IFU

HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

COLUMBIA AGAR, USP

Cat. no. G250	Columbia Agar, USP, 15x 100mm Plate, 18ml	10 plates/bag

INTENDED USE

Hardy Diagnostics Columbia Agar, USP is recommended for use as a general purpose medium for the isolation and cultivation of nonfastidious and fastidious microorganisms and for the growth promotion of *Clostridium* spp. as recommended by the U.S. Pharmacopeia.

SUMMARY

Columbia Agar, USP is recommended by the U.S. Pharmacopeia for use in growth promotion testing of Clostridia.[2] *Clostridium* species have variable physiological capacities that govern their tolerance of oxygen and may range from strictly anaerobic to aerotolerant metabolisms.

Columbia Agar without enrichment can be used as a general purpose medium. This nutritionally rich medium was developed by Ellner et al. from Columbia University.[1] The formula calls for a combination of peptones from pancreatic digest of casein, peptic digest of animal tissue and beef extract, which support growth. Additional metabolic energy is derived from corn starch and yeast extract. Yeast extract also serves as a source of B-complex vitamins. Sodium chloride is added to maintain osmotic balance. Agar is the solidifying agent.

FORMULA

Ingredients per liter of deionized water:*

Pancreatic Digest of Casein	10.0gm
Meat Peptic Digest	5.0gm
Heart Pancreatic Digest	3.0gm
Yeast Extract	5.0gm
Maize Starch	1.0gm
Sodium Chloride	5.0gm
Agar	13.5gm

Final pH 7.3 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. 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 Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic 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

Method of Use: Allow the plates to warm to room temperature and the agar surface to dry before inoculating. The U.S. Pharmacopeia recommnends subculturing from Reinforced Clostridial Medium, USP (Cat. no. U172).[2] Heavily inoculate and streak the specimen for isolation with a sterile loop as soon as possible after collection. Incubate plates aerobically or anaerobically at 30-35ºC. for 48 hours to 5 days, depending on growth requirements. Examine colonial morphology.

INTERPRETATION OF RESULTS

Examine Columbia Agar, USP for growth. The presence of *Clostridia* is indicated by the occurrence of anaerobic growth. Further examination of colonies may be expected to show gram-positive rods (with or without endospores) that yield a negative catalase reaction.[2] Consult listed references for interpretation criteria and further biochemical testing of growth.[1, 2]

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, and 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® 25923**	A	24-48 hrs	35°C	Aerobic	Growth
Streptococcus pyogenes ATCC® 19615**	A	24-48 hrs	35°C	Aerobic	Growth
Escherichia coli ATCC® 25922**	A	24-48 hrs	35°C	Aerobic	Growth
Clostridium sporogenes ATCC® 19404**	J	48 hrs	30-35°C	Anaerobic	Growth

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

**Tested in accordance with USP <62>.[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

Columbia Agar, USP should appear hazy, and light amber in color.

REFERENCES

1. Ellner, P. D., C. J. Stoessel, E. Drakeford, and F. Vasi. 1966. A new culture medium for medical bacteriology. Am. J. Clin. Pathol. 45:502-504.

2. The Official Compendia of Standards. USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. *USP-NF*. United States Pharmacopeial Convention Inc., Rockville, MD.

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Ordering Information

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

HDQA 2207H [D]