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Instructions for Use

BACTI-LAB STREPLATE™

Cat. no. A150	StrePlate™, 15x100mm Monoplate, with CO_2 pill pocket and 10 CO_2 pills,22ml	10 plates/bag

INTENDED USE

Hardy Diagnostics' Bacti-Lab StrePlate™ is on enriched media providing increased CO_2 concentration, for the selective isolation of all *Streptococcus* spp., including beta-hemolytic group A (*Streptococcus pyogenes*), group B (*Streptococcus agalactiae*), groups C, D, F and G; and *Streptococcus pneumoniae.*

SUMMARY

In children over the age of five and in adults, the only significant cause of bacterial, non-pneumonic, respiratory infections is group A beta-hemolytic streptococci.(1) Approximately 10% of those patients presenting a complaint of a pharyngitis will be infected with this bacteria. Regardless of the clinical picture, a throat culture is essential for the precise diagnosis of streptococcal pharyngitis if the physician is to prevent the more dangerous sequelae of rheumatic fever and chronic glomerulonephritis. Rheumatic fever has been stated to occur at a reasonably constant endemic rate of 0.3% following a streptococcal infection, with a rate possibly exceeding 5% during epidemics.(2) The attack rate of acute glomerulonephritis may be much more subtle and varied.(3) The development of nephritis, secondary to streptococcal cutaneous involvement, dictates that skin lesions, such as impetigo, pyoderma, and even otitis media, also be cultured in order to establish an appropriate treatment program.

One older comparative study of office streptococcal cultures resulted in an unacceptably high average of 53% incorrect diagnosis.(4) Reasons for these errors include failures to recognize the organism, errors in streaking, improper blood concentration, expired or hemolyzed media, and lack of an anaerobic culture environment.

In a comparative study using Bacti-Lab StrePlate™ products, para-professional aides doing on-site overnight interpretations were able to achieve excellent correlations with split control mail-in fluorescent antibody test results performed at a state laboratory.(5) These studies further revealed that a number of variables that were heretofore either too difficult to control or even considered as being unimportant are of major importance for the accurate detection of streptococcal throat organisms. These variables in part are:

1. Use of a highly selective medium so that a heavier than usual inoculum can be employed still resulting in inhibition of any confusing hemolytic non-streptococcal colonies.

2. Creation of an anaerobic growth environment in order to facilitate the detection of Streptolysin O, an anaerobic hemolysin produced by essentially all beta-hemolytic streptococci. This beta hemolysis (a clear zone surrounding the colony) is sometimes not seen on the aerobic (air) exposed surface of a typically surface-streaked streptococcal culture plate.

3. Provision of an excess CO_2 environment that can improve the growth rate by an approximate additional 10%. This also increases the hemolytic activity of the Streptolysin O.

4. Use of the PYR test (Cat. no Z75) or Bacitracin Differentiation Disks (Cat. no. Z7021) to eliminate false-positive results.

5. Using an accurate pre-set incubator temperature not to exceed 35ºC. This factor alone may account for a great many unsatisfactory results.[2]

These variables have all been optimally controlled so that the use of Bacti-Lab StrePlate™ products and ancillary aid constitutes the most advanced and accurate means available for the detection of group A beta-hemolytic streptococci.

Hardy Diagnostics' Bacti-Lab StrePlate™ is a disposable diagnostic test kit that provides an improved, simplified culture procedure for the detection of alpha- and beta-hemolytic streptococci. The kit contains ten culture plates with pill pocket filled with selective streptococcal sheep blood agar, and ten CO_2 pills.

Sterile throat swabs are required, but not supplied. CO_2 tablets and incubation pouches are provided to simplify the diagnosis and increase the yield of beta-hemolytic organisms by creating a CO_2 enriched growth environment. For confirmatory testing, PYR Test Kits (Cat. no. Z75), Bacitracin Disks (Cat. no. Z7021), Optochin Disks (Cat. no. Z7011), and Catalase test (Cat. no. Z62) are available separately upon request.

