IFU

Instructions for Use

PURPLE BROTH WITH DURHAM TUBE

Cat. no. Y100	Purple Broth Base, 16x125mm Tube, 9ml	20 tubes/box
Cat. no. Y102	Purple Broth with Arabinose, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. Y108	Purple Broth with Lactose, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. Y109	Purple Broth with Maltose, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. Y110	Purple Broth with Mannitol, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. Y111	Purple Broth with Raffinose, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. Y114	Purple Broth with Sorbitol, 16x125mm Tube, 10ml	20 tubes/box
Cat. no. Y115	Purple Broth with Sucrose, 16x125mm Tube, 10ml	20 tubes/box

INTENDED USE

Hardy Diagnostics Purple Broth with Durham Tube is recommended for the determination of fermentation reactions of microorganisms, especially enteric bacilli and *Enterococcus* spp.

SUMMARY

The ability of bacteria to form organic compounds by metabolizing certain carbohydrates and related compounds is a widely used method for the identification of microorganisms.

Hardy Diagnostics Purple Broth consists of a sugar-free basal medium and a specific pH indicator. A 1% concentration of a specific carbohydrate is added in order to detect fermentation reactions. The 1% concentration is recommended to decrease the possibility of reversal reactions. Reversion occurs when the carbohydrate is depleted, thereby resulting in the masking of acid by-products by alkaline by-products of peptone degradation. The acid produced by carbohydrate breakdown causes a decrease in pH resulting in a color shift in the medium from blue-purple to yellow. Gas production is noted by the appearance of bubbles in the durham tube.

FORMULA

Ingredients per liter of deionized water:*

Purple Broth Base:

Dipeptone	10.0gm
Pancreatic Digest of Casein	6.0gm
Sodium Chloride	5.0gm
Beef Heart Infusion	2.0gm

Yeast Extract	2.0gm
Bromcresol Purple	20.0mg

Final pH 7.6 +/- 0.2 at 25ºC.

Purple Broth with 1% carbohydrate contains 10.0gm of a specific carbohydrate.

* 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, 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 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.

PROCEDURE

Specimen Collection: Specimen collection is not applicable since this medium is not intended for primary isolation from clinical specimens. As a general rule, 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, the specimen should be inoculated onto an appropriate transport media and refrigerated until inoculation. Consult listed references for information on specimen collection.[2-5]

Method of Use:

1. Allow medium to warm to room temperature prior to inoculation.

2. Inoculate the Purple Broth (carbohydrate of choice) with isolated colonies from an 18-24 hour pure culture of the organism. **Note:** A broth or saline suspension can be made to allow inoculation of a battery of carbohydrates.

3. Inoculate a control tube of Purple Broth Base (Cat. no. Y100) in parallel with the carbohydrate based media.

4. Incubate inoculated media aerobically at 35-37ºC. for 3-5 days.
Note: Increased incubation up to 30 days may be necessary for some microorganisms.

5. Observe daily for development of a yellow color in the medium.

INTERPRETATION OF RESULTS

The development of a yellow color in the medium is indicative of a positive carbohydrate fermentation reaction.

Lack of yellow color development is indicative of a negative carbohydrate fermentation reaction.

Gas formation is indicated by the appearance of gas bubbles in the durham tube.

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 may be necessary to invert the tube prior to inoculation if bubbles are trapped in the durham tube. Trapped bubbles that are not released may lead to false-positive 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, slides, staining supplies, other culture media, microscopes, incinerators, and incubators, 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	
Purple Broth Base:					
Escherichia coli ATCC® 25922	A	24hr	35°C	Aerobic	Growth; remains purple
Staphylococcus aureus ATCC® 25923	A	24hr	35°C	Aerobic	Growth; remains purple
Enterococcus faecalis ATCC® 29212	A	24hr	35°C	Aerobic	Growth; remains purple
Salmonella enterica ATCC® 14028	A	24hr	35°C	Aerobic	Growth; remains purple
Purple Broth with Lactose, Maltose, Mannitol, and Sorbitol:					
Escherichia coli ®	A	24-48hr	35°C	Aerobic	Growth; turns yellow

ATCC 25922					
Proteus mirabilis ATCC® 12453	A	24-48hr	35°C	Aerobic	Growth; remains purple
Purple Broth with Arabinose and Raffinose:					
Enterobacter aerogenes ATCC® 13048	A	24-48hr	35°C	Aerobic	Growth; turns yellow
Serratia marcescens ATCC® 8100	A	24-48hr	35°C	Aerobic	Growth; remains purple
Purple Broth with Sucrose:					
Enterobacter aerogenes ATCC® 13048	A	24-48hr	35°C	Aerobic	Growth; turns yellow
Salmonella enterica ATCC® 14028	A	24-48hr	35°C	Aerobic	Growth; remains purple

* 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

Purple Broth should appear clear and purple in color.

REFERENCES

1. 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.

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

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

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

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

6. Hindler, J. 1996. June Seminar. What Can We Do About Vancomycin-Resistant Enterococci (VRE) in Southern California, UCLA Medical Center, Los Angeles, CA.

IFU-10695[B]

1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
Ordering Information

Distribution Centers:
California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

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

HDQA 2207F [D]