IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

V AGAR

Cat. no. A80	V Agar, 15x100mm Plate, 17ml	10 plates/bag
Cat. no. A81	V Agar with CNA , 15x100mm Plate, 17ml	10 plates/bag
Cat. no. J181	V Agar / Starch Agar, 15x100mm Biplate, 10ml/10ml	10 plates/bag

INTENDED USE

Hardy Diagnostics V Agar is an enriched media used for the isolation and differentiation of *Gardnerella vaginalis* .

SUMMARY

V Agar is a Columbia Agar Base media with human blood added for differentiation of *G. vaginalis* from other genitourinary flora by its hemolytic reaction. *G. vaginalis* exhibits no hemolysis on Sheep Blood Agar, however, it is beta-hemolytic on Human Blood Agar.

V Agar with CNA contains additionally colistin and nalidixic acid for selective isolation of gram-positive cocci and certain gram-negatives such as *G. vaginalis* .

FORMULA

Ingredients per liter of deionized water:*

Columbia Agar Base	42.5gm
Proteose Peptone No. 3	10.0gm
Human Blood	50.0ml

V Agar with CNA, additionally, contains:	
Colistin	10.0mg
Nalidixic Acid	15.0mg

Final pH 7.1 +/- 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.

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, specimen should be inoculated into an appropriate transport media and refrigerated until inoculation.

Method of Use: Prior to inoculation, the medium should be brought to room temperature. Inoculate media with specimen and streak for isolation using four quadrant technique. For testing an isolated organism, touch the top of a colony with a sterile wire loop and streak for isolation. Incubate in 5-10% CO_2 at 35ºC. for 24-48 hours. Examine plate for growth and typical colony morphology and hemolysis.

INTERPRETATION OF RESULTS

Typical colonies of *G. vaginalis* appear convex, opaque and gray surrounded by a hazy zone of beta-hemolysis after 24-48 hours of incubation.

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.

V Agar is not selective for *G. vaginalis* and will support growth of other genitourinary organisms. *G. vaginalis* can be differentiated from other genitourinary organisms by its hemolytic reaction on V Agar.

V Agar with CNA is a semi-selective media for *G. vaginalis* . V Agar with CNA will support the growth of gram-positive cocci and certain gram-negative organisms such as *G. vaginalis* and *Bacteriodes* species. *G. vaginalis* can be differentiated from other organisms by its hemolytic reaction and biochemical reactions such as catalase, oxidase,

hippurate hydrolysis, and antibiotic sensitivities.

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	
V Agar:					
Gardnerella vaginalis ATCC® 14018	A	24-48hr	35°C	CO_2**	Growth; pinpoint colonies with hazy beta-hemolysis
Streptococcus agalactiae ATCC® 12386	A	24hr	35°C	Aerobic	Growth; with beta-hemolysis
Additionally for V Agar with CNA:					
Proteus mirabilis ATCC® 12453	B	24hr	35°C	Aerobic	Partial to complete inhibition
Escherichia coli ATCC® 25922	B	24hr	35°C	Aerobic	Inhibited

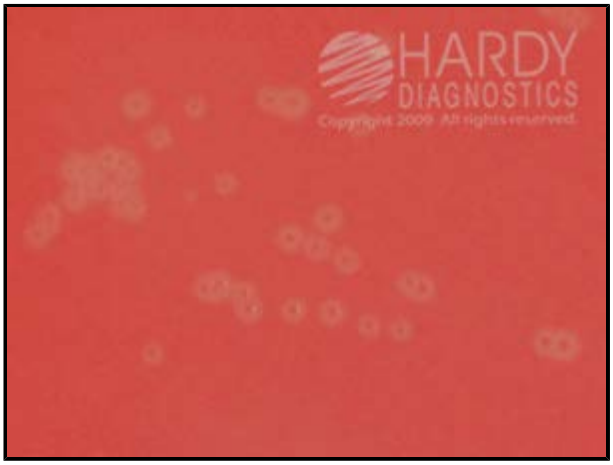
* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

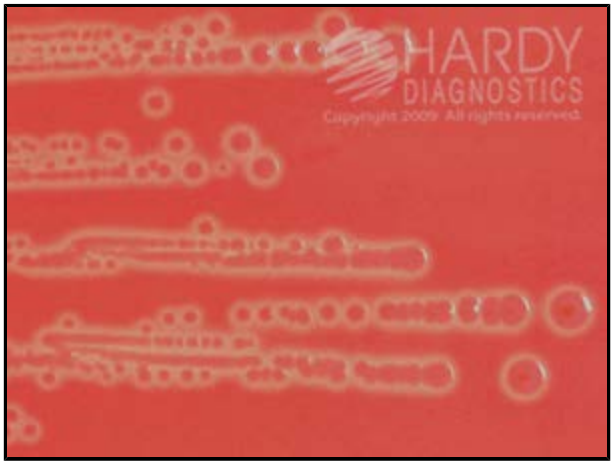
End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory 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

V Agar and V Agar with CNA should appear opaque, and cherry red in color.



Gardnerella vaginalis (ATCC® 14018) colonies growing on V Agar (Cat. no. A80). Photographed with backlight to emphasize hemolysis zones. Incubated in CO_2 for 48 hours at 35ºC.



Streptococcus agalactiae (ATCC® 12386) colonies growing on V Agar (Cat. no. A80). Photographed with backlight to emphasize hemolysis zones. Incubated aerobically for 24 hours at 35ºC.

Uninoculated plate of V Agar (Cat. no. A80).

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. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

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

IFU-10836[A]

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]