IFU

Instructions for Use

REPROCESSED ENDOSCOPE MICROBIAL SAMPLING, CULTURE, AND SURVEILLANCE PROCEDURES

Cat. no. U334	0.01M Phosphate Buffered Saline (PBS) with 0.02% Tween® 80, 125ml Polycarbonate Bottle, 50ml	16 bottles/box
Cat. no. U336	Sterile Water, 125ml Polycarbonate Bottle, 50ml	16 bottles/box

INTENDED USE

Hardy Diagnostics 0.01M Phosphate Buffered Saline with 0.02% Tween® 80 (PBST) and Sterile Water are recommended for use in performing microbial sampling, culture, and surveillance procedures for reprocessed endoscopes.

SUMMARY

Flexible endoscopes are commonly used for diagnostic procedures as well as for therapeutic purposes. Endoscopes can be used for medical conditions involving the lungs (bronchoscopy); the esophagus, stomach and small intestines (gastroscopy and enteroscopy); the biliary tract and pancreas (duodenoscopy with endoscopic retrograde cholangiopancreatography (ERCP)); or the large bowel (colonoscopy).[7,10] Consequently, infections related to the use of flexible endoscopic procedures can be the result of the patient's own flora (endogenous) or the result of microbes introduced via the flexible endoscope or its accessories (exogenous). Though infection by these sources may be considered uncommon, such incidences are preventable with strict adherence to reprocessing guidelines or the use of surveillance techniques to monitor the efficacy of disinfection procedures.[7,8,10,11]

Endoscopes may potentially contain a high bioburden of microorganisms or organic debris after use and are notoriously difficult to clean and disinfect because of their complicated and intricate design, especially in the distal tip where the forceps elevator is located. Most modern endoscopes are composed of one or more materials that may be chemically sensitive or which may degrade over time and use. In addition, due to the delicate and complex design and heat labile components and adhesives used, endoscopes cannot be sterilized by steam in an autoclave. Therefore, the vast majority of modern endoscopes cannot be sterilized: a term used to describe the complete removal or destruction of all microbial cells, including spores. Chemical disinfection is commonly used to reprocess modern endoscopes. More recently, the Food and Drug Administration (FDA) has listed supplemental sterilization measures for facilities to consider, in addition to meticulous cleaning, monitoring and proficiency testing of personnel, including ethylene oxide (EtO) sterilization, use of a liquid chemical sterilant processing system, or repeat high-level disinfection to reduce the risk of infection transmission.[18]

By definition, disinfection is not the same as sterilization. Disinfection involves removing or killing the vast majority of microorganisms, but not all of them. High-level disinfection is considered adequate for the reprocessing of endoscopes because it removes or kills microorganisms most likely to cause disease. High-level disinfection for endoscope reprocessing must kill all forms of bacteria (Gram-positive, Gram-negative, and mycobacteria), viruses (both the more sensitive lipid-coated viruses such as HIV and the more resistant viral forms like polio), fungi (e.g. *Candida* spp.) and protozoa (e.g. Giardia). However, there are many practical barriers to adequate reprocessing, including the potential for

inadequate cleaning, staff error, mechanical endoscope defects, endoscope design flaws, aging endoscopes that may develop irregularities at junctions, crack or split at internal (non-visible) surface layers and channels, and the risk of contaminated rinse water. Consequently, pathogenic bacteria may proliferate because these defects, or the presence of biofilms or layers of organic debris, may shield microorganisms from adequate cleaning or disinfection. Many reprocessing systems use a combination of chemicals and modest heat to achieve high-level disinfection, but failures in endoscope reprocessing are reported in the literature.[7-11,16,17]

