IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

CRITERION™ SIM (SULFIDE, INDOLE, MOTILITY) MEDIUM

Cat. no. C6940	CRITERION™ SIM Medium	59.4gm
Cat. no. C6941	CRITERION™ SIM Medium	500gm
Cat. no. C6942	CRITERION™ SIM Medium	2kg
Cat. no. C6943	CRITERION™ SIM Medium	10kg
Cat. no. C6944	CRITERION™ SIM Medium	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ SIM Medium is recommended for the differentiation of gram-negative enteric bacilli, such as *Salmonella* and *Shigella*, on the basis of sulfide production, indole formation, and motility.

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

The formulation of SIM Medium is designed to allow the detection of sulfide production, indole formation and motility.

The medium contains ferrous ammonium sulfate and sodium thiosulfate, which together serve as indicators for the production of hydrogen sulfide. Hydrogen sulfide production is detected when ferrous sulfide, a black precipitate, is produced as a result of ferrous ammonium sulfate reacting with H_2S gas.

Casein peptone, another component of SIM Medium, is rich in tryptophan. Organisms possessing the enzyme tryptophanase degrade tryptophan to indole. Indole is detected upon the addition of Kovacs Indole Reagent (Cat. no. Z67) following incubation of the inoculated medium. Indole combines with p-dimethylaminobenzaldehyde and produces a red band at the top of the medium. A negative indole test produces no color change upon the addition of Kovacs Indole Reagent.

The small amount of agar added to the medium provides a semi-solid structure allowing for the detection of bacterial motility. Motile organisms extend from the stab line and produce turbidity or cloudiness throughout the medium. Non-motile organisms grow only along the stab line and leave the surrounding medium clear.

SIM Medium also contains animal tissue which provides amino acids and nutrients necessary for bacterial growth.

FORMULA

Gram weight per liter:	30.0gm/L

Pancreatic Digest of Casein	20.0gm
Peptic Digest of Animal Tissue	6.1gm
Ferrous Ammonium Sulfate	0.2gm
Sodium Thiosulfate	0.2gm
Agar	3.5gm

Final pH 7.3 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing 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 2-30ºC.

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 29.7gm of the dehydrated culture media in 1 liter of distilled or deionized water.

2. Heat to boiling and mix to dissolve completely.

3. Dispense medium into tubes to an approximate depth of 3 inches.

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

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. Q30.

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.

The inoculum should be taken from a solid medium. Use of an inoculum from a liquid or broth suspension will delay the initiation of growth and may result in erroneous results.

When inoculating semi-solid media, it is important that the inoculating needle be removed along the exact same line used to inoculate the medium. A fanning motion may result in growth along the stab line that may result in false-positive interpretation.

Motility and H_2S results must be interpreted prior to addition of Indole Kovacs Reagent.

Weak motile organisms or organisms that possess damaged flagella (due to heating, shaking, or other trauma) often result in false-negative motility tests. Motility results may be confirmed by performing a hanging drop motility test. Consult listed references for procedure.[2-4,6]

Some microorganisms, such as *Yersinia enterocolitica*, demonstrate motility best at 25ºC.

Organisms that require oxygen for growth, such as *Pseudomonas aeruginosa*, will produce a spreading film on the surface of the medium and will not extend from the line of inoculation where oxygen is depleted.

Erroneous results may occur if caps are not loose during incubation.

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	
Salmonella enterica ATCC® 14028	D	18-24hr	35°C	Aerobic	Growth; motility positive, H_2S positive (black color along stab line), indole negative

Escherichia coli ATCC® 25922	D	18-24hr	35°C	Aerobic	Growth; motility positive, H_2S negative, indole positive (Kovacs Reagent turns pink after adding three drops)

* 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™ SIM Medium powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear as a semi-solid medium, slightly opalescent, and medium amber in color.

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. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology*, J.B. Lippincott Company, Philadelphia, PA.

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

HDQA 2207B [D]