IFU

Instructions for Use

CATALASE REAGENT

Cat. no. Z62	Catalase Reagent, 3%	15ml
Cat. no. Z76	Catalase Reagent, 3%	60ml
Cat. no. Z262	Catalase Reagent, 15%	15ml

INTENDED USE

Hardy Diagnostics' Catalase Reagents are useful in the presumptive identification and differentiation of many bacteria. Beta-hemolytic organisms, such as *Streptococcus* species (catalase-negative), *Staphylococcus* species (catalase-positive), and *Listeria* species (catalase-positive) can be differentiated by their catalase reaction using 3% hydrogen peroxide. For catalase testing of anaerobic bacteria, 15% hydrogen peroxide appears to be more sensitive than 3% hydrogen peroxide.

SUMMARY

Most cytochrome containing organisms produce a catalase enzyme which breaks down hydrogen peroxide into oxygen and water. When a small amount of a catalase producing organism is introduced into hydrogen peroxide, bubbles of oxygen form as a result of the enzyme's activity.

REAGENT FORMULA

Z91 and Z76 include:

Hydrogen Peroxide, 3%, and Acetophenetidine.

Z262 includes:

Hydrogen Peroxide, 15% and Acetophenetidine.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-30ºC away from direct light. Products 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 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

Specimen Collection: These products are not intended for primary isolation of patient specimens. These products are used in conjunction with other biochemical tests to identify cultures of isolated organism.

Method of Use:

Catalase Reagent, 3%:

With a loop or sterile wooden stick, transfer a small amount of a well isolated, 18 to 24 hour old colony from a non-blood-containing agar onto the surface of a clean, dry, glass slide. Immediately place a drop of Catalase Reagent, 3% onto a portion of the colony on the slide. Do not introduce a metallic loop into the drop, because this often causes a false-positive reaction.

Catalase Reagent, 15%:

Touch the center of a well isolated, 24 to 72 hour old colony with a non-metallic-loop or sterile wooden stick; avoid contact with the agar. Transfer growth onto the surface of a clean, dry, glass slide. Immediately place one drop of Catalase Reagent, 15% onto the smear. Do not introduce a metallic loop into the drop, because this often causes a false-positive reaction.

INTERPRETATION OF RESULTS

Observe for the immediate evolution of gas bubbles indicating a positive test. Formation of rare bubbles after 20 to 30 seconds is considered a negative catalase test.

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.

Aerobic organisms must be taken from an 18 to 24 hour old culture. Organisms lose their catalase activity with age. For slower growing anaerobic organisms, an older (24-72 hours) culture may be acceptable. Anaerobic cultures should be exposed to ambient air for a minumum of 30 minutes before testing.

It is recommended that colonies to be tested with the Catalase Test be taken from non-blood containing media due to the endogenous catalase activity present in animal red blood cells. For genera that require blood-containing media for growth, use isolates from a nonselective blood agar and avoid touching the agar with the loop.

Do not introduce a metallic loop into the drop of Catalase Reagent, because this often causes a false-positive reaction.

Bacteria grown on media with low levels or no glucose may yield conflicting results from pseudocatalase, a non-iron enzyme. The pseudocatalase reaction can be prevented by using media with 1% glucose.

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, microscope slides, incinerators, incubators, pasteur pipets, 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	**Reaction**
Catalase Reagent, 3% (Cat. no. Z62 and Z76):	
Staphylococcus aureus ATCC® 25923	Positive, bubbles seen
Streptococcus pyogenes ATCC® 19615	Negative, no bubbles seen
Catalase Reagent, 15% (Cat. no. Z262):	
Bacteroides fragilis ATCC® 25285	Positive, bubbles seen
Clostridium perfringens ATCC® 13124	Negative, no bubbles seen

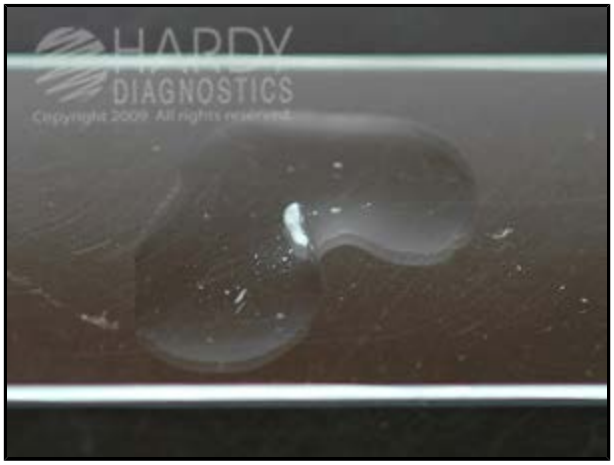
USER QUALITY CONTROL

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

Catalase Reagent should appear clear and colorless.

Showing positive catalase test
Growth from a 24 hour *Staphylococcus aureus* (ATCC® 25923) culture on TSA (Cat. no. G60) was applied to a sterile slide. A drop of Catalase Reagent (Cat. no. Z62) was dropped onto the applied growth. The production of gas bubbles was indicative of a positive catalase reaction. Catalase tests should not be performed from growth cultured on a blood-containing medium.



Showing negative catalase test
Growth from a 24 hour *Streptococcus pyogenes* (ATCC® 19615) culture on TSA (Cat. no. G60) was applied to a sterile slide. A drop of Catalase Reagent (Cat. no. Z62) was dropped onto the applied growth. The absense of gas bubbles was indicative of a negative catalase reaction. Catalase tests should not be performed from growth cultured on a blood-containing medium.

REFERENCES

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2. Tille, P.M., 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. 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.

6. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria* , Vol. I. Williams & Wilkins, Baltimore, MD.

7. Centers for Medicare and Medicaid, *Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services* . Subpart K - Quality System for Non-Waived Testing. 493;1200-1265. www.cms.hhs.gov/clia .

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

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