Hardy Diagnostics' Bacti-Lab StrePlate™ employs 5% defibrinated sheep blood agar that include selective agents. These agents improve the quality of diagnostic interpretations by inhibiting the growth of hemolytic staphylococci, gram-negative bacteria, and other interfering contaminant microorganisms that could be confused with hemolytic strep.[6] The use of sheep blood further minimizes the growth of hemolytic *Haemophilus* species that may mimic group A strep.[7]

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	15.0gm
Papaic Digest of Soybean Meal	5.0gm
Sodium Chloride	5.0gm
Selective Agents	15.3mg
Sheep Blood	50.0ml
Agar	15.0gm

Final pH 7.3 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), hemolysis, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Handling: Organisms that may appear upon culture should be considered as pathogens. Their primary mode of transmission in the laboratory is by hand. Generous hand washing with germicidal soaps is recommended after the handling of all culture materials. Occasionally a mold or other contaminant may be noted within the culture plate before usage. These plates should be discarded without opening and replacement requested.

Disposal: Sterilize all biohazard waste before disposal. A conveniently placed container of CaviCide® (Cat. no. 131000) for a ten minute bactericidal immersion of used swabs is recommended. The same solutions can be used to flood culture plates after studies are completed. Follow local public health department recommendations for disposal.

PROCEDURE

Specimen Collection: A properly acquired specimen is critical for reliable results. A good light and tongue blade (Cat. no. 704) are essential. With the mouth wide open, the extended tongue is depressed until the back of the throat is clearly visible, not just the back of the tongue or the hard palate but the actual posterior throat (pharynx). Then, using a dacron tipped swab (Cat. no. 258062PD), the area at the very back edge of the throat is swabbed on each side. This should be done vigorously, enough to induce a gag reflex, which rapidly brings more posterior pharynx into view and offers an opportunity to swab additional areas. Particular attention should be taken to swab any red, raw or raised bumps along the side and any areas coated with pus, whitish exudate or ulceration. When the tonsils are present, they should also be swabbed, but not to the exclusion of the area behind the tonsils. The mouth and its saliva should be avoided, and heavy mucous draining down the back of the throat from the nose is also undesirable culture material.[2] Consult additional listed references for information on specimen collection.[9,12,14,16]

Infectious material should be submitted directly to the laboratory without delay and protected from excessive heat and cold. If there is to be a delay in processing, specimens should be inoculated into an appropriate transport media (Amies Gel transport swab, Cat. no. 4108BX) and refrigerated until inoculation.

Remove culture plate from the bag and re-seal the bag with the twist tie. Allow the plate to come to room temperature.

1. Roll the swab back and forth repeatedly across the entire width of the upper end of one section.

2. Starting at the rolled upper end, streak the inoculum using the point of the same swab across the length of the entire section so as to completely cover it.

3. If desired, with dry forceps (alcohol or iodine rinse can cause false-positive hemolysis) position a Bacitracin Differentiation Disk (Cat. no. Z7021) over puncture site C and tap it to ensure adhesion.

4. The use of excess CO_2 is recommended for best recovery, growth, and development of hemolysis for strep cultures. To create an excess CO_2 environment, use the CO_2 tablet with zip-lock bag provided. Before closing the lid, place a CO tablet into the empty pill pocket, do not add water. The humidity in the bag will activate the tablet. Place the

culture plate into the incubation pouch and carefully zip-lock to effect an air-tight closure. Alternatively, a CO_2 candle extinction jar or a CO_2 incubator may be used to create an excess CO_2 environment.

5. Label the inoculated section (on the bottom, not the lid) and incubate (lid side down) at a maximum temperature of 35 +/- 1ºC. Note that most incubators heat from the bottom and the temperature on the shelf may be a number of degrees higher than recorded by the outside thermometer.

6. Most cultures can be reliably read the next day (18-24 hours), but any doubtful specimens should be reincubated for another 24 hours.

INTERPRETATION OF RESULTS

Typical colonies of group A streptococci appear as small, white, and convex surrounded by a clear zone of beta-hemolysis after 24-48 hours of incubation. Refer to the listed references for more information.[12,13,16]

First determine if the organism is a beta-hemolytic *Streptococcus*.

1. Hold the culture plate up to a bright light and view the growth through both the top surface and underside of the plate. The culture may reveal growth of various streptococci and pneumococci on the surface of the agar.

2. A beta-hemolytic positive culture is one in which the blood red color has been completely dissolved away, leaving the clear agar visible. Observe plates for beta hemolysis, even if the clear zone is small.

Alpha-hemolytic (green) streptococci lack Streptolysin O and do not display these sub-surface clear hemolytic zones. Both viridans strep (normal flora) and *S. pneumoniae* are alpha-hemolytic and will produce green zones of hemolysis.

3. A Catalase test (Cat. no. Z62) should be performed to confirm that the suspected colony is a member of the strep family. *Streptococcus* spp. and *Enterococcus* spp. are catalase-negative; staph, *Candida*, and gram-negative bacteria are catalase-positive.

