the protective vial, closing the screw cap. The inoculated CULTURE-PADDLE® may be incubated immediately or stored or transported to a laboratory for incubation and/or interpretation. If stored or transported to a laboratory, the URICULT® cap should be tightened. Storage or transportation should not exceed 48 hours at 45...77°F (7...25°C). Stored or transported Uricult should be incubated at 97°F ± 4°F (36°C ± 2°C) for 18–24 hours. URICULT® paddles which have been stored or transported up to 48 hours before incubation can only be used for growth and/or colony count.
Transportation of URICULT® Urine CULTURE-PADDLES® with tight caps may result in inconclusive agar color reactions and atypical colony morphology, making presumptive identification impossible.

exceed 24 hours.

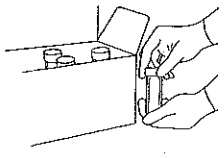
Note

URICULT® test results may be affected if the patient has been receiving antibiotics or anti-infective treatment. Should URICULT® test results show the presence of bacterial growth during the course of therapy, the physician may wish to reassess the dosage or organism susceptibility to the anti-infective being used.
URICULT® testing may be used to assess the effectiveness of antibiotic or anti-infective therapy. In this instance, it is recommended that a test be performed *no sooner* than 48 hours (2 days) following the administration of the final dose of medication.

Test procedure

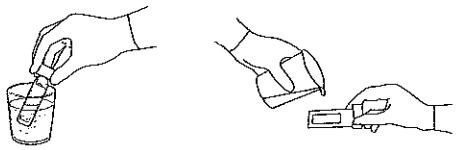
Compliance with the following directions is required to achieve reliable test results.

1



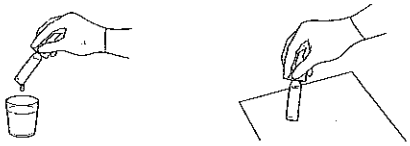
Remove the URICULT® Urine CULTURE-PADDLES® from the protective vial by unscrewing the vial cap.

2



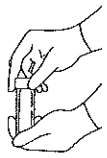
Handling the URICULT® Urine CULTURE-PADDLE® *by the cap*, dip the CULTURE-PADDLE® into the urine specimen to fully immerse the agar surfaces. If the urine volume is not adequate to fully immerse the agar surfaces, as is sometimes the case with infants or small children, the urine may be poured over the agar surfaces.

3



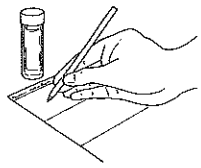
Allow the excess urine to drain from the URICULT® Urine CULTURE-PADDLE®. The base of the culture-paddle may be blotted on absorbent paper if desired.

4



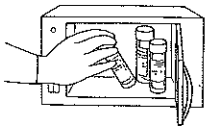
Replace the inoculated URICULT® Urine CULTURE-PADDLE® in its protective vial.

5



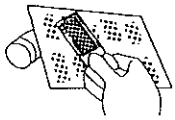
Complete patient label indicating patient's name, date and time of inoculation. Attach label to URICULT® vial.

6



Place inoculated URICULT® vial upright in incubator 97°F ± 4°F (36°C ± 2°C) for 18 to 24 hours. Incubation should not exceed 24 hours. Incubation exceeding 24 hours may cause bacterial overgrowth resulting in difficult interpretation of colony counts and possibly misleading biochemical reactions.

7



Remove URICULT® vial from incubator following incubation period. Compare colony count density on the agar surfaces with the Colony Density Chart provided to obtain a semiquantitative colony count in CFU/ml of urine. Compare only the number of colonies present, not the size of the colonies or the agar surface area they cover. The colonies on the agar surface may also be observed at this time for morphology and agar color reactions which may be used for presumptive identification of the bacterial growth.

8

Negative cultures may be incubated for an additional 24 hour period, if desired. This will allow for the detection of slow growing bacteria.

Culture disposal

Because bacterial colonies on inoculated URICULT® Urine CULTURE-PADDLES® are actual or potential pathogens, they should not be touched and should not be unduly exposed to other office personnel or patients. It is advised that the procedure to dispose of inoculated culture media be in accordance with existing state or local laws.
To avoid any risk of contamination after a culture has been interpreted, it is also recommended that used URICULT® Urine CULTURE-PADDLES® be promtly and completely immersed in a cup of bactericidal *"biocide"* solution such as 3% phenol, Staphene® (Vestal Labs) or Cidex® (Surgikos, Inc.).

Bactericidal-treated paddles and protective vials can then be placed in a large widemouthed jar or other suitable disposal container filled about 1/3 of its capacity with additional biocide. Keep the container tightly capped and discard when filled.

