

# Instructions for Use

## CRITERION™ PYRIDOXINE Y MEDIUM

<a href="#">Cat. no. C9120</a>	CRITERION™ Pyridoxine Y Medium	131.8gm
<a href="#">Cat. no. C9121</a>	CRITERION™ Pyridoxine Y Medium	500gm
<a href="#">Cat. no. C9122</a>	CRITERION™ Pyridoxine Y Medium	2kg
<a href="#">Cat. no. C9123</a>	CRITERION™ Pyridoxine Y Medium	10kg

### INTENDED USE

Hardy Diagnostics CRITERION™ Pyridoxine Y Medium is recommended for use in determining pyridoxine concentration via the microbiological assay technique.

Dehydrated culture media is a raw material not intended for use in the diagnosis of human disease. For proper use, the product requires additional processing and ingredient supplementation before use.

### SUMMARY

There are three types of assay media for use in the microbiological testing of vitamins: stock maintenance media, inoculum media to condition the organism prior to testing, and assay media for vitamin quantitation and performance testing.

CRITERION™ Pyridoxine Y Medium is an assay medium patterned after the formulation proposed by Campling and Nixon, and later modified by Hurley and Parrish, and Loy and Kline.<sup>(3-5)</sup> This formulation is commonly used in the microbiological assay of pyridoxine using *Saccharomyces cerevisiae* ATCC® 9080.

CRITERION™ Pyridoxine Y Medium contains all essential vitamins and nutrients to support the growth of *S. cerevisiae*, except for pyridoxine (vitamin B<sub>6</sub>). When prepared, the addition of pyridoxine in specified concentrations yields growth that can be measured via turbidimetric and titrimetric methods.<sup>(2)</sup>

### FORMULA\*

Gram weight per liter:	65.0gm/L
Dextrose	50.0gm
Amino Acid Mixture	5.23gm
Ammonium Sulfate	5.0gm
Potassium Phosphate Mono	3.75gm
Magnesium Sulfate	1.25gm

Calcium Chloride	0.61gm
Riboflavin	0.025gm
Biotin Salt	0.01gm
Inositol/td>	0.006gm
Trace Nutrients	0.00329gm

Final pH of 2.65% solution 4.4 +/- 0.2 at 25°C.

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

## STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30°C. 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 white to off-white.

Store the prepared culture media at 2-8°C.

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 65.9gm of the dehydrated culture media in 1L of distilled or deionized water. Stir to mix thoroughly.
2. Heat with frequent agitation and boil for 2 to 3 minutes to completely dissolve.
3. Continue stirring to maintain an even precipitation and dispense in 5.0ml aliquots into scrupulously cleaned and sterile flasks.
4. Add the standard or test samples.

5. Aseptically adjust flask volume to 10.0ml with sterile purified water.

6. Allow to boil for 10 minutes at 100°C.

## PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references.<sup>(1-5)</sup>

## 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, and incubators, etc., and other culture media and equipment, are not provided.

## QUALITY CONTROL

Hardy Diagnostics tests CRITERION™ Pyridoxine Y Medium for pH, and appearance.

### 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™ Pyridoxine Y Medium powder should appear homogeneous, free-flowing, and white to off-white in color. The prepared medium should appear yellow to bright (neon) yellow with precipitate.

## REFERENCES

1. *Official Methods of Analysis*. Association of Official Analytical Communities, Washington, D.C.
2. *United States Pharmacopeia and National Formulary*. USP-NF. United States Pharmacopeial Convention, Rockville, MD.
3. Campling J.D. and D.A. Nixon. 1954. The inositol content of foetal blood and foetal fluids. *J. Physiol.* 126:71-80.
4. Hurley. 1960. *J. Assoc. Off. Agri. Chem.* 43:43.
5. Parrish, W.P., H.W. Loy and O.L. Kline. 1955. A study of the yeast method for vitamin B<sub>6</sub>. *J. Assoc. Off. Agri. Chem.* 39:506.

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

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[Ordering Information](#)

Distribution Centers:

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