisms in the sample material are protected from drying by moisture in the transport medium. The medium is designed to maintain the viability of organisms during transit to the laboratory. BD BBL CultureSwab pouches are made of a plastic film which retards the penetration of atmospheric air into the product.

BD BBL CultureSwab media are contained in a constricted (venturi) tube. Nitrogen gas is flushed into the transport tube during the media filling and capping process. During final packaging of the swab and tube, air is removed from the pouch by vacuum and nitrogen gas is flushed inside.

REAGENTS

Approximate Formula Per Liter Distilled Water

Amies Liquid Medium	Stuart Liquid Medium	Cary-Blair Agar Medium
Calcium Chloride 0.10 g	Calcium Chloride 0.10 g	Bacteriological Agar 5.60 g
Disodium Phosphate 1.15 g	Mercaptoacetic Acid 1.0 mL	Calcium Chloride 0.09 g
Magnesium Chloride 0.10 g	Sodium Glycerophosphate 10.00 g	Disodium Hydrogen Phosphate 1.10 g
Monopotassium Phosphate 0.20 g		Sodium Chloride 5.00 g
Potassium Chloride 0.20 g		Sodium Thioglycollate 1.15 g
Sodium Chloride 3.00 g		
Sodium Thioglycollate 1.00 g		

Precautions: For *in vitro* Diagnostic Use.

It must be assumed that all specimens contain infectious microorganisms; therefore, all specimens should be handled with appropriate precautions. After use, tubes and swabs must be disposed of according to laboratory regulations for infectious waste.

② BD BBL CultureSwab is for single use only; reuse may cause a risk of infection and/or inaccurate results.

Storage: Store BD BBL CultureSwab devices at 5–25 °C.

Product Deterioration: Contents sterile if unopened or not damaged. Do not use if they show evidence of damage, dehydration or contamination. Do not use if past expiration date.

SPECIMEN COLLECTION AND HANDLING

The BD BBL CultureSwab devices are available with different applicator shafts which facilitate the collection of specimens from various sites of the patient. For specific recommendations about collection of specimens for microbiological analysis and primary isolation techniques, consult appropriate references.²⁻⁴ Once a swab sample is collected, it should be placed in the tube of medium, transported to the laboratory as soon as possible and cultured onto appropriate primary isolation media.

PROCEDURE

Materials Provided: Fifty (50) units of sterile BD BBL CultureSwab devices, which contain media, are contained in each Vi-Pak Pouch.

One hundred (100) units of sterile BD BBL CultureSwab swab and transport tubes are contained in each Vi-Pak Pouch.

Materials Required But Not Provided: Appropriate materials for isolating, differentiating and culturing aerobic and anaerobic bacteria. These materials include culture media plates or tubes and incubation systems, gas jars or anaerobic workstations.

Directions For Use:

The directions for use are printed on each BD BBL CultureSwab unit, along with descriptive diagrams, and are summarized as follows:

1. Peel open the BD BBL CultureSwab pouch.
 2. Remove cap from transport tube.
 3. Remove applicator swab and collect specimen.
- During specimen collection, the applicator tip should only touch the area where the infection is suspected to minimize potential contamination.
4. Place applicator swab in transport tube.
 5. Record patient's name and information on tube label.
 6. Send specimen to the laboratory for immediate analysis.

EXPECTED RESULTS

The survival of bacteria in a transport medium depends on many factors. These include the types of bacteria, duration of transport, storage temperature, concentration of bacteria in the sample and formulation of the transport medium. BD BBL CultureSwab devices maintain viability of many microorganisms for 24–48 h. For fastidious bacteria, such as *Neisseria gonorrhoeae* and *Streptococcus pneumoniae*, swab specimens should be plated directly onto culture medium or transported immediately to the laboratory and cultured within 24 h.

LIMITATIONS OF THE PROCEDURE

BD BBL CultureSwab Amies Liquid Medium and Stuart Liquid Medium are intended for the collection and transport of bacteriological samples only. Preferred samples for anaerobic investigations are: tissue samples obtained during surgical procedures, biopsies from tissue or bone, fluid, pus, or aspirates collected using a syringe. For detailed information and recommendations for transporting fluid and tissue specimens from anaerobic culture, refer to specific publications.³⁻⁷ Samples containing viruses or chlamydia should be collected and transported using alternative specific transport systems.