05	06	04
PP	PS	PE-LD
Tube	Slide	Cap

BD BBL™ Taxo™ Discs for Differentiation of Group A Streptococci

7/14

English: pages 1 – 2
Français : pages 2 – 4
Deutsch: Seiten 4 – 5
Italiano: pagine 5 – 6
Español: páginas 7 – 8

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2012-02

Pokyny vám poskytne místní zástupce společnosti BD. / Kontakt den lokale BD repræsentant for at få instruktioner. / Kasutusjuhiste suhtes kontakteeruge oma kohaliku BD esindajaga. / Επικοινωνήστε με τον τοπικό αντιπρόσωπο της BD για οδηγίες. / A használati utasítást kérje a BD helyi képviseletétől. / Naudojimo instrukcijų teiraukitės vietos BD įgaliotojo atstovo. / Kontakt din lokale BD-representant for mer informasjon. / Aby uzyskać instrukcje użytkowania, skontaktuj się z lokalnym przedstawicielstwem BD. / Contacte o seu representante local da BD para obter instruções. / Inštrukcie získate u miestneho zástupcu spoločnosti BD. / Kontakta lokal Becton Dickinson-representant för anvisningar. / Свържете се с местния представител на BD за инструкции. / Contactați reprezentantul dumneavoastră local BD pentru instrucțiuni. / Talimatlar için yerel BD temsilcilerinize danışın. / Obratite se svom lokalnom predstavniku kompanije BD za uputstva. / Для получения инструкций свяжетесь с местным представителем компании BD. / Өзіңіздің жергілікті БД өкіліне жүгініп нұсқау алыңыз. / Kontaktiraj lokalnog predstavnika BD za upute.

INTENDED USE

Taxo™ A discs are for the presumptive identification of group A beta-hemolytic streptococci based on susceptibility to a low level of bacitracin. Discs are intended for use with pure cultures, with the exception noted under "Specimens."

SUMMARY AND EXPLANATION

Taxo A discs are impregnated with a low level of bacitracin. According to the work of Maxted, of Levinson and Frank, and others, the group A streptococci may be differentiated from the other Lancefield groups of hemolytic streptococci by the formation of a zone of inhibition around the disc.[1-6]

PRINCIPLES OF PROCEDURE

Group A beta-hemolytic streptococci are sensitive to small amounts of bacitracin, while beta-hemolytic streptococci of other serologic groups are more resistant. The **Taxo** A disc on a blood agar plate can be used for presumptive identification of group A beta-hemolytic streptococci after overnight incubation.

REAGENTS

Taxo A discs are impregnated with approximately 0.04 unit of bacitracin per disc.

Warnings and Precautions:

For *in vitro* Diagnostic Use.

Taxo A discs *are not for susceptibility testing.*

Observe aseptic techniques and established precautions against microbiological hazards throughout all procedures. After use, test plates and other contaminated materials must be sterilized by autoclaving before discarding. Directions for use should be read and followed carefully.

Storage Instructions: On receipt, store at -20 to +8°C. After use, store vial or cartridge to protect product integrity at 2 to 8°C.

Use oldest discs first and discard expired discs. Allow containers to come to room temperature before opening. Return unused discs to the refrigerator when application of discs has been completed. Vials and cartridges from which discs have been frequently removed during one week and discs left out overnight in the laboratory should be discarded, or the discs should be tested for performance with control organisms prior to continued use.

SPECIMENS

Taxo A discs are not for use directly with clinical specimens or other sources containing mixed flora. The organism to be presumptively identified must first be isolated as separate colonies by streaking the specimen onto appropriate culture media; e.g., **Trypticase™** Soy Agar with 5% Sheep Blood (TSA II). However, the **BBL™** Group A Selective Strep Agar with 5% Sheep Blood (**ssA™**) plate, which may be used for the primary isolation of group A streptococci from throat specimens, was designed specifically for use with the **Taxo** A disc.[7]

PROCEDURE

Material Provided: Taxo A Discs.

Materials Required But Not Provided: Ancillary culture media, quality control organisms and laboratory equipment as required for this procedure.

Test Procedure

1. Inoculate a **Trypticase** Soy Agar with 5% Sheep Blood plate with the test organism exhibiting beta-hemolysis on the primary isolation plate. If the plate is inoculated with a suspension, it should be adjusted to provide just confluent growth over the surface of the plate. With sterile forceps or single disc dispenser place the **Taxo** A disc in the center of the inoculated area. If the organism is streak-inoculated, the disc should be placed in the primary streak area or at the junction of the primary and secondary streak area. For further information regarding the use of the **Taxo** A disc with **ssA**, consult **ssA** product literature.
2. Incubate plate(s) in ambient air (or in an atmosphere enriched with 5 to 10% CO_2) at 35 to 37°C for 18 to 24 hours.
3. Observe plate for presence of a zone of growth inhibition around the bacitracin disc.

User Quality Control: At the time of use, check performance with pure cultures of stable control organisms producing known, desired reactions. The use of *Streptococcus pyogenes* ATCC™ 12384 is recommended to demonstrate zone formation. One or more beta-hemolytic streptococcal species belonging to groups B, C, D and/or G may be employed to demonstrate lack of zone formation.

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control