

9<sup>th</sup> Annual Arizona Tribal Collaborative Conference  
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# InSure FIT™

## Designed for Screening



**InSure® FIT™**  
Fecal Immunochemical Test

CGS11 Commercial in Confidence

# Designed For Screening

First released in 2000, InSure is a “CLIA waived” fecal immunochemical test (FIT) used to screen millions of people around the world.

The InSure FIT product portfolio includes everything required for:

- Easy to use Collection Kit allows Participants to collect samples at home and return to the lab or office
- Physician or pathology processing - no equipment required. Test can be developed either at provider’s facilities or a third party lab.

# Intended Use

## **INTENDED USE/INDICATIONS FOR USE**

The InSure® FIT™ Test is a fecal immunochemical test (FIT) that qualitatively detects human hemoglobin from blood in stool samples.

The samples will generally be collected by the test subject at home and the test developed at laboratories or professional offices.

Fecal immunochemical tests are useful screening aids for detecting primarily lower gastrointestinal disorders that may be related to iron deficiency anemia, diverticulitis, ulcerative colitis, polyps, adenomas, colorectal cancers or other gastrointestinal lesions that can bleed.

Health professionals recommend InSure® FIT™ for use as part of routine physical examinations and in screening for colorectal cancer

# Why InSure FIT™ ?

InSure FIT was designed for use in colorectal cancer screening programs. InSure's advantages include:

- Simple brush collection method shown to increase patient compliance<sup>1</sup>
- Dried sample collection improves stability
- No automation required for reading the results
- Good clinical performance
- No medicinal or dietary restrictions before or during taking the test

The success of InSure FIT is due to being convenient, easy to use, and accurate, detecting up to nine out of ten colorectal cancers.

(1) An increased patient compliance of 66% over other fecal occult blood tests has been shown. Cole SR, et al . A randomised trial of the impact of new faecal haemoglobin test technologies on population participation in screening for colorectal cancer. J Med Screen 2003;10:117-112

# Convenient and easy

InSure is the most user friendly FIT and most likely to be completed by patients

- Collection in privacy at home (two samples)
- Patient-friendly toilet water-based sampling with no fecal handling
- Long handled brush collection method
- No special sample storage requirements i.e. refrigeration not required
- Post-office accepted for simple mailing

Unlike other tests that require fecal sampling or test card smears, InSure FIT™ requires a gentle brushing of the stool in water for 5 seconds, followed by application of the water sample to the collection card.

# Accurate

InSure is proven:

- Greater accuracy with lower false positive rates - specificity 98%<sup>2</sup>
- High sensitivity for colorectal cancer detection - 88% sensitivity from two separate bowel movement samples<sup>2</sup>

InSure FIT detects human Hemoglobin (Hb) as an indicator of blood in the stool.

Unlike guaiac-based fecal occult blood test (gFOBT), InSure FIT detects the protein part of human Hb, not the heme. The presence of globin (from hemoglobin) in the stool indicates lower G.I. bleeding in the colon or rectum.

FIT is now recognized as the best test for population-based CRC screening to replace gFOBT.<sup>3</sup>

(2) Smith et al. Cancer 2006;107:2152

(3) Halloran et al. Endoscopy 2012;44(S03):SE65-SE87

# InSure Collection Kit - Procedure

Insure test developed,  
patient notified of  
results

Patient receives  
collection kit from  
doctor as part of  
routine colorectal  
cancer screening visit