PERFORMANCE CHARACTERISTICS

Recovery studies were performed using BD BBL CultureSwab products with a variety of aerobic organisms. Swabs were dosed with inoculum and inserted into the transport tube containing transport media. The tubes were stored at room temperature prior to subculturing onto appropriate culture media. Listed are the organisms tested with the various transport media.

Organism	Amies Liquid form	Transport Media Stuart Liquid form	Cary-Blair Agar
<i>Neisseria gonorrhoeae</i> ATCC® 43069	*	*	
<i>Streptococcus pyogenes</i> ATCC 19615	*	*	
<i>Haemophilus influenzae</i> ATCC 19418	*	*	
<i>Campylobacter jejuni</i> ATCC 33291			*
<i>Shigella flexneri</i> ATCC 12022			*
<i>Yersinia enterocolitica</i> ATCC 9610			*

REFERENCES

1. Amies CR. 1967. A modified formula for the preparation of Stuart's transport medium. Can. J. Public Health. 58: 296-300.
2. Isenberg H.D., F.D. Schoenkencht, and A. von Graevenitz. 1979. Cumitech 9, Collection and processing of bacteriological specimens. Coordinating ed., S.J. Rubin. American Society for Microbiology, Washington, D.C.
3. Balows, A., W.J. Hausler, Jr, K.L. Herrmann, H.D. Isenberg, and H.J. Shadomy (ed.). 1991. Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
4. Isenberg, H.D. (ed.). 1992. Clinical microbiology procedures handbook, vol. 1. American Society for Microbiology, Washington, D.C.
5. Zavala, M.K., D.M. Citron, E.J.C. Goldstein. 1998. Evaluation of a novel specimen transport system for anaerobic bacteria. Clin. Infect. Dis. 25 (supplement 2): S123-133.
6. Perry, J.L. 1997. Assessment of swab transport systems for aerobic and anaerobic organism recovery. J. Clin. Microbiol. 35: 1269-1271.
7. Summanen, P., E.J. Baron, D.M. Citron, C.A. Strong, H.M. Wexler, and S.M. Finegold. 1993. Wadsworth anaerobic bacteriology manual, 5th ed. Star Publishing Co., Belmont, Calif.

TECHNICAL INFORMATION: In the United States contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com.

ATCC is a trademark of the American Type Culture Collection.

© 2016 BD. BD, the BD Logo, and all other trademarks are property of Becton, Dickinson and Company.

FRANÇAIS

APPLICATION

Les dispositifs BD BBL CultureSwab sont des systèmes stériles prêts à l'emploi destinés au prélèvement, au transport et à la conservation d'échantillons cliniques à des fins d'analyses bactériologiques.

RESUME ET EXPLICATION

Une procédure courante du diagnostic d'infections bactériennes consiste à prélever sur le patient puis à transporter de manière sûre un échantillon clinique jusqu'au laboratoire d'analyse. Elle peut être accomplie grâce au dispositif de prélèvement et de transport BD BBL CultureSwab. Chaque unité BD BBL CultureSwab consiste en une pochette stérile pelable contenant un écuvillon applicateur à embout en rayon ou polyester, servant à prélever l'échantillon et un tube rempli de milieu de transport dans lequel l'écuvillon applicateur est placé après le prélèvement.

Les milieux de transport BD BBL CultureSwab (milieu liquide Amies, milieu liquide Stuart et milieu gélosé de transport Cary-Blair) ne sont pas nutritifs ; ils sont tamponnés au phosphate et maintiennent un environnement réduit du fait de leur teneur en thioglycolate de sodium.¹ L'eau contenue dans le milieu de transport protège les organismes présents dans l'échantillon contre le dessèchement. Le milieu a été conçu pour assurer la viabilité des organismes pendant le transport jusqu'au laboratoire. Les pochettes BD BBL CultureSwab sont en plastique, ce qui retarde la pénétration de l'air atmosphérique dans le produit.

