PRODUCT INFORMATION

InSure® FIT™/InSure® ONE™ is CLIA Waived.

InSure® FIT™ FOBT Controls (REF 16800)

Within the USA, to place an order or for more information, call Enterix Inc. at 1-800-531-3681 or visit our website at www.insuretest.com. Within all other countries please contact your local distributor

SYMBOL USE


Protect from Heat and Direct Sunlight


Attention, see instructions for use

IVD In vitro diagnostic medical device


Manufacturer


Contains sufficient for 25 tests


Biohazard

REF Catalog number

LOT Batch code


Temperature limitation


Use by (Year Month Day)

EC REP Authorized Representative in the European Community

INTENDED USE

InSure® FIT™ FOBT Controls are for *in vitro* diagnostic use only and include a positive control containing stabilized human hemoglobin and a negative control containing a buffer. This is an assayed positive and negative control and intended for the qualitative test determinations of InSure® FIT™/InSure® ONE™ product. InSure® FIT™ FOBT Controls are for exclusive use with InSure® FIT™/InSure® ONE™ product. These controls can be used to independently verify the functionality and performance of the InSure® FIT™/InSure® ONE™ test by laboratories and other professional medical institutions as part of a comprehensive quality assurance program.

COMPOSITION

InSure® FIT™ Positive Control (1.5mL)
Contains purified human hemoglobin, borate salts, ethanol (10%), bovine serum albumin and 0.09% sodium azide as preservative.

InSure® FIT™ Negative Control (1.5mL)
Contains borate salts, ethanol (10%), bovine serum albumin and 0.09% sodium azide as preservative.

EC REP CE

mdi Europa GmbH
Langenhagener Str. 71
D-30855 Langenhagen
Germany

Enterix Inc.
A Clinical Genomics Inc. Company
236 Fernwood Ave.
Edison, NJ 08837 USA
Phone 1-800-531-3681
Fax 1-732-429-1898
www.insuretest.com

InSure® FIT™
Fecal Immunochemical Test

FOBT Controls
Instructions for Use

MATERIALS REQUIRED

Materials Provided

InSure® FIT™ Positive Control (l.5mL)
InSure® FIT™ Negative Control (1.5mL)
lnSure® FIT™ FOBT Controls.
Instructions for Use

Materials Not Provided

Timer, Tape

Materials required for running quality controls

InSure® FIT™/InSure® ONE™ TestCards for QC (11018)
InSure® FIT™/InSure® ONE™ Test Strip - Vial of 25 (12045)

InSure® FIT™/InSure® ONE™ Run Buffer. lL (14103)
InSure® FIT™/InSure® ONE™ Dropper Bottle (14104)

OR

InSure® FIT™/InSure® ONE™ Test Cards for QC (11018)
InSure® FIT™/InSure® ONE™ Developer Kit (80025)

WARNINGS AND PRECAUTIONS

- *For in vitro diagnostic use only.*
- **CAUTION:** The source material for the Positive Control has been tested non-reactive for hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), hepatitis C virus (HCV), anti-HIV-I, anti-HIV-2, and human T-cell lymphotrophic virus type 1 (HTLV-1). However, no test method can offer complete assurance that HIV, HBsAg, or other infectious agents are absent, therefore the Positive Control, and components that come into contact with it, should be handled as being potentially infectious. These potentially infectious materials should be handled at Biosafety Level 2, as defined by the U.S. Centers for Disease Control and Prevention.
- The areas for running Positive and Negative Controls should be wiped down and cleaned to avoid contamination.
- Change gloves after running controls to avoid contamination.
- Gloved hands and the test area should be kept clean and free of blood to avoid contamination of the Test Cards and Test Strips.
- When handling the Test Strip avoid the middle area of the Test Strip (nitrocellulose portion). Handle the end opposite of the arrows at all times when holding Test Strip.
- DO NOT remove Test Strips from their packaging until ready for use.
- DO NOT interchange bottle caps between Positive and Negative Controls.
- DO NOT contact the Test Card sample pad with the bottle tips of the Positive and Negative Controls to avoid contamination of reagents.
- DO NOT use Test Cards, Test Strips, Run Buffer, and Positive and Negative Controls beyond their labeled expiration dates.
- Use only InSure® FIT™/InSure® ONE™ Run Buffer to develop the Test Cards.
- DO NOT use any Run Buffer, Positive Control or Negative Control from a container that appears to have leaked.
- **WARNING:** The Run Buffer, and Positive and Negative Controls contain sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide buildup.
- Avoid reagent contact with eyes, mucous membranes or skin lesions. If contact occurs, flush affected area with water for 15 minutes and consult a physician.

