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HARDY DIAGNOSTICS
A Culture of Service™

Instructions for Use

# COLISCREEN™

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|---|---|---|
| Cat. no. Z204 | ColiScreen™, 15x45mm Vial | 20 tests/kit |

## INTENDED USE

Hardy Diagnostics ColiScreen™ is recommended for the presumptive identification of *Escherichia coli*.

## SUMMARY

Hardy Diagnostics ColiScreen™ is to be used as a rapid screening test to assist in the identification of *E. coli*. The performance of a spot indole test alone is not an adequate screen for *E. coli*, since there are at least 52 species of gram-negative bacilli that grow on MacConkey, are indole-positive, and ferment lactose. The more common ones include *Klebsiella oxytoca, Citrobacter freundii, C. sedlakii, C. braakii, C. koserii, C. amalonaticus, C. youngae, Aeromonas hydrophila* and *Serratia odorifera*. The test is designed to be used on isolates demonstrating typical appearance on EMB and/or MacConkey Agar. Although most *E. coli* exhibit lactose-fermentation on these media, it should be noted that approximately 5% of *E. coli* are non-lactose-fermenters.[2] Using this test system, glucuronidase-positive, indole-positive, gram-negative organisms are presumptively identified as *E. coli*. Hydrolysis of the additive nitrophenyl-beta-glucopyranosiduronic acid denotes the production of glucuronidase and is detected by the development of a yellow color in the medium. Indole production is detected by addition of Kovacs Indole Reagent after the yellow color has developed. According to Thompson, approximately 96% of all *E. coli* strains are glucuronidase-positive.[7]

## FORMULA

Ingredients per liter of deionized water:*

| **ColiScreen™ Tubes:** | |
|---|---|
| Columbia Agar | 18.0gm |
| Tryptophane | 2.0gm |
| Nitrophenyl-beta-Glucopyranosiduronic Acid | 330.0mg |

## REAGENT FORMULA

| **Kovacs Indole Reagent (Cat. no. Z67, sold separately):** | |
|---|---|
| p-Dimethylaminobenzaldehyde | 50.0gm |
| Hydrochloric Acid, 37% | 250.0ml |
| n-Amyl Alcohol | 750.0ml |

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

## STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-8ºC. Products should not be used if there are any signs of deterioration, discoloration, contamination, 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

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 organism.

Obtain a heavy, visible inoculum with a sterile wooden applicator stick or loop from an 18-24 hour old culture. Stab into the medium, near the glass of the tube for ease in reading. Incubate the tubes aerobically at 35ºC. for one to four hours. If the glucuronidase test is positive (the presence of a bright yellow color), test for indole. Indole production is tested by adding two to three drops of Kovacs Indole Reagent (Cat. no. Z67).

## INTERPRETATION OF RESULTS

A positive glucuronidase test is indicated by the presence of a bright yellow color change. No color change is considered a negative glucuronidase test. A pink to red color developing after the addition of Kovacs Indole Reagent is indicative of a positive test. No color change on addition of this reagent is a negative test.

Presumptive identification of *E. coli* is indicated when both glucuronidase and indole tests are positive and the organism is gram-negative.

## 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.

Organisms must be characterized as having colony morphology typical to that of *Escherichia coli* and must be gram-negative. Approximately 5% *E. coli* isolates are non-lactose-fermenters.[2]

If a colony of typical morphology has been determined to be gram-negative, both glucuronidase and indole must be positive in order to presumptively identify it as *E. coli*.

Although, glucuronidase- and indole-positive, some atypical strains of *E. coli* (*E. coli* group AD) are non-lactose-fermenters.

*E. coli* O157 appear as lactose-fermenters but are glucuronidase-negative and indole-positive.

Proper inoculation of this medium is very important. A heavy inoculum of the test organism should be taken from 18-24 hour old pure cultures of well isolated colonies.

Refer to the document "Limitations of Procedures and Warranty" for more information.

## MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as Kovacs Indole Reagent (Cat. no. Z67), loops, incinerators, incubators, other culture media, 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 | Inoculation Method* | Incubation | | | Results |
|---|---|---|---|---|---|
| | | Time | Temperature | Atmosphere | |
| *Escherichia coli* ATCC® 25922 | E | 1-3hr | 35°C | Aerobic | Glucuronidase-positive: bright yellow; Indole-positive: dark pink/red |
| *Klebsiella pneumoniae* ATCC® 13883 | E | 4hr | 35°C | Aerobic | Glucuronidase-negative: no color change; Indole-negative: no color change |

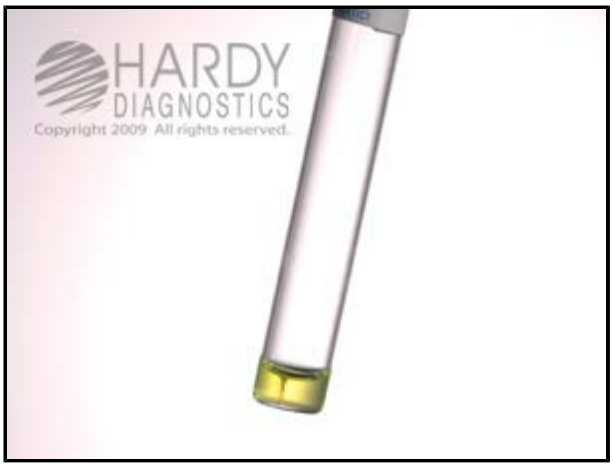
* Refer to the document "Inoculation Procedures for Media QC" for more information.

### 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

- ColiScreen™ media should appear clear, and slightly yellowish-gray in color.
- Kovacs Indole Reagent should appear translucent with a yellow tinge and no precipitate.




*Escherichi coli* (ATCC® 25922) inoculum incubated in ColiScreen™ (Cat. no. Z204) medium. ColiScreen™ tube was incubated aerobically for 3 hours at 35ºC.


*Klebsiella pneumoniae* (ATCC® 13883) inoculum incubated in ColiScreen™ (Cat. no. Z204) medium. ColiScreen™ tube was incubated aerobically for 3 hours at 35ºC.


*Escherichia coli* (ATCC® 25922) inoculum incubated in ColiScreen™ (Cat. no. Z204) medium with Kovacs Indole Reagent (Cat. no. Z67, sold separately) added after incubation. ColiScreen™ tube was incubated aerobically for 3 hours at 35ºC.


*Klebsiella pneumoniae* (ATCC® 13883) inoculum incubated in ColiScreen™ (Cat. no. Z204) medium with Kovacs Indole Reagent (Cat. no. Z67, sold separately) added after incubation. ColiScreen™ tube was incubated aerobically for 3 hours at 35ºC.

## PERFORMANCE CHARACTERISTICS

A total 100 clinical isolates, previously identified by the Vitek® Gram-Negative ID Card, were tested and compared with another commercially available product. Isolates included: *Escherichia coli* (67), *Escherichia coli*AD (1), *Escherichia coli* O157 (5), *Shigella sonnei* (3), *Enterobacter cloacae* (7), *Citrobacter freundii* (4), *Enterobacter aerogenes* (5), *Klebsiella oxytoca* (4) *Salmonella* spp. (4).

Sixty-eight of the seventy-three *E. coli* isolates tested produced both positive glucuronidase and positive indole tests on ColiScreen™. All of the five false-negative isolates were identified as *E. coli* O157. It should be noted, and it is included under the "Limitations" section that, although these strains are lactose-fermenters, they are atypical because they are glucuronidase-negative. One *E. coli* isolate produced positive indole tests on both systems, but glucuronidase test results differed (Hardy product = positive glucuronidase; comparative product = false-negative glucuronidase).

Results of this comparison study reveal Hardy Diagnostics ColiScreen™ test to be 93% (*84.7-97.7%) sensitive. The

sensitivity of the comparative product was 91.8% (*83.0-96.9%). Both devices were 100% (*87.2-100%) specific for the presumptive identification of *Escherichia coli*.

* 95% confidence interval as determined by the Exact Method.

## 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. Versalovic, J., et al. *Manual of Clinical Microbiology.* American Society for Microbiology, Washington, D.C.

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

4. Godsey, J.H., et al. 1981. Rapid identification of Enterobacteriaceae with microbial enzyme activity profiles. *J. Clin. Microbiol.*; 13:483-490.

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

6. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology.* J.B. Lippincott Company, Philadelphia, PA. *E. coli* serotype 0157. *J. Clin. Microbiol.*; 28:2165-2168.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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.



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