In recent years there have been multiple reports of patient exposure to multi-drug resistant organisms (MDRO), such as carbapenem-resistant *Enterobacteriaceae* (CRE), from contaminated duodenoscopes. The transmission of CRE occurred from contaminated duodenoscopes used to perform endoscopic retrograde cholangiopancreatography (ERCP) procedures.[9,16,17] Over 500,000 ERCP procedures are performed annually, resulting in the need to routinely reprocess duodenoscopes multiple times each year. However, CRE make up only the most recent infectious agents associated with contaminated endoscopes. Other pathogens known to be transmitted via endoscopic procedures, including those due to inadequate disinfection by automated flexible endoscope reprocessors (AFERs), that have resulted in infection or patient death include salmonellae, *Mycobacterium tuberculosis* , *Serratia marcescens* , *Helicobacter pylori* , *Clostridium difficile* , *Pseudomonas* spp., vancomycin resistant enterococci (VRE), carbapenem-resistant *Enterobacteriaceae* (CRE), and Hepatitis C.[7-11,14,16,17] Greater still is the potential for transmission of other infectious agents, especially to immune compromised patients, including *Candida* spp., *Rhodotorula rubra* , oocysts of cryptosporidia, *Trophyeryma whipplei* , and prions.[7,10] Prions, or transmissible spongiform encephalopathies (TSEs) such as Classical Creutzfeldt-Jakob Disease (cCJD) or variant CJD (vCJD), occur in mammals and, like human immunodeficiency virus (HIV), have a relatively long incubation time prior to clinical presentation. Consequently, these agents may pose a threat during endoscopic procedures due to inadequate reprocessing.[7,10]

Canada, Australia, New Zealand and other members of the European community, as well as the Asian Pacific community, have already published formal guidelines for microbial surveillance cultures from endoscopes and AFERs.[7,10,11] However, surveillance is not universally mandated and only recently the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) released interim guidance documents to aid U.S. labs.[1-4] Rather than focus solely on the detection of MDRO, the CDC recommends labs look for the presence of large numbers of bacteria and for a variety of “high concern” organisms. The high concern organisms are not normal skin or environmental flora and may represent potential pathogens during endoscopic, especially ERCP, procedures. They include *Staphylococcus aureus* , *Enterococcus* spp., *Streptococcus* spp, viridans group, *Pseudomonas aeruginosa* , *Klebsiella* spp., *Salmonella* spp., *Shigella* spp., and other enteric Gram-negative bacilli . The interim guidance documents provided by the CDC include a method for presence/absence testing, as well as a quantitative culture method for obtaining colony counts from samples.[1,2] Labs, in conjunction with infection control, should evaluate the need, frequency, and method of microbial surveillance testing based on the differential risks of transmission in conjunction with the method of endoscope disinfection.

Hardy Diagnostics 0.01M PBS with 0.02% Tween® 80 (Cat. no. U334) is useful for the recovery of microbial cells, including spores, from environmental samples. Hardy Diagnostics Sterile Water (Cat. no. U336) is useful for performing rinsing procedures because it provides a higher sterility assurance level (SAL) than tap water.[7,10] 0.01M PBS with 0.02% Tween® 80 (PBST) contains sodium chloride, sodium phosphate, and potassium phosphate. Phosphate salts are nontoxic to living cells and have a high buffering capacity; consequently, pH maintenance is important in retaining cell viability and in the recovery and revitalization of injured or damaged cells. In addition, Tween® 80 is effective at neutralizing the antimicrobial effects of disinfectants or cleaning solutions and in the germination of environmental spores. Used in conjunction with general culture or selective plated media such as Blood Agar (Cat. no. A10), MacConkey Agar (Cat. no. G35) or HardyCHROM CRE (Cat. no. G323), 0.01M PBS with 0.02% Tween® 80 and Sterile Water can be used to establish microbial sampling and testing protocols in endoscope reprocessing surveillance procedures as detailed in communication published by the CDC and FDA.[1-3,18]

FORMULA

Ingredients per liter of deionized water:*

0.01M PBS with 0.02% Tween ® 80 (PBST)	

Sodium Chloride	8.5gm
Monopotassium Phosphate	0.22gm
Disodium Phosphate	1.2gm
Tween ® 80	0.2gm

Final pH 7.5 +/- 0.1 at 25ºC.

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

Cat. no. U336 contains sterile deionized water.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-30ºC away from direct light. Media should not be used if there are any signs of deterioration, discoloration, 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 blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory 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.

