Clinical Review

InSure® ONE™
One Day Fecal Immunochemical Test

The InSure fecal immunochemical test technology is a highly accurate method for detecting hemoglobin in stool, and an aid in the detection of lower gastrointestinal bleeding. A number of medical conditions may be associated with lower gastrointestinal bleeding, including colorectal cancer, iron deficiency anemia, diverticulitis, ulcerative colitis, polyps, and adenomas.

Overcoming patient objections to testing is a critical factor for achieving patient compliance. The InSure test uses a unique brush sampling method that only requires a sample of toilet water following a bowel movement. There is no need to collect stool or sample feces directly. The user simply brushes the surface of the stool to release any blood into the surrounding water.

The InSure ONE one day fecal immunochemical test has the same intended use and technological characteristics as the predicate device, InSure® FIT™. The InSure ONE test is an easy-to-use test method to reliably detect human hemoglobin from blood in toilet bowl water containing defecated stool that may be an indication of gastrointestinal pathology. The clinical performance of the InSure ONE sampling and test method support a substantial equivalence claim.

About Colorectal Cancer

Colorectal cancer is the second leading cause of cancer death in the United States, with more than 130,000 people per year expected to be diagnosed with the disease and as many as 49,000 will die from it. According to the 2016 U.S. Preventive Services Task Force[1] recommendations, screening for colorectal cancer in adults who are at average risk, aged 50 to 75 years reduces colorectal cancer mortality. Recent updated guidelines from the American Cancer Society now recommends regular screening commence at age 45 years.[2] Many people, however, are not screened according to guidelines, and studies show aversion to colonoscopy and other methods may factor into decisions not to screen. The disease is often highly treatable when caught in early stages.

Considerations for Colorectal Cancer Screening Programs

The U.S. Preventive Services Task Force recommendation statement[1] (2016) observed that about one-third of eligible adults in the United States have never been screened for colorectal cancer and the goal of screening programs should be to maximize the total number of persons who are screened, since this will have the largest effect on reducing colorectal cancer deaths. Offering a choice of strategies may increase patient uptake.

Table: USPSTF Recommended Colorectal Cancer Screening Strategies[1]

Screening	Frequency
Stool-Based Tests	
gFOBT	Every year
FIT	Every year
FIT-DNA	Every 1 or 3 years
Direct Visualization Tests	
Colonoscopy	Every 10 years
CT Colonography	Every 5 years
Flexible Sigmoidoscopy	Every 5 years
Flexible sigmoidoscopy with FIT	Flexible sigmoidoscopy every 10 years plus FIT every year

In the 2017 update for colorectal cancer screening, the U.S. Multi-Society Task Force[3] proposed a new 3 tier ranking system based on clinical performance, cost, and practical considerations. The report concludes that both colonoscopy and fecal immunochemical tests (FITs) are cornerstones of screening, and are ranked Tier 1 and the preferred tests in all screening settings where multiple testing options are offered.

Table: 2017 Multi-Society Task Force Ranking of Current Colorectal Cancer Screening Tests[3]

Screening Method	Frequency
Tier 1	
Colonoscopy	Every 10 years
FIT	Annually
Tier 2	
CT Colonography	Every 5 years
FIT-fecal DNA	Every 3 years
Flexible Sigmoidoscopy	Every 10 years (or every 5 years)
Tier 3	
Capsule colonoscopy	Every 5 years
Available tests not currently recommended	
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By limiting multiple screening options to colonoscopy and FIT, the recommendations propose that will simplify the discussion between patients and physicians, encouraging testing adherence and testing effectiveness. If patients decline the two preferred tests, then physicians have the choice to offer one or more of the other test options in tier 2 and then tier 3.

InSure FIT Clinical Performance

InSure FIT had significantly higher sensitivity for advanced colorectal neoplasia than OC-FIT CHEK and Hemoccult II SENSA, a highly sensitive gFOBT[4]

A Comparison of Fecal Immunochemical and High-Sensitivity Guaiac Tests for Colorectal Cancer Screening	*Shapiro J.A. et al, Am J Gastroenterol advance online publication, 10 October 2017; doi: 10.1038/ajg.2017.285*	In a study of more than 1,006 asymptomatic patients, aged 50-75 years, scheduled to receive a screening colonoscopy; InSure FIT was statistically significantly more sensitive than both OC-FIT-CHEK and Hemoccult II SENSA for detecting advanced colorectal neoplasia (i.e. 26.3%, 15.1%, and 7.5%, respectively). Specificities were relatively high for all tests (between 96.8% and 98.6%)

InSure FIT had a significantly higher specificity than gFOBT [5]

Comparison of fecal occult blood tests for colorectal cancer screening in an Alaska native population with high prevalence of Helicobacter pylori infection, 2008-2012	*Redwood, D. et.al. Prev. Chronic Dis. 2014; 11:130281*	In 304 asymptomatic Alaska native adults aged 40 years and older, InSure FIT demonstrated significantly higher specificity than guaiac FOBT (i.e. 92% for InSure FIT versus 76% for gFOBT). Higher specificity was observed for participants with current H.pylori infection (i.e. 93% for InSure FIT versus 69% for gFOBT). Overall, sensitivity did not differ significantly

Uptake of mailed FOBT varies by test type; the test that required the fewest samples had the highest uptake [6]

Uptake and positive predictive value of fecal occult blood tests: A randomized controlled trial	*Chubak J. et. al. Prev Med 2013; doi: 10.1016/j. ypmed.2013.08.032*	A cohort of 1431 subjects, aged 50-74 years, returned one of three FOBT kits: InSure FIT, OC-Auto, and Hemoccult SENSA. At 6 months, the proportions screened by any FOBT were 0.69 for OC-Auto, 0.64 for InSure, and 0.61 for Hemoccult SENSA. Uptake for 1 sample > 2 sample > 3 sample.