Les milieux BD BBL CultureSwab sont contenus dans un tube à étranglement (venturi). L'azote est chassé en force dans le tube de transport pendant le remplissage du tube avec le milieu et le bouchage du tube. Au moment de l'emballage final du tube et de l'écuvillon, l'air de la pochette est éliminé par aspiration puis remplacé par de l'azote.

REACTIFS

Formule approximative par litre d'eau distillée

Milieu liquide Amies	Milieu liquide Stuart	Milieu gélosé Cary-Blair
Chlorure de calcium 0,10 g	Chlorure de calcium 0,10 g	Gélose bactériologique 5,60 g
di-Sodium	Acide mercaptoacétique 1,0 mL	Chlorure de calcium 0,09 g
hydrogénophosphate 1,15 g	Glycérophosphate	di-Sodium
Chlorure de magnésium 0,10 g	de sodium 10,00 g	Hydrogénophosphate 1,10 g
Phosphate monopotassique 0,20 g		Chlorure de sodium 5,00 g
Chlorure de potassium 0,20 g		Thioglycolate de sodium 1,15 g
Chlorure de sodium 3,00 g		
Thioglycolate de sodium 1,00 g		

Précautions : Réservé au diagnostic *in vitro*.

Il faut supposer que tous les échantillons contiennent des microorganismes infectieux et doivent par conséquent être manipulés avec les précautions appropriées. Après utilisation, tous les tubes et les écuvillons doivent être éliminés conformément aux règlements en vigueur dans le laboratoire, relatifs aux déchets infectieux.

② BD BBL CultureSwab est à usage unique exclusivement ; toute réutilisation pourrait engendrer un risque d'infection et/ou des résultats.

Conservation : Conserver les dispositifs BD BBL CultureSwab à 5–25 °C.

Produit Deterioration : Contenu stérile si non ouvert ou non endommagé. Ne pas utiliser si le produit est visiblement endommagé, déshydraté ou contaminé. Ne pas utiliser au-delà de la date de péremption.

PRELEVEMENT ET PREPARATION DES ECHANTILLONS

Le dispositif BD BBL CultureSwab est disponible avec différents manches d'applicateur, conçus pour faciliter le prélèvement d'échantillons à partir de sites divers sur le patient. Pour obtenir des recommandations spécifiques concernant le prélèvement d'échantillons à des fins d'analyse microbiologique ou d'isolement primaire, consulter les références appropriées.²⁻⁴

Une fois que l'échantillon est prélevé par écuvillonnage, il doit être placé dans le tube de milieu, transporté au laboratoire dès que possible et mis en culture sur les milieux d'isolement primaire appropriés.

MODE OPERATOIRE

Matériel fourni : Chaque pochette Vi-Pak contient cinquante (50) dispositifs stériles BD BBL CultureSwab remplis de milieu.

Chaque pochette Vi-Pak contient cent (100) tubes avec écuvillon stérile BD BBL CultureSwab.

Matériaux requis mais non fournis : Tout le matériel nécessaire pour isoler, différencier et mettre en culture des bactéries anaérobies et aérobies, à savoir boîtes de Pétri ou tubes de culture et systèmes d'incubation, flacons sous atmosphère gazeuse et postes de travail anaérobies.

Mode d'emploi :

Le mode d'emploi est imprimé sur chaque dispositif BD BBL CultureSwab avec les diagrammes descriptifs ; il peut être résumé comme suit :

1. Ouvrir la pochette BD BBL CultureSwab.
 2. Retirer le capuchon du tube de transport.
 3. Retirer l'écuvillon applicateur et prélever l'échantillon.
- Pendant le prélèvement de l'échantillon, l'extrémité de l'applicateur ne doit toucher que la zone supposée infectée afin de minimiser le risque de contamination.
4. Placer l'écuvillon applicateur dans le tube.
 5. Noter le nom et informations concernant le patient sur l'étiquette du tube.
 6. Envoyer l'échantillon au laboratoire pour une analyse immédiate.