PROCEDURE

For current information on materials, reagents, and procedures, refer to the Centers for Disease Control and Prevention (CDC) interim guidance documents or other appropriate guidance documents, as applicable, for sampling, culture, and surveillance methods and for determining standards on the frequency of testing.[1-4]

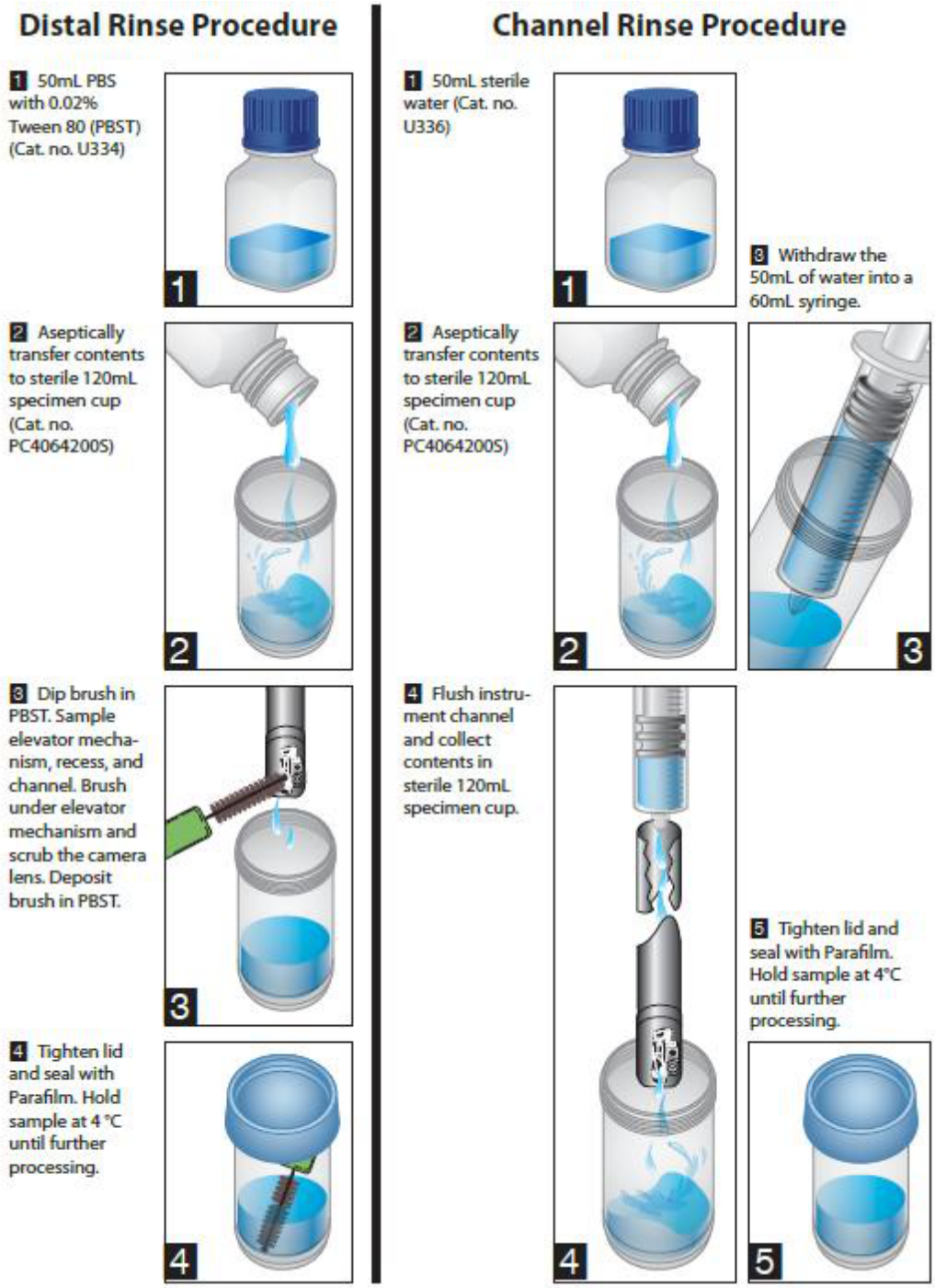
Sample Method :

Prior to obtaining cultures, clean and disinfect counters and surfaces where sampling will be performed using an EPA approved disinfectant for hard, non-porous surfaces. Observe the manufacturer's instructions on contact time and disinfection procedures. Don sterile gowns, face masks/shields, hair coverings, and gloves to reduce the chance of contamination due to aseptic technique. Use only sterile sampling equipment, such as a disposable or reusable sterile

brush.

