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Instructions for Use

PEPTIC DIGEST AGAR (PDA) WITH FILDES AND NAFCILLIN

Cat. no. G141	PDA with Fildes and Nafcillin, 15x100mm Plate, 19ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Peptic Digest Agar (PDA) with Fildes and Nafcillin is an enrichment medium recommended for the selective isolation of *Haemophilus* species.

SUMMARY

Peptic Digest Agar with Fildes and Nafcillin is composed of Columbia Agar Base supplemented with Fildes enrichment and nafcillin. Fildes enrichment is a sterile digest of sheep blood which is rich in hemin (X-Factor) and nicotinamide adenine dinucleotide (V-Factor), the factors required by *Haemophilus influenzae* and other members of the *Haemophilus* group. Nafcillin inhibits most normal respiratory flora, thereby making the medium selective for *Haemophilus* spp.

FORMULA

Ingredients per liter of deionized water:*

Yeast Enriched Peptone	10.0gm
Peptic Digest of Animal Tissue	8.0gm
Pancreatic Digest of Casein	5.0gm
Sodium Chloride	5.0gm
Corn Starch	1.0gm
Nafcillin	2.0mg
Fildes Supplement	25.0ml
Agar	14.0gm

Final pH 7.3 +/- 0.3 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), 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: 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.

Method of Use: Prior to inoculation, the medium should be brought to room temperature. Inoculate the specimen onto the medium and streak for isolation using the four quadrant technique. Incubate the plate in 5-10% CO_2 at 35-37ºC. for 24-48 hours. Examine plates for growth and typical colonial morphology.

INTERPRETATION OF RESULTS

Colonies of *Haemophilus* spp. appear transparent, moist, convex and smooth and emit a distinctive "mousy" odor.

Gram stain and biochemical testing must be performed on isolated organism(s) to confirm identification.

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.

This product is used in conjunction with other biochemical tests to identify cultures of isolated organism.

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, other culture media, swabs, applicator sticks,

incinerators, 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	
Haemophilus influenzae ATCC® 10211	A	24-48hr	35°C	CO_2**	Growth
Staphylococcus aureus ATCC® 25923	B	24hr	35°C	Aerobic	Inhibited

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

** Atmosphere of incubation is enriched with 5-10% CO_2.

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

Peptic Digest Agar (PDA) with Fildes and Nafcillin should appear transparent and colorless.

Haemophilus influenzae (ATCC® 10211) colonies growing on PDA with Fildes and Nafcillin (Cat. no. G141). Incubated in CO_2 for 24 hours at 35ºC.

Staphylococcus epidermidis (ATCC® 12228) growth inhibited on PDA with Fildes and Nafcillin (Cat. no. G141). Incubated aerobically for 24 hours at 35ºC.

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

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

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