RESULTATS ATTENDUS

The survival of bacteria in a transport medium depends on many factors. These include the types of bacteria, duration of transport, storage temperature, concentration of bacteria in the sample and formulation of the transport medium. BD BBL CultureSwab devices maintain viability of many microorganisms for 24–48 h. For fastidious bacteria, such as *Neisseria gonorrhoeae* and *Streptococcus pneumoniae*, swab specimens should be plated directly onto culture medium or transported immediately to the laboratory and cultured within 24 h.

LIMITES DE LA PROCEDURE

BD BBL CultureSwab Amies Liquid Medium and Stuart Liquid Medium are intended for the collection and transport of bacteriological samples only. Preferred samples for anaerobic investigations are: tissue samples obtained during surgical procedures, biopsies from tissue or bone, fluid, pus, or aspirates collected using a syringe. For detailed information and recommendations for transporting fluid and tissue specimens from anaerobic culture, refer to specific publications.³⁻⁷ Samples containing viruses or chlamydia should be collected and transported using alternative specific transport systems.

PERFORMANCE CHARACTERISTICS

Recovery studies were performed using BD BBL CultureSwab products with a variety of aerobic organisms. Swabs were dosed with inoculum and inserted into the transport tube containing transport media. The tubes were stored at room temperature prior to subculturing onto appropriate culture media. Listed are the organisms tested with the various transport media.

Organism	Liquide Amies	Liquide Stuart	Gélosé Cary-Blair

<tbl_r cells="4" ix="5" maxcspan="

ZU ERWARTENDE ERGEBNISSE

Die Überlebensrate von Bakterien in einem Transportmedium hängt von vielen Faktoren ab. Dazu gehören die Bakterienart, die Transportdauer, die Aufbewahrungs temperatur, die Bakterienkonzentration in der Probe und die Zusammensetzung des Transportmediums. In **BD BBL CultureSwab**-Systemen bleiben viele Mikroorganismen 24–48 Std. lebensfähig. Abstriche von empfindlichen Bakterien, wie z. B. *Neisseria gonorrhoeae* und *Streptococcus pneumoniae*, sollten direkt auf einer Kulturplatte ausgestrichen oder unverzüglich zum Labor geschickt und innerhalb von 24 Std. kultiviert werden.

VERFAHRENSBESCHRÄNKUNGEN

BD BBL CultureSwab-Systeme mit Amies-Flüssigmedium und Stuart-Flüssigmedium sind ausschließlich zur Entnahme und zum Transport von bakteriologischen Proben vorgesehen. Bevorzugte Proben zum Nachweis von Anaerobiern sind: während einer Operation entnommene Gewebeportionen, Gewebe- oder Knochenbiopsien und mit einer Spritze entnommene Flüssigkeiten, Eiter oder Aspirate. Ausführliche Informationen und Empfehlungen zum Transport von Flüssigkeits- und Gewebe Proben für Anaerobier-Kulturen bitte den entsprechenden Veröffentlichungen entnehmen.³⁻⁷ Proben, die Viren oder Chlamydien enthalten, sollten mit anderen spezifischen Transportsystemen entnommen und transportiert werden.

LEISTUNGSMERKMALE

Isolierungsstudien wurden unter Verwendung von **BD BBL CultureSwab**-Systemen mit einer Reihe von aeroben Mikroorganismen durchgeführt. Die Abstrichtupfer wurden mit einem Inokulum beschickt und in die Röhrchen mit Transportmedium gegeben. Die Röhrchen wurden vor der Subkultivierung auf geeigneten Kulturmedien bei Raumtemperatur aufbewahrt. Die mit den verschiedenen Transportmedien getesteten Organismen sind nachstehend aufgeführt.

Organismus	Amies- Flüssigmedium	Transportmedien Stuart- Flüssigmedium	Cary- Blair-Agar
<i>Neisseria gonorrhoeae</i> ATCC 43069	*	*	
<i>Streptococcus pyogenes</i> ATCC 19615	*	*	
<i>Haemophilus influenzae</i> ATCC 19418	*	*	
<i>Campylobacter jejuni</i> ATCC 33291			*
<i>Shigella flexneri</i> ATCC 12022			*
<i>Yersinia enterocolitica</i> ATCC 9610			*

LITERATUR: Siehe „References“ im englischen Text.