Details on the CDC recommendations for sample types, number of samples, and sampling methods can be found in the Interim Sampling Method for the Duodenoscope - Distal End and Instrument Channel and Interim Duodenoscope Culture Methods guidance documents.[1,2]

Refer to the following illustration as an example of how to collect samples from the distal end and instrument channel of reprocessed duodenoscopes:



Once the sample has been collected in a sterile specimen cup (e.g. Cat. no. PC4064200S) and labeled for proper identification and traceability, the sample should be sent immediately to the microbiology laboratory for culture. If transit time to the lab is anticipated to be more than 30 minutes, the sample should be held on ice or refrigerated until cultured. Samples should not be held refrigerated for longer than 24 hours prior to culture since this may affect results.[7,10]

Additional international reference methods for sample collection can be found in the literature.[7,10]

Culture Method :

See culture method A for the presence/absence enrichment method or method B for the quantitative method as outlined by the CDC, or refer directly to the CDC guidelines for Interim Duodenoscope Culture Methods for determining the incidence of "high concern" isolates in reprocessed duodenoscopes.[2]

Culture Method A - Presence/Absence by Enrichment

Note: Process irrigation water and PBST negative controls using the same protocol as the samples.

1. Vortex the sample for 2 minutes in 10 second bursts.

2. Aseptically remove the channel-opening brush.

3. Transfer the fluid samples (instrument channel flush, channel-opening brush fluid) to a sterile 50cc centrifuge tube (Cat. no. 227270).

4. Consider including internal process controls to determine organism viability and detection after disinfection.

    a. Aliquot 5ml of the instrument channel flush sample to a sterile connical tube. Reserve the remaining 45ml sample for further processing as described in step 5.

    b. Inoculate the 5mL instrument channel flush sample with a concentration of a known Gram-positive organism (e.g. *S. aureus*) and/or a known Gram-negative organism (e.g. *E. coli*) using a 1-100 colony forming unit (CFU) density.

    c. Process the controls in a similar manner to duodenoscope samples and take adequate precautions to reduce the risk of cross-contamination of duodenoscope samples with controls.

5. Concentrate by centrifugation on a benchtop centrifuge equipped for high volume suspensions (range: 3,500-5,000xg) for 10 to 15 minutes.

6. Remove supernatant for a final volume of 1ml without disrupting the pellet, or re-suspend the pellet to a final volume of 1ml using PBST.

7. Transfer the 1ml sample to 5ml of TSB (Cat. no. K89).

8. Incubate TSB and sample at 35-37ºC for 48hr.

9. Check and record turbidity at 18-24hrs (overnight) and again at 48hr if turbidity is not detected after overnight incubation.

10. If the sample is turbid, streak the broth for isolation onto a Blood Agar Plate (Cat. no. A10) and MacConkey Agar (Cat. no. G35). Note: If selective culture for multi-drug resistant organisms such as CRE is desired, streak the broth to a HardyCHROM CRE plate (Cat. no. G323) to detect the presence of carbapenem-resistant *Enterobacteriaceae*.

11. Incubate MacConkey Agar plates at 35-37ºC for 18-24hrs (overnight) and Blood Agar plates at 35-37°C for 48hr. If HardyCHROM CRE is used, incubate plates at 35-37°C for 24hrs (overnight).

12. Observe plates for suspect colonies and streak colonies to purity plates for further identification and characterization.

