IFU

Instructions for Use

CRITERION™ MODIFIED CASMAN AGAR BASE

Cat. no. C7620	CRITERION™ Modified Casman Agar Base	88.4gm
Cat. no. C7621	CRITERION™ Modified Casman Agar Base	500gm
Cat. no. C7622	CRITERION™ Modified Casman Agar Base	2kg
Cat. no. C7623	CRITERION™ Modified Casman Agar Base	10kg
Cat. no. C7624	CRITERION™ Modified Casman Agar Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Modified Casman Agar Base is recommended for the cultivation of fastidious microorganisms, such as *Haemophilus* spp.

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

In 1947, Casman developed a medium for the cultivation of fastidious microorganisms that did not require the use of fresh meat infusion in the basal medium, but instead utilized beef and yeast extracts and peptones.[1] Beef extract enhances the development of pathogenic cocci.[2,3] Along with peptones, beef extract provides amino acids and other complex nitrogenous nutrients. Yeast extract serves as a source of B-complex vitamins. Dextrose, corn starch and purified agar are also incorporated into the medium. Dextrose enhances the development of pathogenic cocci while corn starch and purified agar allow for the growth of *Neisseria gonorrhoeae* without interfering with hemolytic reactions.

CRITERION™ Modified Casman Agar Base is a non-selective, peptone-based medium that can be supplemented with blood for the growth of fastidious microorganisms. Blood supplies hemin (X-factor) and nicotinamide adenine dinucleotide (NAD or V-factor), which are growth factors required by *Haemophilus influenzae* . Rabbit and horse bloods are generally preferred as they are relatively free of the enzyme NADase that destroys V-factor. However, sheep blood has a longer shelf life and is less prone to spontaneous hemolysis and contamination. Therefore, if sheep blood is used, nicotinamide (also known as niacinamide or nicotinic acid amide) should be incorporated into the medium to inhibit the nucleotidase of sheep blood erythrocytes that can destroy the V-factor.[3] CRITERION™ Modified Casman Agar Base formulation contains this ingredient.

CRITERION™ Modified Casman Agar Base can also be supplemented with antibiotics, such as bacitracin, thereby making the medium selective for *Haemophilus* spp. Modified Casman Agar is also useful in identifying the various species of *Haemophilus* by pattern of hemolysis. *H. influenzae* and *H. parainfluenzae* will grow but will not exhibit beta-hemolysis. *H. hemolyticus* and *H. parahemolyticus* will also grow but will not be beta-hemolytic. Bacitracin can be used to inhibit most strains of streptococci, staphylococci, *Neisseria* and *Micrococcus* species.

FORMULA*

Gram weight per liter:	44.2gm/L
Yeast Etract	5.0gm
Casein Peptone	10.0gm
Meat Peptone	5.0gm
Sodium Chloride	5.0gm
Beef Extract	3.0gm
Corn Starch	1.0gm
Niacinamide	0.5gm
Glucose	0.5gm
Agar	14.0gm

Additional ingredients, if desired: **	
Animal blood (horse, rabbit and/or sheep)	50.0ml
Bacitracin	375.0mg

Final pH 7.3 +/- 0.2 at 25ºC.

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

** Items sold separately.

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 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 44.2gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat to boiling for one minute to dissolve completely.

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

4. Cool to 45-50ºC.

5. Aseptically add 50ml of animal blood (horse, rabbit and/or sheep) and 375mg of bacitracin, if desired. Stir while dispensing.

6. Aseptically pour into desired sterile containers.

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. J82 for *Haemophilus* identification.

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.

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, antibiotics, animal blood 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	
Haemophilus parahaemolyticus ATCC® 10014	A	24-48hr	35°C	CO_2**	Growth; faint beta-hemolysis at 48hrs

Haemophilus influenzae ATCC® 10211	A	24-48hr	35°C	CO_2**	Growth; no hemolysis

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

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

*** Expected results when prepared with 5% sheep blood.

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™ Modified Casman Agar Base powder should appear homogeneous, free-flowing, and beige in color. The prepared basal media should appear opaque, and beige in color. The prepared media, after the addition of animal blood, should appear opaque, with no hemolysis, and red in color.

REFERENCES

1. Casman. 1947. *Am. J. Clin. Pathol.*; 17:281.

2. Casman. 1942. *J. Bacteriol.*; 43:33.

3. Casman. 1947. *J. Bacteriol.*; 53:561.

4. 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.

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

6. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

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

8. *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.

HDQA 2207B [D]