

Instructions for Use

CATSCREEN™

Cat. no. Z110	CatScreen™	25 tests/kit
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INTENDED USE

Hardy Diagnostics CatScreen™ is a rapid test for the detection of the enzyme butyrate esterase in bacteria isolated on culture media for the presumptive identification of *Moraxella (Branhamella) catarrhalis*.

SUMMARY

The CatScreen™ is used to confirm the identification of *Moraxella (Branhamella) catarrhalis* when used in conjunction with chromogenic substrate tests or carbohydrate fermentations, oxidase reaction, Gram stain and morphology. For presumptive identification of *M. catarrhalis*, the CatScreen™ may be used along with the oxidase reaction, gram stain and colony morphology.⁽⁵⁾

The value of tributyrin hydrolysis for differentiating *M. catarrhalis* from *Neisseria* spp. was first reported by Berger in 1962. Subsequently, several authors have reported the usefulness of butyrate esterase in differentiating the two organisms using various substrates.⁽⁵⁾ Butyrate hydrolysis is listed in standard reference texts as a key test in differentiating *M. catarrhalis* from *Neisseria* spp.^(1,4,6)

Disks impregnated with bromo-chloro-indolyl butyrate serve as the substrate for the detection of butyrate esterase. Hydrolysis of the substrate by the butyrate esterase yields a chromogenic compound which appears blue to blue-green in color.

REAGENT FORMULA

The CatScreen™ Kit contains 25 disks impregnated with 0.35% bromo-chloro-indolyl butyrate in a volatile organic solvent, followed by desiccation.

STORAGE AND SHELF LIFE

Upon receipt store at -20°C, in the dark. This product should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Protect disks from light and moisture. Leave desiccant in vial.

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: This product is not intended for primary isolation of patient specimens. This product is used in conjunction with other biochemical tests to identify cultures of isolated organisms.

The appropriate organism for performing the butyrate test is an oxidase-positive, gram-negative diplococcus exhibiting typical morphology of *Moraxella (Branhamella) catarrhalis*.

Method:

1. Remove disk from vial and place on a clean glass slide or petri dish lid.
2. Add one drop of distilled or deionized water to moisten the disk.
3. Obtain a heavy, visible inoculum with a sterile wooden applicator stick or loop from a 24-72 hour old culture and rub it onto the disk.
4. Incubate at room temperature (15-30°C.) for up to 5 minutes.

INTERPRETATION OF RESULTS

A positive test resulting in a blue to blue-green color within 5 minutes indicates the hydrolysis of bromo-chloro-indolyl butyrate by butyrate esterase. A negative test is indicated by no color change.

Incubation for slightly longer periods may yield false-positive results. Do not read after 5 minutes.

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.

Non-human species of *Branhamella* subgenus *Moraxella* are butyrate esterase-positive.

Some strains of the subgenus *Moraxella* (bacilli) may give a positive or weak positive reaction.

Unrelated organisms such as staphylococci and pseudomonads may also give positive results.

False-negatives may result from using too small an inoculum.

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, other culture media, swabs, applicator sticks, 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	Reaction
<i>Moraxella (Branhamella) catarrhalis</i> ATCC® 25240	Positive: Development of blue to blue-green color change within 5 minutes
<i>Neisseria gonorrhoeae</i> ATCC® 43069	Negative: Does not turn blue within 5 minutes

* Refer to the document "[Inoculation Procedures for Media QC](#)" for more information.

