IFU

Instructions for Use

CRITERION™ STAPH SELECTIVE AGAR

Cat. no. C7000	CRITERION™ Staph Selective Agar	202gm
Cat. no. C7001	CRITERION™ Staph Selective Agar	500gm
Cat. no. C7002	CRITERION™ Staph Selective Agar	2kg
Cat. no. C7003	CRITERION™ Staph Selective Agar	10kg
Cat. no. C7004	CRITERION™ Staph Selective Agar	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Staph Selective Agar is a selective medium used for the isolation and differentiation of pathogenic staphylococci.

This dehydrated culture medium is a raw material intended to be used in the making of prepared media products, which will require further processing, additional ingredients, or supplements.

SUMMARY

Staph Selective Agar is an agar medium used for the selective isolation and differentiation of pathogenic staphylococci. The formulation contains a lower concentration of salt (4.0%) than Mannitol Salt Agar (7.5%). The lower salt concentration enhances the growth of most staphylococci. However the addition of selective agents is required to inhibit gram-negative and non-pathogenic staphylococci. The medium also contains bromcresol purple indicator which imparts a violet color to the prepared medium. Pathogenic staphylococci produce yellow colonies surrounded by yellow zones in a violet background.

FORMULA

Gram weight per liter:	101.0gm/L
Sodium Chloride	40.0gm
Selective Agents	14.0gm
Pancreatic Digest of Casein	10.0gm
Peptic Digest of Animal Tissue	10.0gm
Mannitol	10.0gm
Beef Extract	2.0gm
Bromcresol Purple	2.0mg

Agar	15.0gm

Final pH 7.4 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30ºC. Dehydrated culture medium is very hygroscopic. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. The dehydrated culture media should be discarded if it is not free-flowing or if the color has changed from its original bluish-beige.

Store the prepared culture media at 2-8ºC.

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.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 101.0gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat to boiling and mix to dissolve completely.

3. Sterilize in the autoclave at 121ºC. for 15 minutes.

4. Dispense into sterile containers as desired.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, cosult listed references.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies

from pure culture for complete identification.

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

Additional serological and biochemical tests are required for complete identification, please see listed references for more information.[1-3]

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclaves, incinerators, and incubators, etc., 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	
Staphylococcus aureus ATCC® 25923	A	24-48hr	35°C	Aerobic	Good growth; yellow colonies
Staphylococcus epidermidis ATCC® 12228	A	24-48hr	35°C	Aerobic	Poor growth; clear colonies
Escherichia coli ATCC® 25922	B	24-48hr	35°C	Aerobic	Inhibited

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

USER QUALITY CONTROL

Users of dehydrated 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. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ Staph Selective Agar powder should appear homogeneous, free-flowing, and bluish-beige in color. The prepared media should appear clear to slightly opalescent, and violet in color.

REFERENCES

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

2. Vanderzant, Carl. 1992. *Compendium of Methods For the Microbiological Examination of Foods*, 3rd ed. American

Public Health Association, Washington, D.C.

3. Marshall, R.T., et al. 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. American Public Health Association, Washington, D.C.

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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 2207B [D]