4. It is recommended that a PYR test (Cat. no. Z75) be performed to confirm the identification of group A strep. The only other gram-positive bacteria that will be PYR positive are *Enterococcus* spp., which will not be beta-hemolytic on blood agar. PYR is recommended over bacitracin disk tests due to its greater specificity (lack of false-positives).

See the "Additional Tests" section for more details on confirmatory testing.

STREP IDENTIFICATION CHART						
Bacterial growth on StrePlate Media	**Hemolysis on Blood**	**PYR Test**	**Bacitracin**	**Optochin**	**Catalase**	**Pathogenicity**
Group A Strep (*Streptococcus pyogenes*)	Beta (clear zone)	Positive	Zone of inhibition	Zone <14 mm	Negative	Respiratory Pathogen
Group B, C, F, and G Strep (various *Streptococcus* spp.)	Beta (clear zone)	Negative	Occasional zone of inhibition	Zone <14 mm	Negative	Normally not a respiratory pathogen
Pneumococci (*Streptococcus pneumoniae*)	Alpha (green zone)	Negative	Occasional zone of inhibition	Zone ≥14 mm	Negative	Respiratory pathogen
Viridans Strep (*Streptococcus viridans* and others)	Alpha (green zone) or gamma (no zone)	Negative	No zone	Zone <14 mm	Negative	Normal respiratory flora
Enterococci (*Enterococcus* spp., and group D strep)	Alpha (green zone) or	Positive	No zone	Zone <14 mm	Negative (occasionally a	Normal respiratory flora

	gamma (no zone)				weak positive)	

a. BETA STREP (*Streptococcus pyogenes*): About 0.5 mm transparent or translucent colonies, domed and surrounded by a well-defined zone of complete beta-hemolysis (a brilliant, clear zone) some 2-4 times the diameter of the colony. A convenient method of reporting their presence would be: 1+ = 10 colonies or less; 2+ = 11-50; 3+ = 51-199, and 4+ = 200 or more colonies. Numerous colonies are usually seen when beta-hemolytic *Streptococcus* is the cause of infection. Their absence may be regarded as excluding the diagnosis of streptococcal disease. When only a few hemolytic colonies are present on the plate, their presence may represent the carrier state rather than an acute infection; or it may be due to inadequate specimen collection. Group A beta-hemolytic strep will be positive for PYR. Groups B, C, F, and G are also beta-hemolytic.

b. PNEUMOCOCCI (*Streptococcus pneumoniae*): Small, shiny, transparent and flattened colonies, often with a crater-like raised margin. May resemble alpha strep as they also produce an adjacent zone of green (alpha) hemolysis. Identification of *S. pneumoniae* must be confirmed by the use of an Optochin Sensitivity Disk (Cat. no. Z7011) or Bile Spot Test (Cat. no. Z61).

c. ALPHA STREP (*Streptococcus viridans*): Small, raised, opaque appearing colonies, but with a green (several millimeter wide) zone of partial, or alpha-hemolysis; commonly present as a part of a patient's normal flora.

d. GAMMA STREP: Small gray colonies producing neither alpha- nor beta-hemolysis, sometimes referred to as no hemolysis. These microorganisms are not pathogenic.

e. ENTEROCOCCI: Small, light gray, raised colonies producing alpha-hemolysis or no hemolysis. Enterococci are positive for PYR. Rare strains of enterococci may produce beta-hemolysis; consequently, additional biochemical testing, using a pure culture, may be necessary to separate group A streptococci (*S. pyogenes*) from beta-hemolytic enterococci.

SUPPLEMENTAL TEST PROCEDURES

EXTRACELLULAR TOXINS AND HEMOLYSIS

Group A streptococci elaborate a large number of extracellular toxins that can contribute to their pathogenicity. Two such toxins are hemolysins called Streptolysin O (oxygen-sensitive and antigenic) and Streptolysin S (serum-nonantigenic). These hemolysins produce zones of complete red blood cell breakdown (beta-hemolysis) around streptococcal colonies grown on blood agar. Because some strains of group A beta-hemolytic streptococci do not produce beta-hemolysis under aerobic conditions, it is essential the correct atmospheric conditions are used for Streptolysin O is to be detected.[8,9] Most personnel performing routine strep cultures are either unaware of this fact Streptolysin S, if present, is not oxygen sensitive.