13. Work-up pure isolates for characterization of "low-concern" bacteria, which represent flora from skin and the environment, and perform species identification of "high-concern" bacteria.

    a. "Low-concern" bacteria include, but are not limited to, coagulase-negative staphylococci, micrococci,

diptheroids, *Bacillus* spp., and other Gram-positive rods.

b. "High-concern" bacteria include, but are not limited to, *Staphylococcus aureus* , *Enterococcus* spp., *Streptococcus* spp, viridans group, *Pseudomonas aeruginosa* , *Klebsiella* spp., *Salmonella* spp., *Shigella* spp., and other enteric Gram-negative bacilli.

Culture Method B - Quantitative

Note: Process irrigation water and PBST negative controls using the same protocol as the samples .

1. Vortex the sample for 2 minutes in 10 second bursts.

2. Aseptically remove the channel-opening brush.

3. Transfer the fluid samples (instrument channel flush, channel-opening brush fluid) to a 50cc conical tubes (Cat.no. 227270).

4. Consider including internal process controls to determine organism viability and detection after disinfection.

a. Aliquot 5ml of the instrument channel flush sample to a sterile connical tube. Reserve the remaining 45ml sample for further processing as described in step 5.

b. Inoculate the 5mL instrument channel flush sample with a concentration of a known Gram-positive organism (e.g. *S. aureus*) and/or a known Gram-negative organism (e.g. *E. coli*) using a density of 1-100 colony forming units (CFU).

c. Process the controls in a similar manner to duodenoscope samples and take adequate precautions to reduce the risk of cross-contamination of duodenoscope samples with controls.

5. Choose either centrifugation or membrane filtration to concentrate the samples:

Centrifugation:

a. Concentrate by centrifugation on a benchtop centrifuge equipped for high volume suspensions (range: 3,500-5,000xg) for 10 to 15 minutes.

b. Remove the supernatant without disrupting the pellet to a final volume of 1ml. If needed, add PBST to a final volume of 1ml and re-suspend.

c. Prepare a 1:10 dilution by adding 100µl of sample to 900µl of PBST.

d. Vortex the sample for 10 seconds.

e. Pipet the following on to Blood Agar plates (Cat. no. A10) and MacConkey Agar plates (Cat. no. G35) in triplicate and spread evenly to allow for counting colonies:

i. 100µl of the undiluted sample (final dilution 10^{-1})

ii. 100µl 1:10 dilution (final dilution 10^{-2})

f. Continue with step 6 outlined below.

Membrane Filtration:

a. Set up appropriate sterile filtration equipment (e.g. filtering flask, vacuum, filter housings, gridded filters (e.g.

Cat. no. 1140647ACN), forceps, etc.) such as a Combisart® Filter Station and/or a Microsart® Disposable Funnel System, as needed.

b. The minimum volume required to obtain duplicate samples for Blood Agar (Cat. no. A10) and MacConkey Agar (Cat. no. G35) plates is 40ml. *Consider other volumes or dilutions based upon observed counts at the specific facility*.

i. Blood Agar: 2-10ml

ii. MacConkey Agar: 2-10ml

c. Filter samples using a gridded membrane filter (e.g. Cat. no. 1104647ACN) and rinse the filter housing liberally with a sterile buffered solution after each sample. *The minimum appropriate volume to obtain adequate samples using membrane filtration is 10ml. If filtering 1ml samples, add at least 9ml of a sterile buffered solution to the filter housing with the filter closed. Add the 1ml sample to the sterile buffered solution and open the value to create a vacuum that will allow for filtration.*

d. Place a gridded membrane filter (e.g. Cat. no. 1140647ACN), grid-side-up, on the agar plate using sterile forceps. Beginning from one side, roll the membrane filter onto the surface of the agar plate to avoid the formation of air bubbles between the filter and agar surface or to reduce the fomation of creases in the filter.

e. Continue with step 6 outlined below.

6. Add 0.5ml of the instrument channel flush sample to an enrichment broth containing 5ml of TSB (Cat. no. K89).

7. Incubate samples aerobically. For MacConkey Agar plates, incubate at 35-37ºC for 18-24hrs (overnight) and Blood Agar plates at 35-37°C for 48hr. Incubate TSB for 48hr.