Interval FIT analyses can be used to detect missed or rapidly developing lesions in surveillance programs [7]

Interval fecal immunochemical testing in a colonoscopic surveillance program speeds detection of colorectal neoplasia	*Lane J.M. et.al. Gastroenterology 2010; 139:1918-1926*	In a mixed cohort of 2,351 screening subjects and 161 diagnostic subjects; InSure FIT was more sensitive than Hemoccult II SENSA for cancers (i.e. 87.5% versus 54.2%) and significant adenomas (i.e. 42.6% versus 23%)

Providing FIT to eligible patients during a pharmacy-based influenza vaccination campaign increases screening rates more than colorectal cancer screening education alone [8]

Comparative effectiveness of two pharmacy-based colorectal cancer screening interventions during an annual influenza vaccination campaign	*Potter M.B. et.al. J Am Pharm Assoc 2010; 50*	In a cohort of 133 subjects, aged 50 to 80 years were provided with InSure FIT (n=86) or CRC screening education (n=28) upon visiting a pharmacy; 59.3% of the InSure FIT arm versus 14.8% of the CRC screening education arm completed the screening

InSure in single-stool mode has similar sensitivity and specificity to the same test in standard two-stool mode. Improved population participation and reduced costs might be achieved if bowel cancer screening programs use validated single stool screening tests [9]

A fecal immunochemical test for hemoglobin using a single stool sample is effective for detecting significant colorectal neoplasia	*Cole S.R. DDW Abstract 2009*	Insure FIT using new single-stool sampling method (aka InSure ONE) has similar sensitivity and specificity to the same test using the standard 2- stool sampling method. Sensitivity for cancer was 83.3% for both single and 2-stool sampling methods. While sensitivity for advanced adenomas was 26.2% for the single-stool method, and 27.9% for the 2-stool method. The specificity of the single stool method was 89.4% and 93.2%; compared to 89.8% for the 2-stool method.

The brush-sampling FIT is more sensitive for cancers and significant adenomas than a sensitive gFOBT [10]

Comparison of a brushsampling fecal immunochemical test for hemoglobin with a sensitive guaiac-based fecal occult blood test in detection of colorectal neoplasia	*Smith A, et. al. Cancer 2006: 107(9):2152-2159*	In a mixed cohort of 2,351 screening subjects and 161 diagnostic subjects; InSure FIT was more sensitive than Hemoccult II SENSA for cancers (i.e. 87.5% versus 54.2%) and significant adenomas (i.e. 42.6% versus 23%)

InSure FIT offered as an alternative to colonoscopy screening, demonstrated a higher compliance and detection of additional pathology in patients with a past history of colonic neoplasia [11]

Interval faecal occult blood testing in a colonoscopy based screening programme detects additional pathology	*Bampton PA, et.al. Gut. 2005 Jun; 54(6):803-6*	In a study of 1,641 subjects with a personal history of colorectal neoplasia or a significant family history, 47.8% voluntarily completed an InSure FIT test as part of an interval screening program. Further; of the 57 InSure FIT positives, 52 completed a colonoscopy, with 14 having significant neoplastic legions (i.e. 6 colorectal cancers and 8 significant adenomas).

The brush-sampling FIT for hemoglobin (InSure) achieves the best participation rates by simplifying sampling and removing the need for restrictions of diet and drugs [12]

A randomized trial of the impact of new fecal hemoglobin test technologies on population participation in screening for colorectal cancer	*Cole S.R., et. al. J Med Screen 2003: 10:117-122*	In 1,818 subjects aged between 50 and 69 years, the participation rate was highest using InSure FIT (39.6%), compared to Hemoccult (23.4%) and FlexSure (30.5%). Participation was increased by 28% by removal of dietary restrictions, and by 30% by simplification of sampling using the InSure brush sampling method; an overall increased participation rate of 66%

InSure FIT is as sensitive and specific as FlexSure OBT for fecal hemoglobin. The novel stool sampling method of InSure allows discrimination between normal and classes of neoplasia, and is highly preferred [13]

Prescreening evaluation of a brush-based fecal immunochemical test for hemoglobin	*Young G.P. et. al. J Med Screen 2003; 10:123-128*	In patients aged between 24 and 90 years, scheduled for diagnostic colonoscopy, InSure FIT demonstrated similar sensitivity to FlexSure OBT for cancers (i.e. 75% versus 80.5%, n=36); adenomas >10mm (i.e. 41.4% versus 44.8%, n=29), and adenomas <10mm (i.e. both 14.3%, n=56). Specificities of both tests were also similar (i.e. 97.8% for Insure FIT and 97.2% for FlexSure OBT).

InSure® ONE™ is a fecal immunochemical test (FIT) that qualitatively detects human hemoglobin from blood in fecal samples. The samples will generally be collected by the test subject at home and the test developed at laboratories or professional offices. The InSure® ONE™ test is used to aid in the detection of lower gastrointestinal bleeding.

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References:

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