QUALITY CONTROL TESTING

Controls should be run in accordance with internal procedures, appropriate federal, national, state and local guidelines or accreditation requirements concerning the use of external controls.

LIMITATIONS

Because InSure® FIT™ FOBT Controls do not contain feces, they do not test sample collection, handling and application which may be influenced by the sample matrix in the product instructions. Therefore, they may not detect certain test malfunctions that would affect the testing of human feces.

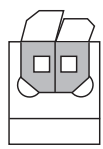
STORAGE AND HANDLING

- Store InSure® FIT" FOBT Controls at 2º-8ºC/ 36º- 45ºF. DO NOT FREEZE. When stored as directed, closed vials of InSure® FIT™ FOBT Controls are stable until their labeled expiration date and opened vials are stable 120 days from initial opening.
- InSure® FIT™/InSure® ONE™ Test Cards must be protected from heat (37°C /99°F) and direct sunlight, and used before their labeled expiration date.
- InSure® FIT™/InSure® ONE™ Test Strips must be stored in their unopened packaging at 2°-25°C/36°-77°F. DO NOT FREEZE. When stored as directed, Test Strips are stable until their labeled expiration date.
- InSure® FIT"/InSure® ONE™ Run Buffer should be stored at 2-8°C/36°-46°F until the labeled expiration date. DO NOT FREEZE.

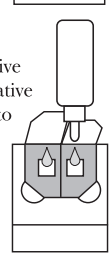
DIRECTIONS FOR USE

⚠ **Do not touch the Test Strip or Test Card with reagent bottles**

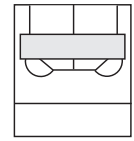
1. Open the front sample port flap(s) of the Test Card.



2. Add <u>one</u> drop of Positive (BLUE CAP) <u>OR</u> Negative Control (GREY CAP) to <u>each</u> sample port.



3. Seal sample port flap(s) of the Test Card with tape.

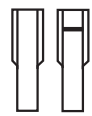


4. Proceed with the Directions for Use detailed in the product instructions for InSure® FIT™/ InSure® ONE™

INTERPRETATION OF TEST RESULTS

POSITIVE

NEGATIVE



INVALID

- Carefully look for the appearance of a test line in the test line area. A colored line is a positive result even if the test line appears lighter or darker than the Control Line.
- Positive test results may appear prior to 5 minutes. To confirm a negative test result, wait a full 5 minutes after adding the Run Buffer before interpreting the results.
- Test results should not be read after 5 minutes.
- Neither the intensity nor the shade of the test line produced by the Positive Control should be used as a reference for the appearance of a positive test result
- If invalid results occur repeatedly or for technical assistance, contact Enterix. (+I 800 531 3681 or +1 732 4291899) or your local distributor.

PERFORMANCE CHARACTERISTICS

Ten replicates from three lots each of Positive and Negative InSure® FIT™ Controls all produced positive and negative results, respectively, on InSure® FIT™/InSure® ONE™ product. The Positive Control contains purified human hemoglobin and gives a positive result with InSure® FIT™/InSure® ONE™. The Negative Control contains a buffer and no human hemoglobin and gives a negative result with InSure® FIT™/InSure® ONE™.

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