IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

SUGAR FREE AGAR

Cat. no. G445	Sugar Free Agar, 15x100mm Plate, 20ml	10 plates/bag
Cat. no. G445BX	Sugar Free Agar, 15x100mm Plate, 20ml	100 plates/box
Cat. no. U405	Sugar Free Agar, 250ml Polycarbonate Bottle, 225ml	12 bottles/box

INTENDED USE

Hardy Diagnostics Sugar Free Agar is recommended by the International Dairy Federation for the enumeration of microbial contaminants in butter or other processed dairy products.[1]

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

Sugar Free Agar was first developed by Ritter and Eschmann and further described by Thomas and Mossel.[2-4] The formulation is described by the International Dairy Federation for the enumeration of psychrotrophic and mesophilic gram-negative rods in butter and other processed dairy products.[1] Dairy products, like butter, may become contaminated during the manufacturing process. Though pasteurization normally destroys contaminating microorganisms in the final product, it is useful for dairy manufacturers to routinely monitor the manufacturing process at various stages to trace the source of contamination.

Gram-negative rods commonly found as contaminants in dairy products are able to deaminate proteins as a source of carbon, while other organisms such as enterococci are inhibited by the lack of a carbohydrate source.[5] Hardy Diagnostics Sugar Free Agar contains gelatin and tryptone peptones, which can be broken down by target strains and utilized as a carbon source for cellular metabolism. Sodium chloride is added to help cells maintain osmotic equilibrium. Agar is the solidifying agent. The medium conforms to the formulation described in the International Dairy Federation (I.D.F.).[1]

FORMULA*

Gelatin Peptone	7.5g
Tryptone	7.5g
Sodium Chloride	5.0g
Agar	14.0g

Final pH 7.6 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt, store Cat. no. G445 and G45BX at 2-8ºC and Cat. no. U405 at 2-30 ºC away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive: protect from light, excessive heat, moisture, 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 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.

PROCEDURE

Sample Collection: Consult reference methods for information on sample collection.[1] Samples 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 sample should be inoculated onto an appropriate transport medium and refrigerated until inoculation.

Method of Use:Allow medium to warm to room temperature prior to inoculation. Consult references for information concerning inoculation procedures.[1]

INTERPRETATION OF RESULTS

Consult listed references for appropriate interpretation of results.[1]

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.

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, swabs, applicator sticks, other culture media,

incinerators, 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	
Staphylococcus aureus ATCC® 6538	J	18-48hr	35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 9027	J	18-48hr	35°C	Aerobic	Growth
Bacillus subtilis ATCC® 6633	J	18-48hr	35°C	Aerobic	Growth
Escherichia coli ATCC® 8739	J	18-48hr	35°C	Aerobic	Growth
Candida albicans ATCC® 10231	J	5-7days	20-25°C	Aerobic	Growth
Aspergillus brasiliensis ATCC® 16404	J	5-7days	20-25°C	Aerobic	Growth
Bifidobacterium breve ATCC® 15700	B	18-24hr	35°C	Anaerobic	Inhibited
Lactobacillus acidophilus ATCC® 4356	B	18-24hr	35°C	CO_2**	Inhibited

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

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

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

Sugar Free Agar should appear light to medium amber to tan in color.

REFERENCES

1. International Dairy Federation. 1964. International standard count of contaminating organisms in butter. *International Standards* FIL-IDF 30.

2. Ritter P. and K.H. Eschmann. 1966. The bacteriological testing and assessment of table butter. *Alimenta*. 2:43-45.

3.Thomas S. B. 1969. Methods of assessing the psychrotrophic bacterial content of milk. *J. Appl. Bacteriol.* 3(3)2:269

4. Mossel, D.A.A, B.Krol, and P.C. Moerman. 1972. *Alimenta*. 11(2):51-60.

5. American Public Health Association. *Standard Methods for the Examination of Dairy Products.* APHA, 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 2207D [D]