8. For agar plates, check and record growth at 18-24hrs (overnight) for MacConkey Agar and Blood Agar and approximately 48hrs for Blood Agar.

a. Count and record the number of colonies from plates.

b. Calculate the CFU/ml from the Blood Agar plates, accounting for the volume of the sample to determine the total CFU/sampled duodenoscope (50ml sample).

9. For TSB, check and record turbidity at 18-24hrs (overnight) and approximately 48hrs (two days).

a. If the sample is turbid, streak the broth for isolation onto Blood Agar (Cat. no. A10) and MacConkey Agar (Cat. no. G35). Note: If selective culture for multi-drug resistant organisms such as CRE is desired, streak the broth to a HardyCHROM CRE plate (Cat. no. G323) to detect the presence of carbapenem-resistant *Enterobacteriaceae* .

b. Incubate plates at 35-37ºC; MacConkey Agar at 18-24hr (overnight) and Blood Agar for 48hrs (two days). If HardyCHROM CRE is used, incubate plates at 35-37ºC for 24hrs (overnight).

c. Observe plates for suspect colonies.

10. Streak suspect colonies for isolation.

11. Work up pure isolates for characterization of "low-concern" bacteria, which represent flora from skin and the environment, and species identification of "high-concern" bacteria.

a. "Low-concern" bacteria include, but are not limited to, coagulase-negative staphylococci, micrococci, diptheroids, *Bacillus* spp. and other Gram-positive rods.

b. "High-concern" bacteria include, but are not limited to, *Staphylococcus aureus* , *Enterococcus* spp., *Streptococcus* spp, viridans group, *Pseudomonas aeruginosa* , *Klebsiella* spp., *Salmonella* spp., *Shigella* spp., and other enteric gram-negative bacilli.

Additional international reference methods for microbial culture can be found in the literature.[7,10]

Surveillance Method :

Refer to the CDC recommendations for the Interim Duodenoscope Surveillance Protocol for monitoring the bacterial contamination of duodenoscopes after reprocessing.[3]

Additional international reference methods for microbial surveillance can be found in the literature.[7,10]

INTERPRETATION OF RESULTS

Consult with infection control on the presence of "high-concern" isolates identified from method A or B or the presence of suspected pathogens obtained from selective media.[2,3,7,10] See also, the CDC recommendations for Interim Duodenoscope Culture Methods.

Sampling and surveillance methods should take into account procedures for the immediate removal of suspect endoscopes from service and a risk evaluation on patients or procedures that may have been affected by the results.[7,10]

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.

The protocols for sample collection, culture, and surveillance as described by the CDC have not been validated. Verification and validation are key parts of the laboratory quality assurance program. The laboratory must have a detailed verification protocol for the evaluation of a method before beginning verification. In addition, a systematic approach (validation) must be in place for continuous monitoring of established methods to determine testing consistency and that testing personnel remain competent to perform tests and report results.

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, swabs, applicator sticks, sterile specimen cups (Cat.no. PC4064200S), sterile 50cc centrifuge tubes (Cat. no. 227270), the Combisart® filtration system or Microsart® membrane filtration products, 0.45µm gridded filters (Cat. no. 1140647ACN), other culture media such as TSB (Cat. no. K89), Blood Agar (Cat. no. A10), MacConkey Agar (Cat. no. G35), HardyCHROM CRE (Cat. no. G323), incinerators, 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	
Bacillus cereus ATCC ® 13061	** on BAP (A10)	18-24hr	35°C	Aerobic	Growth

Bacillus cereus ATCC ® 13061	** in BHI (R20)	18-24hr	35°C	Aerobic	Growth

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

** 0.01M PBS with 0.02% Tween® 80 (Cat. no. U334) is tested for recovery of spores after performing heat shock procedures.

Sterile Water (Cat. no. U336) is not a growth medium and is tested for sterility only.

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

0.01M PBS with 0.02% Tween® 80 and Sterile Water should appear clear and colorless.

Phosphate Buffered Saline (PBS) w/0.02% Tween ® 80 (Cat. no. U334).

Sterile Water (Cat. no. U336).