PYR DISK TEST (Available separately, Cat. no. Z75)

A PYR test can be performed on isolated colonies for the presumptive identification of group A streptococci (*Streptococcus pyogenes*) and group D enterococci, which are both PYR positive. To do so, moisten a PYR disk slightly with distilled or deionized water. **Do not saturate**. Alternatively, the disk may be placed on an uninoculated portion of a blood agar plate, which will adequately moisten the disk. Using a sterile disposable loop (Cat. no. HST10F), pick 2-3 well isolated, 18-24 hour colonies and rub a small area of the PYR disk so that there is a visible paste. After the test organism has been inoculated onto the disk, allow it to react for two minutes. After this incubation period, add one drop of chromogenic solution (PYR Reagent). A bright pink or cherry red color will appear within one minute if the test is positive. A negative test is indicated by no color change. The development of an orange, salmon, or yellow color should be interpreted as a negative reaction.

BACITRACIN (0.04 units) SENSITIVITY TEST (Available separately, Cat. no. Z7021)

In order to differentiate group A streptococci from other beta-hemolytic streptococci, a paper disk containing 0.04 units of bacitracin may be employed. The concentration of regular bacitracin disks used for susceptibility testing is too strong. After specimen inoculation of the culture plate, a bacitracin disk is placed in the area of heaviest inoculation.

Following incubation, a presumptive positive test for group A streptococci can be concluded by noting the presence of any size zone of growth inhibition around the disk. A negative test shows growth right up to the disk margin or no inhibition. It is important to interpret results only from beta-hemolytic streptococci, inasmuch as some strains of alpha-hemolytic strep (producing green zones), e.g. *S. viridans* 8%, and *S.* (diplococcus) *pneumoniae* 48% can also be bacitracin sensitive. Over 10% of non-group A beta-hemolytic streptococci (groups C and G) can also show sensitivity. Of the greatest clinical importance was the finding that 99.5% of group A streptococci are susceptible to bacitracin and the conclusion that it is preferable to have more false-positive results (an over-diagnosis) rather than false-negative results.[10] The users of bacitracin should realize that bacitracin inhibits the growth of some strains of beta-hemolytic streptococci other than group A. Reporting results for the presumptive identification of beta-hemolytic colonies that are PYR positive and catalase-negative should be as follows: (i) "beta-hemolytic strep presumptively group A by bacitracin," or (ii) "beta-hemolytic strep presumptively not group A by bacitracin." Too few colonies may not give clear-cut zones for interpretation, and these colonies should be transferred and spread on an adjacent agar section and retested. Due to the high rate of false-positives (low specificity) with bacitracin, it is recommended that a rapid PYR test be used instead to confirm group A beta-hemolytic streptococci.

OPTOCHIN SENSITIVITY TEST (Available separately, Cat. no. Z7011)

This test is designed to distinguish pneumococci from alpha streptococci since both display alpha-hemolysis (green) on blood agar. Pneumococci cells are lysed by the optochin contained in the disk; whereas, alpha streptococci are resistant. Following specimen inoculation and placement of the disk, overnight incubation is performed. A positive presumptive test for pneumococci reveals a zone of growth inhibition of at least 14mm in diameter, including the disk. A negative test implying alpha streptococci shows either no zone or less than 14mm in diameter. This test will also give occasional false-positive and negative results.[9] Alternatively, a Bile Spot Test (Cat. no. Z61) may be performed.

CATALASE TEST (Available separately, Cat. no. Z62)

Microorganisms able to live in oxygenated environments produce enzymes which neutralize toxic forms of oxygen. One such enzyme, catalase, breaks down hydrogen peroxide into water and molecular oxygen. Organisms that are positive for catalase will produce gas bubbles when placed into contact with hydrogen peroxide. Members of the genera *Streptococcus* and *Enterococcus* are catalase-negative, as opposed to staph, *Candida*, and gram-negative species, all of which test positive.

Using a sterile disposable loop (Cat. no. HST10F), transfer a small amount of a well isolated, 18 to 24 hour old colony onto the surface of a clean, dry glass slide. Immediately place a drop of Catalase Reagent onto a portion of the colony on the slide. Organisms tested for catalase production must be taken from an 18-24 hour old culture, as organisms lose their catalase activity with age. In addition, care should be taken not to collect any blood cells from the agar medium when removing a colony, as red blood cells will cause a false-positive result. Any formation of gas bubbles appearing around the bacteria denotes a positive reaction.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

It should be noted that excessive inoculum concentrations and/or an atmosphere of aerobic incubation may result in the absence of a bacitracin zone of inhibition (false-negative) with some group A streptococci. It has been reported that 5% of group B and 10% of groups C and G streptococci may produce zones of inhibition or false-positive results.[16]

The bacitracin disk test is presumptive, and a positive result should be followed with more specific tests for confirmatory identification such as the PYR test or specific latex antibody test (such as the StrepPRO™ Grouping Kit, Cat. no. PL030HD).