Technischer Kundendienst: setzen Sie sich mit Ihrer zuständigen BD-Vertretung oder www.bd.com.

ITALIANO

USO PREVISTO

I dispositivi **BD BBL CultureSwab** sono sistemi sterili e predisposti all'uso, predisposti per il prelievo, il trasporto e la conservazione di campioni clinici per l'esame batteriologico.

SOMMARIO E SPIEGAZIONE

Una delle procedure di routine nella diagnosi delle infezioni batteriche consiste nel prelievo di un campione clinico dal paziente e nel trasporto del campione al laboratorio in condizioni di sicurezza. Il sistema di prelievo e trasporto **BD BBL CultureSwab** permette di eseguire queste procedure. Ogni unità **BD BBL CultureSwab** include una busta sterile tipo peel-pack, contenente un tampone applicatore con punta di rayon o poliestere per il prelievo del campione e una provetta con terreno da trasporto in cui viene introdotto il tampone dopo il prelievo.

I terreni da trasporto **BD BBL CultureSwab** (terreno liquido Amies, terreno liquido Stuart e terreno da trasporto Cary-Blair) sono non-nutritivi, tamponati con fosfato e generano un ambiente ridotto per via della formulazione con tioglicollato di sodio.¹ L'umidità del terreno da trasporto protegge dalla disidratazione i microrganismi presenti nel materiale prelevato. Il terreno ha lo scopo specifico di assicurare la sopravvivenza degli organismi durante il trasporto al laboratorio. Le buste **BD BBL CultureSwab** sono di materiale plastico che ritarda la penetrazione dell'aria atmosferica nel prodotto.

I terreni **BD BBL CultureSwab** sono contenuti in una provetta a compressione (Venturi). La provetta da trasporto viene irrigata di gas azoto durante il riempimento con il terreno e la chiusura con il tappo. Al confezionamento finale del tampone e della provetta, si aspira l'aria dalla busta e vi si immette il gas azoto.

REAGENTI

Formula approssimata per litro di acqua distillata

Terreno liquido Amies	Terreno liquido Stuart	Terreno agar Cary-Blair
Cloruro di calcio 0,10 g	Cloruro di calcio 0,10 g	Agar batteriologico 5,60 g
Fosfato disodico 1,15 g	Ácido mercaptoacético 1,0 mL	Cloruro di calcio 0,09 g
Cloruro di magnesio 0,10 g	Glicerofosfato di sodio 10,00 g	Fosfato di sodio dibasico 1,10 g
Fosfato monopotásico 0,20 g		Cloruro di sodio 5,00 g
Cloruro di potassio 0,20 g		Tioglicollato di sodio 1,15 g
Cloruro di sodio 3,00 g		
Tioglicollato di sodio 1,00 g		

Precauzioni: Per uso diagnostico *in vitro*.

Si deve supporre che tutti i campioni contengano microrganismi infettivi e occorre quindi trattarli con le dovute precauzioni. Dopo l'utilizzo, smaltire provette e tamponi secondo le disposizioni del laboratorio relative ai rifiuti infetti.

 **BD BBL CultureSwab** è esclusivamente monouso; il riutilizzo può causare rischio di infezione e/o risultati inaccordati.

Conservazione: Conservare i dispositivi **BD BBL CultureSwab** a 5–25 °C.

Deterioramento del prodotto: Il contenuto del dispositivo è sterile se la confezione non è aperta o danneggiata. Non usare il prodotto se si presenta danneggiato, disidratato e contaminato o se è stata superata la data di scadenza.

PRELIEVO E TRATTAMENTO DEI CAMPIONI

L'applicatore **BD BBL CultureSwab** è disponibile montato su diversi tipi di bastoncino per facilitare il prelievo dei campioni dai vari siti. Per raccomandazioni specifiche sul prelievo dei campioni ai fini dell'indagine microbiologica e sulle tecniche di isolamento primario, consultare la bibliografia in merito.²⁻⁴ Una volta prelevato il campione, introdurre il tampone nella provetta di terreno, trasportarlo in laboratorio al più presto e metterlo in coltura su terreni di isolamento primario idonei.