**InSure<sup>®</sup> FIT<sup>™</sup>**  
Fecal Immunochemical Test

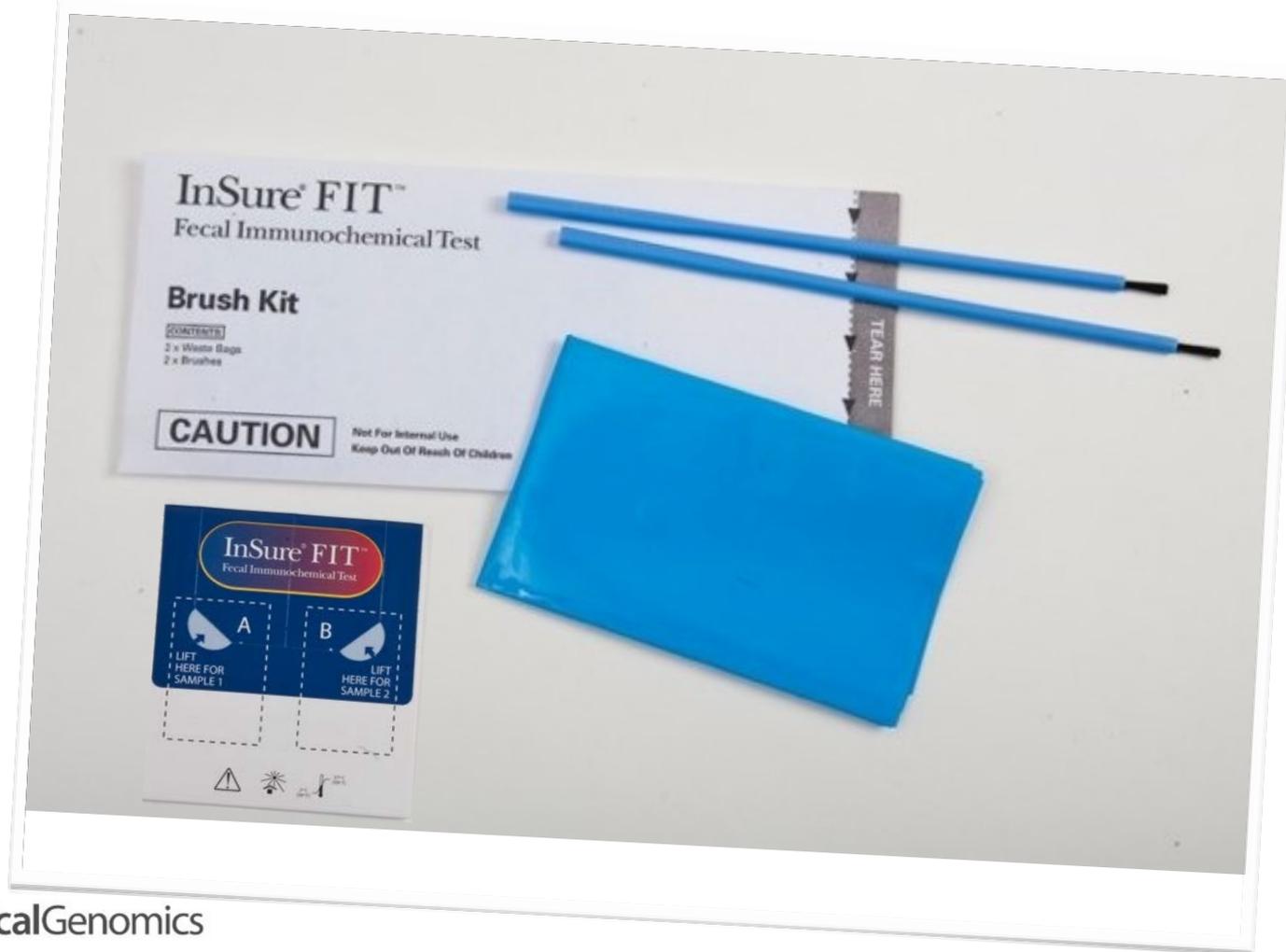
Patient completes  
sample collection at  
home using brush  
collection method and  
test card

Patient returns test by  
mail or in person

# Collection Kit

Easy and convenient to use in the privacy of home

Collection kit contains test card, two brushes, and two waste bags



# Patient Instruction Information

**1**



- Take these instructions, Brush Kit and Test Card into the bathroom.
- Flush the toilet **BEFORE** your bowel movement.

**2**



- After your bowel movement, **DO NOT PLACE USED TOILET PAPER IN THE TOILET BOWL.** Instead, use one of the waste bags provided.
- **DO NOT FLUSH** the toilet.

**3**



- Lift the flap marked "A" on the Test Card to uncover the small white square underneath.

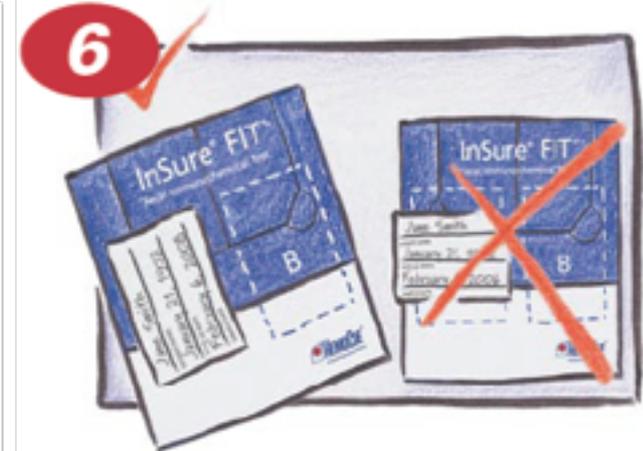
# Patient Instruction Information



- Using one of the blue brushes, gently brush the surface of the stool for about 5 seconds.
- If the stool is loose, simply stir the water around the stool.
- Remove the brush from the water and gently shake it once to remove excess water and any clumps of stool.



