IFU

Instructions for Use

RAPID UREA MEDIUM

Cat. no. Z54	Rapid Urea Medium, 15x45mm Vial, 2ml Deep	10 tubes/box

INTENDED USE

Hardy Diagnostics Rapid Urea Medium is used for the rapid determination of urease activity in bacteria such as *Proteus*spp., *Helicobacter pylori*, or in yeast, such as *Cryptococcus neoformans*.

SUMMARY

Urease activity can be described as the splitting of urea via hydrolysis by a urease enzyme. The end products from this reaction yield ammonium carbonate and ammonia, which are alkaline in nature. Organisms that possess this urease enzyme may be characterized by this activity in a specific, yet rapid test formulated by Goldie.[4] The test is non-toxic, and the pH change that occurs from accumulation of alkaline end products is detected by a pH indicator in the media. *Helicobacter pylori* is an organism that may be easily identified by this test because of its very high endogenous urease activity. This method has been used to help simplify the diagnosis of *H. pylori*, especially those specimens originating from duodenal and gastric ulcers, and chronic antral gastritis (type B). The urease reaction obtained from *H. pylori* in Rapid Urease Medium occurs more quickly than that seen by other organisms which may split urea. As a result, it is an effective presumptive test for the presence of *H. pylori*.

REAGENT FORMULA

Ingredients per liter of deionized water:*

Urea	20.0gm
Monosodium Phosphate	0.7gm
Phenol Red	0.1gm
Agar	4.0gm

Final pH 6.0 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Upon receipt store at 2-8ºC away from direct light. Media should not be used if there are any signs of contamination, deterioration, (shrinking, cracking or discoloration) 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

Isolated Organism: Using a sterile wooden applicator stick or platinum loop, obtain a loopful of a 24-48 hour old isolated organism from a non-selective agar plate (such as Chocolate Agar, Cat. no. E14). Inoculate the media by stabbing. Incubate at room temperature (15-30ºC) aerobically. Observe at 15-20 minutes and again at one, three, and six hours of incubation for the development of a pink-red or red-violet color. Continue incubation of negative tests for up to 20 hours. Rapid Urea Medium may be incubated at 35ºC. in order to obtain faster reaction times.

Biopsy Specimen: Biopsy specimens are to be placed in 0.5ml of lactated Ringers solution at pH 6.5. Transport to laboratory on wet ice. Consult appropriate references for detailed directions on specimen collection.

Grind biopsy specimens with a sterile tissue grinder, and place a portion of the ground specimen into the Rapid Urea Medium. As an alternative to this method, the biopsy may be placed directly into the Rapid Urea Medium at the time of endoscopy, if desired. Submerge the specimen in the Rapid Urea Medium. Incubate at room temperature (15-30ºC.) aerobically. Observe at 15-20 minutes and again at one, three, and six hours of incubation for the development of a pink-red or red-violet color. Continue incubation of negative tests for up to 20 hours. Rapid Urea Medium may be incubated at 35ºC in order to obtain faster reaction times.

INTERPRETATION OF RESULTS

A positive reaction is indicated by the appearance of a pink-red to violet color. No color change is indicative of a negative reaction. A strong positive reaction may be determined within minutes of inoculation into the Rapid Urea Medium.

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.

Nichrome inoculating loops can generate an immediate false-positive result. A sterile wooden stick or a platinum loop should be used to transfer the specimen into the Rapid Urea Medium vial.

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, incinerators, incubators, forceps, 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	Results
Proteus mirabilis ATCC® 12453	Positive; color change from the original yellow to pink-red, slower reaction time than *H. pylori*
Escherichia coli ATCC® 25922	Negative; no color change observed

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

Rapid Urea Medium should appear slightly hazy, and bright yellow to yellowish-orange in color. Do not use if media appears pink-red.

Proteus mirabilis (ATCC® 12453) in Rapid Urea Medium. The pink-red color development was indicative of a positive urease reaction. Incubated aerobically at room temperature for one hour. A stronger reaction will be observered after longer incubation. Alternatively, incubation can be conducted at 35ºC. for faster

Escherichia coli (ATCC® 25922) in Rapid Urea Medium. No pink-red color development was indicative of a negative urease reaction. Incubated aerobically at room temperature for 20 hours.

reaction.

REFERENCES

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

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

3. 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.

4. Goldie, J., et al. 1989. Optimization of medium for rapid urease test for detection of *Campylobacter pylori* in gastric antral biopsies. *J. Clin. Microbiol.*; 27:2080-2082.

5. Pique, J.M., et al. 1989. Notes: Rapid detection of gastric *Campylobacter pylori*colonization by a simple biochemical test.*J. Clin. Microbiol.*; 27:2604-2605.

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

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

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