PROCEDURA

Materiale fornito: Ogni busta Vi-Pak include cinquanta (50) unità di dispositivi sterili **BD BBL CultureSwab** contenenti terreno di coltura.

Ogni busta Vi-Pak include cento (100) unità di tamponi e provette da trasporto sterili **BD BBL CultureSwab**.

Materiale richiesto ma non fornito: Materiale necessario per l'isolamento, la differenziazione e la coltura di batteri aerobi e anaerobi, cioè piastre o provette con terreno di coltura e sistemi di incubazione, contenitori di gas o stazioni di lavoro in anaerobiosi.

Istruzioni per l'uso:

Le istruzioni per l'uso sono stampate su ciascuna unità **BD BBL CultureSwab**, insieme ai rispettivi schemi descrittivi, e possono essere riassunte come segue.

- Aprire la busta del dispositivo **BD BBL CultureSwab**.
- Togliere il cappuccio dalla provetta da trasporto.
- Estrarre il tampone applicatore e prelevare il campione.
Durante il prelievo, la punta dell'applicatore deve toccare solamente la zona di sospetta infezione, per minimizzare il rischio di contaminazione.
- Porre il tampono applicatore nella provetta da trasporto.
- Annotare il nome e i dati del paziente sull'etichetta della provetta.
- Inviare il campione al laboratorio per l'analisi immediata.

RISULTATI PREVISTI

La sopravvivenza dei batteri nel terreno da trasporto dipende da molti fattori, tra cui il tipo di batteri, la durata del trasporto, la temperatura di conservazione, la concentrazione di batteri nel campione e la formulazione del terreno da trasporto. I dispositivi **BD BBL CultureSwab** assicurano la sopravvivenza di molti microrganismi per 24–48 ore. Nel caso di batteri esigenti come *Neisseria gonorrhoeae* e *Streptococcus pneumoniae*, i campioni su tampone devono essere seminati direttamente su piastra con terreno di coltura o trasportati immediatamente in laboratorio e messi in coltura entro 24 ore.

LIMITAZIONI DELLA PROCEDURA

Il terreno liquido Amies e il terreno liquido Stuart **BD BBL CultureSwab** sono predisposti solamente per il prelievo e il trasporto di campioni batteriologici. Per la ricerca di organismi anaerobi sono preferibili i campioni di tessuto prelevati durante procedure chirurgiche, biopsie di tessuto o di osso, fluidi, pus o aspirati prelevati mediante siringa. Per informazioni dettagliate e raccomandazioni sul trasporto di campioni di fluido e di tessuto per la coltura di organismi anaerobi, fare riferimento alle pubblicazioni specifiche.³⁻⁷ Usare altri sistemi di trasporto specifici per i campioni contenenti virus o chlamydiae.

PRESTAZIONI METODOLOGICHE

Sono stati condotti studi di rilevazione utilizzando i prodotti **BD BBL CultureSwab** con vari organismi aerobi. I tamponi sono stati inoculati con dosi specifiche e inseriti in provette da trasporto contenenti il terreno da trasporto. Le provette sono state conservate a temperatura ambiente prima di essere subcolturate su terreni idonei. Segue un elenco degli organismi testati con i vari terreni da trasporto.

Organismo	Terreno liquido Amies	Terreni da trasporto Terreno liquido Stuart	Agar Cary-Blair
<i>Neisseria gonorrhoeae</i> ATCC 43069	*	*	
<i>Streptococcus pyogenes</i> ATCC 19615	*	*	
<i>Haemophilus influenzae</i> ATCC 19418	*	*	
<i>Campylobacter jejuni</i> ATCC 33291			*
<i>Shigella flexneri</i> ATCC 12022			*
<i>Yersinia enterocolitica</i> ATCC 9610			*

RIFERIMENTI: Vedere la sezione "References" nel testo inglese.

Assistenza e supporto tecnico: rivolgersi al rappresentante locale BD o visitare il sito www.bd.com.

ESPAÑOL

USO PREVISTO

Los dispositivos **BD BBL CultureSwab** son sistemas estériles, listos para utilizarse, diseñados para la recogida, transporte y conservación de muestras clínicas para el estudio bacteriológico.

