IFU

Instructions for Use

CRITERION™ STAPHYLOCOCCUS MEDIUM 110

Cat. no. C6990	CRITERION™ Staphylococcus Medium 110	298gm
Cat. no. C6991	CRITERION™ Staphylococcus Medium 110	500gm
Cat. no. C6992	CRITERION™ Staphylococcus Medium 110	2kg
Cat. no. C6993	CRITERION™ Staphylococcus Medium 110	10kg
Cat. no. C6994	CRITERION™ Staphylococcus Medium 110	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Staphylococcus Medium 110 is used for isolating and differentiating staphylococci based on fermentation, pigment formation and gelatinase activity.

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

Staphylococcus Medium 110 is commonly referred to as Staphylococcus Agar No. 110 and/or Stone Gelatine Agar. Staphylococcus Agar No. 110 was developed by Chapman for the primary isolation of staphylococci.[1] The high salt concentration contributes to the selective isolation of pathogenic staphylococci. On this medium, pathogenic strains of staphylococci usually produce yellow to orange pigmented colonies. Orange pigmented colonies are picked and inoculated into Brain Heart Infusion or Tryptose Phosphate Broth for the coagulase test. Mannitol-fermentation is indicated by a color change of bromcresol purple after placing a drop of the dye onto the areas of the agar surface from which the colonies have been removed. Gelatin hydrolysis is determined by flooding the plate with 5ml of a saturated aqueous solution of ammonium sulfate and incubating plate at 35 degrees C. for 10 minutes. A clear zone around the colonies indicates gelatin hydrolysis.

FORMULA

Gram weight per liter:	149.0gm/L
Sodium Chloride	75.0gm
Gelatin	30.0gm
Pancreatic Digest of Casein	10.0gm
Mannitol	10.0gm
Dipotassium Phosphate	5.0gm

Yeast Extract	2.5gm
Lactose	2.0gm
Agar	15.0gm

Final pH 7.0 +/- 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 light 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 149.0gm 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. Cool to 45-50ºC.

5. With gentle agitation to avoid bubbles thoroughly mix medium prior to pouring into sterile plates.

Note: Alternately, the medium may be prepared without sterilization. Boil the medium for five minutes and mix accordingly. However, this method of preparation requires that plates be used the same day they are prepared.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. No. G52.

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.

Enterococcus faecalis may grow on Staphylococcus Medium 110 as tiny colonies with mannitol fermentation. Differentiate these organisms from staphylococci with the gram stain and catalase test.

Suspected staphylococci must be subcultured to Nutrient Broth, Blood Agar, BHI Broth, or Tryptose Phosphate Broth for coagulase testing as the high salt content of Staphylococcus Medium 110 may interfere with results.

Pigment production is not a reliable criterion for differentiation of *Staphylococcus* spp.

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	Growth; mannitol positive/gelatin positive. Pigment is seen as yellow to orange color
Staphylococcus epidermidis ATCC® 12228	A	24-48hr	35°C	Aerobic	Growth; mannitol negative/gelatin positive
Escherichia coli ATCC® 25922	B	24-48hr	35°C	Aerobic	Partial to complete inhibition

* 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™ Staphylococcus Medium 110 powder should appear homogeneous, free-flowing, and light beige in color. The prepared media should appear opalescent with a moderate precipitate, and light amber in color.

REFERENCES

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

2. FDA. 1995. *Bacteriological Analytical Manual*, 8th ed. FDA.

3. Stone, R.V. 1935. A cultural method for classifying staphylococci as of the "food poisoning" type. *Proc. Soc. Exptl. Biol. Med.*, 33:185-187.

4. Chapman, G.H., et al. 1937. Isolation and cultural differentiation of food-poisoning staphylococci. *Food Research*; 2:349.

5. Chapman, G.H. 1945. The significance of sodium chloride in studies of staphylococci. *J. Bacteriol.*; 50:201.

6. Chapman, G.H. 1946. A single culture medium for selective isolation of plasma-coagulating staphylococci and for improved testing of chromogenesis, plasma coagulation, mannitol fermentation and the Stone reaction. *J. Bacteriol.*; 51:409.

ATCC is a registered trademark of the American Type Culture Collection.

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

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