IFU

Instructions for Use

POTASSIUM HYDROXIDE (KOH), 3%

Cat. no. Z173	Potassium Hydroxide (KOH), 3% Solution	15ml

INTENDED USE

Hardy Diagnostics Potassium Hydroxide (KOH), 3% Solution is recommended for performing the KOH String Test as a secondary test to the Gram stain to aid in the identification of gram-negative bacilli.

SUMMARY

The Gram stain is not always truly indicative of an organism's cell wall structure. Poorly controlled decolorizing during the Gram staining procedure may be a source of misleading results. In addition, even with adequate staining technique, some organisms may be problematic. For example, some strains of *Bacillus* spp. or *Clostridium* spp. may stain gram-negative when they have a gram-positive cell wall. Consequently, the KOH String Test is a useful secondary test for differentiation of gram-negative and gram-positive cultures, which relies on the cell's differential resistance to 3% potassium hydroxide. When performing the string test, a portion of a colony is mixed with a small volume of KOH, 3% on a glass slide for no more than 60 seconds. If the cells lyse, the liberated cellular DNA makes the mixture viscous or “stringy.” A positive string test indicates a gram-negative bacilli.

FORMULA

Potassium Hydroxide	30.0g
Deionized Water	1000.0ml

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-30ºC away from direct light. Product should not be used if there are any signs of deterioration, discoloration, contamination, or if the expiration date has passed.

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: This product should be used on pure isolates only.

1. Place a drop of KOH, 3% on a clean glass slide (Cat. no. PF72P or PP72P).

2. Using a loop, remove a visible clump of fresh (18 to 24hr) pure culture from a non-selective agar plate (e.g. Cat. no. A10).

3. Stir the culture into the KOH, 3% solution and mix continuously in a 1-2cm area on the slide for a maximum of 60sec.

4. Slowly lift the loop out of the suspension and observe for the formation of a string.

5. Frequently raise the loop 1cm off the surface of the test if the mixture is becoming viscous and has the ability to "string out."

INTERPRETATION OF RESULTS

If the organism is a gram-negative bacilli, the string test should be positive and show the presence of a string.

If the organism is gram-positive, the string test should be negative and show the absence of a string.

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.

A fresh pure isolate must be used for accurate results. Using mixed specimens or old cultures may result in erroneous results.

A large visible clump of culture must be used for accurate results. Using an insufficient amount of culture may result in the inability to see results within the timeframe of the test.

Do not read the results after 60sec. Reading results after the time period may lead to erroneous results.

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, microscope slides (Cat. nos. PF72P or PP72P), other culture media (Cat. no. A10), 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:

Organism	Results
Escherichia coli ATCC® 25922	Positive; String formation after 60 seconds
Staphylococcus aureus ATCC® 25923	Negative; No string formation

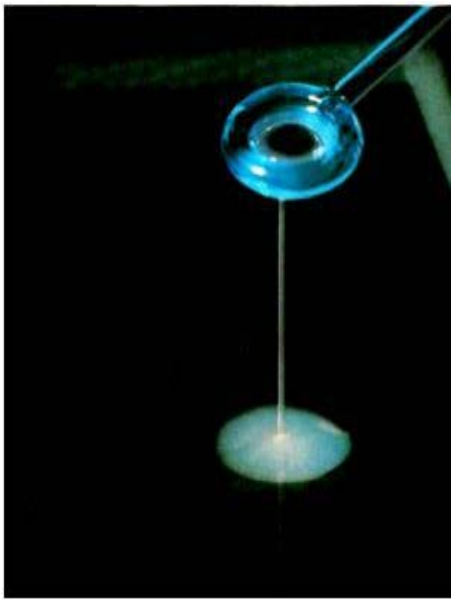
* Refer to the document "Inoculation Procedures for Media QC" for more information.

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

Potassium Hydroxide (KOH), 3% should appear clear and colorless.



Vibrio cholerae showing a positive reaction for the KOH string test.

REFERENCES

1. 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.

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

3. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology.* J.B. Lippincott Company, Philadelphia, PA.

4. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

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

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

7. Centers for Medicare & Medicaid Services (CMS). Individualized Quality Control Plan (IQCP).

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1430 West McCoy Lane, Santa Maria, CA 93455, USA
Phone: (805) 346-2766 ext. 5658
Fax: (805) 346-2760
Website: HardyDiagnostics.com
Email: TechnicalServices@HardyDiagnostics.com
Ordering Information

Distribution Centers:
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 2207F [D]