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops (Cat. no. HST10F), swabs (Cat. no. HD25806), tongue blades (Cat. no. 704), other culture media, incinerators, Bacitracin Disks (Cat. no. Z7021), Optochin Disks (Cat. no Z7011), Catalase test (Cat. no. Z62), PYR Test Kit (Cat. no. Z75), candle jars, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media.* The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Streptococcus pyogenes ATCC® 19615	A	24hr	35°C	CO_2**	Growth; beta hemolysis
Streptococcus pneumoniae ATCC® 6305	A	24hr	35°C	CO_2**	Growth; alpha hemolysis
Escherichia coli ATCC® 25922	B	24hr	35°C	CO_2**	Inhibited
Staphylococcus epidermidis ATCC® 12228	B	24hr	35°C	CO_2**	Inhibited

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

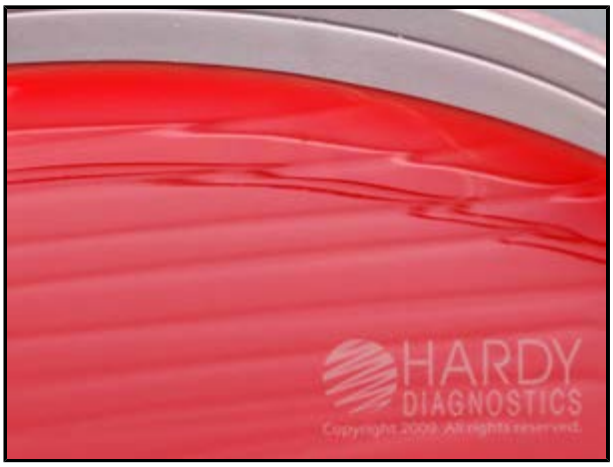
End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

Hardy Diagnostics' Bacti-Lab StrePlate™ should appear opaque, and cherry red in color.

Streptococcus pyogenes (ATCC® 19615) colonies growing on StrePlate™ (Cat. no. A150). Incubated in CO_2 for 24 hours at 35ºC.

Streptococcus pneumoniae (ATCC® 6305) colonies growing on StrePlate™ (Cat. no. A150). Incubated in CO_2 for 24 hours at 35ºC.



Escherichia coli (ATCC® 25922) growth inhibited on StrePlate™ (Cat. no. A150). Incubated in CO_2 for 24 hours at 35ºC.

REFERENCES

1. Adatto, I.J. 1966. Staphylococci in throat cultures, questions and answers. *JAMA*; 197: 222-223.

2. Jackson, H. 1974. Personal Communication.

3. Freedham, P., Meister, P. Siuco, B. Markowitz, A.S., and Dubin, A. 1966. Subclinical Renal Response to Streptococcal Infection. *New Eng. J. Med.*; 275: 795-802.

4. Mondazac, A.M. 1967. Throat Culture Processing in the Office--a Warning. In Letters to the Editor, *JAMA*; 200: 208.

5. Jackson, H. 1974. Preliminary Reports State of Colorado Office and School District Strep Detection Program.

6. Vincent, W.P., Gibbons, W.E., and Gaafar, H.A. 1971. Selective Medium for the Isolation of Streptococci from Clinical Specimens. *Appl. Microbiol.*; 22: 942-943.

7. Rammelkamp, C.H. and Top, F.N. 1972. *Communicable and Infectious Diseases*. C.V. Mosby Co. St. Luis, pp. 630-647.

8. McCarty, M. 1965. *The Hemolytic Streptococci, Bacterial and Mycotic Infections of Man*, Philadelphia, J.B.

Lippincott, Co.

9. Branson, D. 1972. *Methods in Clinical Bacteriology*, pp. 7, 39, 77, Springfield, Illinois, Charles C. Thomas Co.

10. Facklam, R.R., Padula, J.F., Thacker, L.G., Wortham, E.C., and Sconyers, B.J. 1974. Presumptive Identification of Group A, B, and D, Streptococci. *Appl. Microbiol.*; 27: 107-113.

11. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

12. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

13. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

14. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

15. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

16. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207F [D]