REFERENCES

1. CDC. Interim Duodenoscope Sampling Method . Centers for Disease Control and Prevention. Atlanta, GA.

2. CDC. Interim Duodenoscope Culture Method . Centers for Disease Control and Prevention. Atlanta, GA.

3. CDC. Interim Duodenoscope Surveillance Protocol . Centers for Disease Control and Prevention. Atlanta, GA

4. FDA. Infections Associated with Reprocessed Endoscopes . Food and Drug Administration. Silver Springs, MD.

5. FDA. Olympus Validates New Reprocessing Instructions for Model TJF-Q180V Duodenoscopes. Food and Drug Administration. Silver Springs, MD.

6. Olympus Customer Notification. Urgent Safety Notification: New Supplemental Flushing Instructions for EVIS Exera II Duodenovideoscope Olympus TJF Type Q180V Reprocessing Manual. Olympus America, Inc. Center Valley, PA.

7. GESA. *Clinical Update: Infection Control in Endoscopy, 3rd edition. Gastroenterological Society of Australia. Victoria, Australia.*

8. Aumeran, C., E. Thibert, F.A. Chapelle, C. Hennequin, O. Lesens, and O. Traore. 2011. Assessment on Experimental Bacterial Biofilms and in Clinical Practice of the Efficacy of Sampling Solutions for Microbiological Testing of Endoscopes. *J. Clin. Microbiol* . 50(3): 938-942.

9. Carbonne, A., J.M. Thiolet, S. Fournier, N. Fortineau, N. Kassis-Chikhanl, I. Boytchev, M. Aggoune, J.C. Seguier, H. Senechal, M.P. Tavolacci, B. Coignard, P. Astagneau, V. Jarlier. 2010. Control of a multi-hospital outbreak of KPC-producing *Klebsiella pneumoniae* type 2 in France, September to October 2009. *Euro Surveillance*. 15(48):11-16.

10. Public Health Agency of Canada. 2010. Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy. Canada.

11. Gamble, H.P., G.J. Duckworth, G.L. Ridgway. 2007. Endoscope decontamination incidents in England 2003-2004. *J. Hosp. Infect*. 67(4):350-354.

12. Ofstead, Cori, L., Alexandra M. Dirlam Langlay, Natalie J. Mueller MPH, Pritish K. Tosh, Harry P. Wetzler. 2013. Re-evaluating endoscopy-associated risk estimates and their implications. *American Journal of Infection Control*.

13. Bret T. Petersen, Jennifer Chennat, Jonathan Cohen, Peter B. Cotton, David A. Greenwald, Thomas E. Kowalski, Mary L. Krinsky, Walter G. Park, Irving M. Pike, Joseph Romagnuolo, William A. Rutala. 2011. Multi-society Guideline on Reprocessing Flexible GI Endoscopes. *Infection Control and Hospital Epidemiology*. 32(6): 527-537.

14. American Society for Gastrointestinal Endoscopy (ASGE). 2001. Transmission of infection by gastrointestinal endoscopy. *Gastrointestinal Endoscopy*. 54(6): 824-828.

15. Ofstead, Cori, L., Wetzler, H., Snyder, A., Horton, R. 2010, Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors and Automation. *Gastroenterology Nursing*. 33(54): 3-10.

16. Alexandra Dirlam Langlay, Ph.D., Pritish Tosh, MD, Michelle Alfa, PhD, Harry P. Wetzler, MD, MSPH, Cori L. Ofstead, MSPH. 2013. Transmission of multidrug-resistant organisms and other pathogens via contaminated endoscopes: Can buildup of biofilm be eliminated by routine cleaning and high-level disinfection? American Society for Microbiology, Denver, CO, May 18-21.

17. Cori L. Ofstead, MSPH, Alexandra Dirlam Langlay, Ph.D., Harry P. Wetzler, MD, MSPH, Pritish Tosh, MD, Todd Baron, MD 2013. Transmission of multidrug-resistant organisms via contaminated duodenoscopes. American Society for Gastrointestinal Endoscopy/Digestive Disease Week. Orlando, FL. May 18-21.

18. FDA. Supplemental Measures to Enhance Duodenoscope Reprocessing. Food and Drug Administration. Silver Springs, MD.

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

HDQA 2207F [D]