IFU

Instructions for Use

ACETATE DIFFERENTIAL SLANT

Cat. no. L15	Acetate Differential Slant, 16x100mm Tube, Slant	20 or 100 tubes/box

INTENDED USE

Hardy Diagnostics Acetate Differential Slant is used to differentiate *Escherichia coli* from members of the genus *Shigella*.

SUMMARY

The Acetate Differential Slant is formulated with the base formula of Simmons Citrate Agar, but sodium citrate is replaced with sodium acetate. Differentiation is based on the organisms ability to utilize acetate. Approximately 84% of *E. coli* species utilize acetate, whereas the majority of *Shigella* species are incapable of acetate utilization.[5] 7.7% *Shigella flexneri* 4a, mannitol +, and 86% *Shigella flexneri* 4a, mannitol -, are capable of utilizing acetate.[6]

FORMULA

Ingredients per liter of deionized water:*

Sodium Chloride	5.0gm
Sodium Acetate	2.0gm
Monoammonium Phosphate	1.0gm
Dipotassium Phosphate	1.0gm
Magnesium Sulfate	0.1gm
Bromothymol Blue	0.08gm
Agar	20.0gm

Final pH 6.7 +/- 0.2 at 25ºC.

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

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 (shrinking, cracking, or discoloration), hemolysis, contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat 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: Consult listed references for information on specimen collection.[1-4] 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.

The proper performance of the Acetate Differential Slant depends upon the inoculation from a pure culture. Using a light inoculum, inoculate medium with growth from a pure 18-24 hour old culture from a non-inhibitory culture plate. Inoculate the slant by streaking the surface in a serpentine manner. Replace caps loosely on the tube(s).

INTERPRETATION OF RESULTS

A positive result is indicated by the presence of growth and the medium turning blue.

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.

Specimen Collection: This product is not intended for primary isolation of patient specimens. This product is used in conjunction with other biochemical tests to identify cultures of isolated organism.

Certain strains of *Shigella flexneri* are capable of utilizing acetate. 7.7% of *Shigella flexneri* 4a, mannitol +, and 86% of *Shigella flexneri* 4a, mannitol -, are acetate-positive.

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, saline, 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	
Escherichia coli ATCC® 25922	E	24-96hr	35°C	Aerobic	Growth; positive reaction, medium turns blue
Shigella flexneri ATCC® 12022	E	24hr	35°C	Aerobic	Inhibited

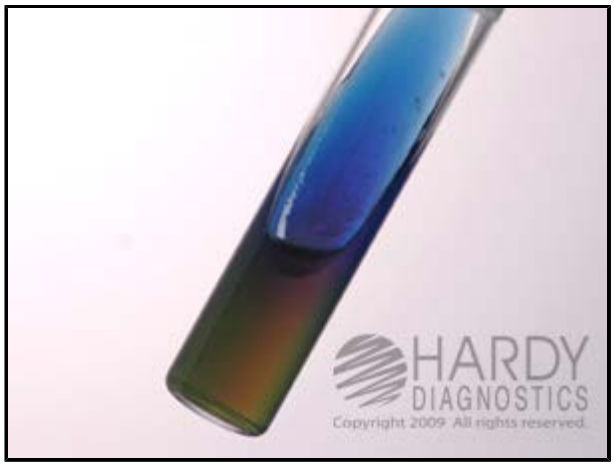
* Refer to the document "Inoculation Procedures for Media QC" for more information.

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

Acetate Differential Slant should appear slightly opalescent, and green in color.



Escherichia coli (ATCC® 25922) colonies growing on Acetate Differential Slant (Cat. no. L15). Incubated aerobically for 24 hours at 35ºC.

Shigella flexneri (ATCC® 12022) inhibited on Acetate Differential Slant (Cat. no. L15). Incubated aerobically for 24 hours at 35ºC.

REFERENCES

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

2. Baron, E.J. and S.M. Finegold. 1990. *Bailey and Scott's Diagnostic Microbiology*, 8th ed. C.V. Mosby Company, St. Louis, MO.

3. 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.

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

5. *Pub. Hlth. Lab.*; 20:137. 1962.

6. Ewing, W.H., et al. 1971. Biochemical Reactions of *Shigella*, Public Health Service, Centers for Disease Control, Atlanta, GA.

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

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