RESUMEN Y EXPLICACION

Uno de los procedimientos de rutina para el diagnóstico de las infecciones bacterianas implica la recogida y transporte seguro al laboratorio de una muestra clínica del paciente. Puede ser llevado a cabo utilizando el dispositivo **BD BBL CultureSwab** para recogida y transporte. Cada unidad **BD BBL CultureSwab** consta de una bolsa despegable estéril que contiene una torunda aplicadora con punta de rayón o poliéster que se utiliza para recoger la muestra y un tubo que contiene medio de transporte, donde la torunda aplicadora es introducida después de obtener la muestra.

Los medios de transporte **BD BBL CultureSwab** (medio líquido Amies, medio líquido Stuart y medio de transporte Cary-Blair) son medios no nutritivos, tamponados con fosfato, que proporcionan un entorno reducido porque han sido formulados con tioglicollato sódico.¹ Los organismos del material de muestra están protegidos contra la desecación por la humedad del medio de transporte. El medio está diseñado para conservar la viabilidad de los organismos durante su transporte al laboratorio. Las bolsas **BD BBL CultureSwab** se fabrican de lámina de plástico que retrasa la penetración de aire atmosférico en el producto.

Los medios **BD BBL CultureSwab** se presentan en un tubo estrecho (Venturi). Se insufla nitrógeno gaseoso al tubo de transporte durante el proceso de introducir el medio y tapar el tubo. Durante el empaquetamiento final de la torunda y el tubo, se extrae el aire de la bolsa por la aplicación de un vacío y se insufla nitrógeno gaseoso.

REACTIVOS

Fórmula aproximada por litro de agua destilada

Medio líquido Amies	Medio líquido Stuart	Medio de agar Cary-Blair
Cloruro cálcico 0,10 g	Cloruro cálcico 0,10 g	Agar bacteriológico 5,60 g
Fosfato disódico 1,15 g	Ácido mercaptoacético 1,0 mL	Cloruro cálcico 0,09 g
Cloruro magnésico 0,10 g	Glicerofosfato sódico 10,00 g	Fosfato de hidrógeno disódico 1,10 g
Fosfato monopotásico 0,20 g		Cloruro sódico 5,00 g
Cloruro potásico 0,20 g		Tioglicollato sódico 1,15 g
Cloruro sódico 3,00 g		
Tioglicollato sódico 1,00 g		

Precauciones: Para uso diagnóstico *in vitro*.

Debe suponerse que todas las muestras contienen microorganismos infecciosos; por lo tanto, todas las muestras deben ser manipuladas con la debida precaución. Despues de utilizarla, los tubos y torundas deben desecharse siguiendo las normas del laboratorio para desechos infecciosos.

 BD BBL CultureSwab es de un solo uso; su reutilización puede causar riesgo de infección o resultados inexactos.

Almacenamiento: Almacene los dispositivos **BD BBL CultureSwab** a 5–25 °C.

Deterioro del producto: El contenido es estéril si no ha sido abierto o dañado. No utilizar si tienen indicios de daño, deshidratación o contaminación. No utilizar si se ha pasado la fecha de caducidad.

RECOGIDA Y PREPARACION DE LAS MUESTRAS

El **BD BBL CultureSwab** se ofrece con diferentes tipos de tallo de aplicador, que facilitan la recogida de muestras de diversos lugares en el paciente, como se indica en la tabla de arriba. Para conocer las recomendaciones específicas sobre la recogida de muestras para análisis microbiológico y las técnicas de aislamiento primarias, consulte las referencias apropiadas²⁻⁴.

Después de recoger una muestra en una torunda, ésta debe ser introducida en el tubo de medio, que se transportará al laboratorio tan pronto como sea posible para su cultivo en medios de aislamiento primario apropiados.

PROCEDIMIENTO

Materiales suministrados: Cincuenta (50) unidades de dispositivos estériles **BD BBL CultureSwab**, con los medios incluidos, en cada bolsa Vi-Pack.

Cien (100) unidades de torundas **BD BBL CultureSwab** y tubos de transporte, estériles, en cada bolsa Vi-Pack. **Materiales necesarios pero no suministrados:** Los materiales apropiados para el a