- Transfer the **WATER** sample by gently dabbing the bristles of the brush onto the small white square on the Test Card for about 5 seconds (some staining of the square may occur).
- Put the used brush into the kit waste bag and throw away in your rubbish bin.



- For the first sample, print your name, date of birth, and the date the sample was collected on one of the labels provided.
- Peel off the label and use it to reseal the flap marked “A”. See diagrams above for the correct positioning of label.

# Patient Instruction Information



- Using the second blue brush, waste bag and the Test Card flap marked “B”, repeat steps 1- 6 shown above. Use the other label to reseal the B flap.
- Place the Test Card in the envelope.
- Return to your physician either by post or personal delivery. Remember to affix first class postage.

# InSure FIT – Developer Kit

## For developing onsite at clinicians' facilities

- Test strip and run buffer to develop assay
- Test development completed in 3 steps
- Results available in 5 minutes
- No special equipment or automation required
- No special training required



# Testing in 3 simple steps

Hemoglobin is detected using a patented antibody formula displaying a visual result, with results in 5 minutes

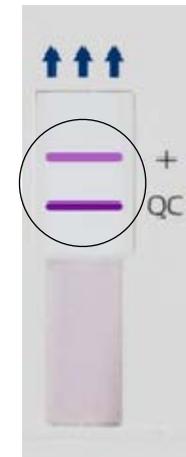
1. Insert test strip



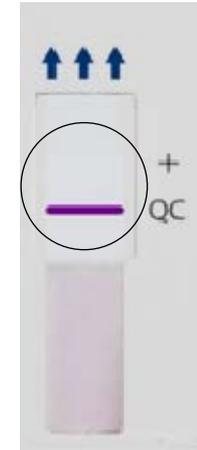
2. Apply run buffer



3. Results



Positive



Negative

# InSure FIT Performance

Clinical Sensitivity:	<ul style="list-style-type: none"> <li>• 87.5% Sensitivity for colorectal cancer <sup>1,2</sup></li> <li>• 40% Sensitivity for advanced adenomas<sup>1,2</sup></li> </ul>
Specificity:	<ul style="list-style-type: none"> <li>• 98% Specificity <sup>1,3</sup></li> <li>• 100% specific for detection of lower GI Bleeding vs. Upper GI Bleeding <sup>3</sup></li> </ul>
Compliance:	<ul style="list-style-type: none"> <li>• 54% Compliance for Australian tests in 2011 <sup>4</sup></li> </ul>
Positive Predictive Value:	<ul style="list-style-type: none"> <li>• 11% for Colorectal Cancer <sup>1</sup></li> <li>• 15% for Advanced Adenomas <sup>1</sup></li> <li>• 41.4% for combined Cancer and Adenoma <sup>1</sup></li> </ul>
Stability of Collection Kit:	<ul style="list-style-type: none"> <li>• 24 Months at constant 40°C <sup>5</sup></li> <li>• 24 Months at constant 2°C <sup>9</sup></li> <li>• 28 Days at constant 50°C <sup>6</sup></li> <li>• 12 Hours at constant 70°C <sup>6</sup></li> </ul>
Stability of Samples after Collection	<ul style="list-style-type: none"> <li>• 14 Days at constant 45°C <sup>7</sup></li> <li>• 14 Days at constant -18°C <sup>7</sup></li> <li>• 7 Days at constant 50°C <sup>7</sup></li> </ul>
Ease of Use:	97.9% of 767 people who responded in a customer survey stated InSure FIT was easy to use <sup>8</sup>

(1) Smith et al.: Cancer, 2006; 107:2152-2159; (2) Lane et al.: Gastroenterology, 2010 Dec; 169(6):1918-26; (3) Enterix Inc. 2001 510(k) submission; (4) Enterix Internal Data; (5) Enterix Internal data (STI002); (6) Enterix Internal data (Project 77D); (7) Enterix Internal data (STI017); (8) Enterix Internal customer survey; (9) Enterix Internal data (STI014)

# Training and Support

Clinical Genomics provides all elements of direct support for InSure FIT to guarantee success in colorectal cancer screening programs



**Distributor Support**  
Flexible terms of trade  
Product Customization



**Technical & product support**  
Reassurance and knowledge  
to provide peace of mind



**Training**  
Full product knowledge and  
support

# Clinical Evidence

The performance of the InSure FIT™ test has been confirmed in multiple clinical studies, four of the more significant studies are discussed below:

**Cole SR, et al . A randomised trial of the impact of new faecal haemoglobin test technologies on population participation in screening for colorectal cancer. J Med Screen 2003;10:117-112**

Insure compared against two other stool products. Demonstrates that a participation rates significantly improves by simplifying stool sampling

**Smith A, et al. Comparison of a brush-sampling faecal immunochemical test for haemoglobin with a sensitive guaiac-based faecal occult blood test in detection of colorectal neoplasia. Cancer, 2006; 107:2152-2159**

Insure compared against gFOBT and demonstrates a higher sensitivity for cancer (88% vs 54%) and advanced adenomas (43% vs 23%)

**Bampton PA, et al. Interval faecal occult blood testing in a colonoscopy based screening programme detects additional pathology. Gut. 2005 Jun; 54(6):803-6.**

Insure offered as an alternative to colonoscopy screening. Demonstrates a higher compliance and detection of additional pathology in patients with a past history of colonic neoplasia

**Lane JM, et al. Gastroenterology 2010;139:1918–1926 Interval Fecal Immunochemical Testing in a Colonoscopic Surveillance Program Speeds Detection of Colorectal Neoplasia**

Insure offered yearly in interval between colonoscopies and demonstrated that Insure FIT screening leads to detection of neoplasias sooner than scheduled surveillance colonoscopy, ie the test can be used to detect missed or rapidly developing lesions.

# Literature References

- Cole SR, Young GP, Esterman A, Cadd B, Morcom J. A randomised trial of the impact of new faecal haemoglobin test technologies on population participation in screening for colorectal cancer. *J Med Screen*. 2003;10(3):117-22.
- Collins JF, Lieberman DA, Durbin TE, Weiss DG; Veterans Affairs Cooperative Study #380 Group. Accuracy of screening for fecal occult blood on a single stool sample obtained by digital rectal examination: a comparison with recommended sampling practice. *Ann Intern Med*. 2005 Jan 18;142(2):81-5.
- Lane JM, Chow E, Young GP, Good N, Smith A, Bull J, Sandford J, Morcom J, Bampton PA, Cole SR. Interval fecal immunochemical testing in a colonoscopic surveillance program speeds detection of colorectal neoplasia. *Gastroenterology*. 2010 Dec;139(6):1918-26. Epub 2010 Aug 16.
- Nakama H, Kamijo N, Fujimori K, Fattah AS, Zhang B. Relationship between fecal sampling times and sensitivity and specificity of immunochemical fecal occult blood tests for colorectal cancer: a comparative study. *Dis Colon Rectum*. 1997 Jul;40(7):781-4.
- Smith A, Young GP, Cole SR, Bampton P. Comparison of a brush-sampling fecal immunochemical test for haemoglobin with a sensitive guaiac-based fecal occult blood test in detection of colorectal neoplasia. *Cancer* 2006; 107:2152-2159.
- Smith RA, Cokkinides V, Brooks D, Saslow D, Brawley OW. Cancer screening in the United States, 2010: a review of current American Cancer Society guidelines and issues in cancer screening. *CA Cancer J Clin*. 2010 Mar-Apr;60(2):99-119.

# About Clinical Genomics

## Company profile

At Clinical Genomics we harness breakthrough science to create new, innovative, and more accessible ways to prevent disease and enhance lives.

Clinical Genomics is a privately held, Sydney-based biotechnology company developing next generation products for colorectal cancer diagnosis and currently holding a portfolio of more than 20 patents and patents pending.

Clinical Genomics was founded in 2006 after establishing Enterix in 1999, developing the InSure colorectal cancer screening portfolio, and subsequently selling this business to Quest Diagnostics. In 2013, Clinical Genomics re-acquired Enterix Inc., which provided Clinical Genomics with a regulatory-licensed manufacturing facility in the US and Australia and access to a specialty pathology laboratory in Australia for selling bowel cancer screening services.

Clinical Genomics owns the patented InSure fecal immunochemical test (FIT) 'Brush Test' product line. In Australia this product is now marketed as ColoVantage Home. This product, combined with the new blood plasma test (ColoVantage Plasma), delivers a portfolio of colorectal cancer screening products aimed at user-friendly, patient-preferred screening solutions.

Clinical Genomics now has offices and laboratories in both Sydney, Australia and Edison, New Jersey in the US, and operates as an FDA-registered and TGA-licensed manufacturer and a NATA-accredited laboratory.

# Regulatory Approvals

InSure FIT is currently registered with the below bodies for manufacture of in-vitro diagnostic devices



US Food and Drug Administration (FDA)



European CE marking



Therapeutic Goods Administration (Australia)