USER QUALITY CONTROL

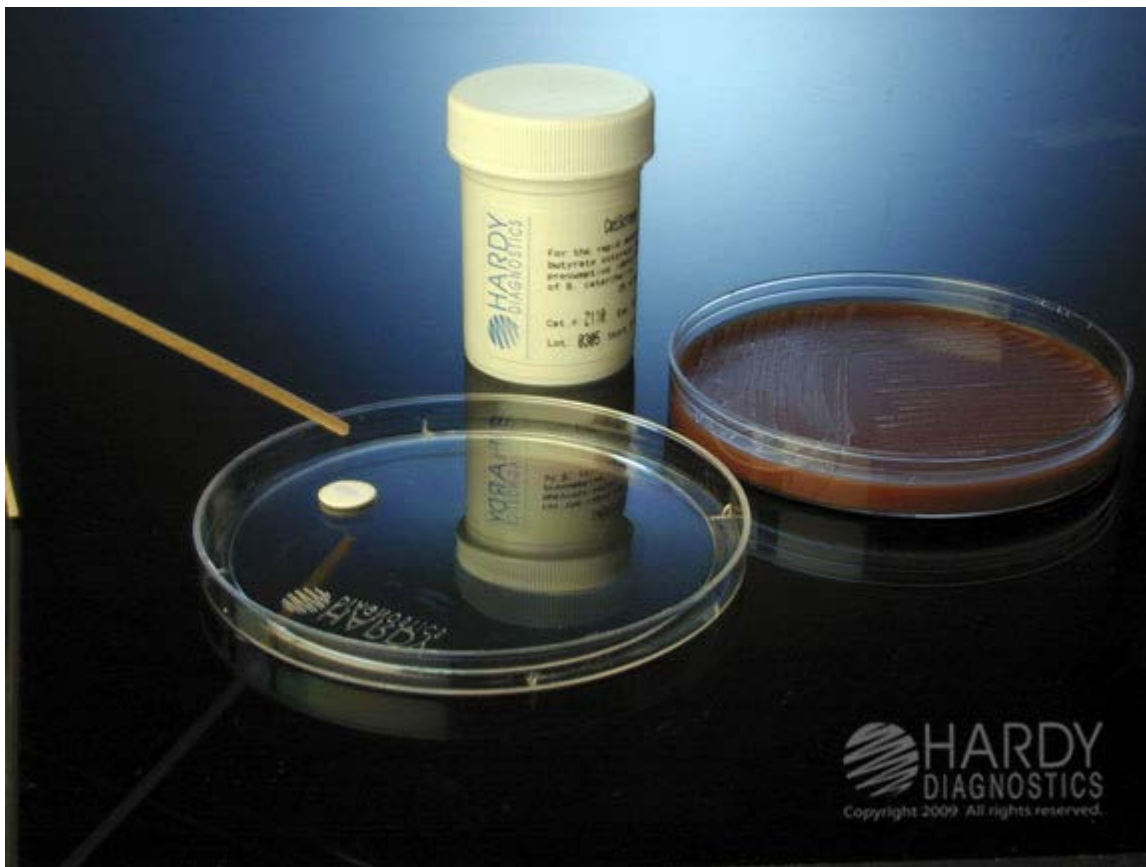
End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory 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

Disk should appear white with no visible blue color.



CatScreen™ Disk (Cat. no. Z110) - **Positive:** *Moraxella (Branhamella) catarrhalis* (ATCC® 25240)



CatScreen™ Disk (Cat. no. Z110) - **Negative:** *Neisseria gonorrhoeae* (ATCC® 43069)

PERFORMANCE CHARACTERISTICS

The laboratory study included 110 previously identified *M. catarrhalis* clinical isolates plus ATCC®25240. (Total 111 *M. catarrhalis* isolates tested.) A side by side comparison was made and recorded with our CatScreen™ and the predicate device - Carr Scarborough's M. cat Butyrate Disc. In addition, 14 negative controls were tested including *Neisseria caviae*, *N. meningitidis*, *N. gonorrhoeae*, *N. sicca*, *N. canis*, *N. flavescens* and *N. subflava*. Of the *B. catarrhalis* organisms tested, 13% were beta-lactamase negative. *Neisseria caviae* (ATCC® 14659) gave a weak positive reaction on both Hardy Diagnostics and Carr Scarborough's disks (false-positive). Overall performance of the disks is as follows:

Relative Sensitivity - 92.9%

Relative Specificity - 100%

REFERENCES

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3. Berger, U. 1962. Uber die spaltung von tributyrin durch Neisseria. *Arch Hyg. Bakteriol.* ; 146:388-391.
4. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.
5. Janda, W.M. and P. Ruther. 1989. B. CAT CONFIRM; A rapid test for confirmation of *Branhamella catarrhalis*. *J. Clin. Microbiol.* ; 27:1390-1391.
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7. Versalovic, J., et al. *Manual of Clinical Microbiology*. American Society for Microbiology, Washington, D.C.
8. Perez, J.L., et al. 1990. Butyrate esterase (tributyryl) spot test, a simple method for immediate identification of *Moraxella* (*Branhamella*) *catarrhalis*. *J. Clin. Microbiol.* ; 28: 2347-2348.

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

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[Ordering Information](#)

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