REFERENCES


8. An inflammation of the intestines, characterized by the formation of pus by the body's normal digestion and by the action of bacterial enzymes. It is then rendered immunochemically non-reactive before reaching the test subject. Hemoglobin from upper gastrointestinal bleeding (i.e., oral cavity, esophagus, stomach or small intestine) is broken down by the body's normal digestion and by the action of bacterial enzymes. It is therefore rendered immunochemically non-reactive before reaching the test subject.


5. Wait for 5 minutes and record the result.

Notes: If the Run Buffer does not flow into the Test Strip due to excess specimen, add two more drops of Run Buffer to each reagent port, until each port has received four drops (~150 μL).

INTERPRETATION OF TEST RESULTS

Positive Test (DETECTED)
The test is positive if the presence of blood, if two lines (Test and Control) are visible on the Test Strip. Any line of a line in the Test Line area is a positive test result.

Negative Test (UNDETECTED)
The test is negative, indicating no blood was detected, if only the Control Line is visible and there are no traces of a line in the Test Line area.

Valid Test: The test is invalid if the Control Line does not appear. If this occurs, the test should be repeated with a new specimen Test Card.

EXPECTED RESULTS

Positive rates with immunochromatographic fecal blood tests may be expected to vary with each type of blood test depending on the use age, ethnicity, predisposition to colorectal disease, and other factors that may be associated with lower gastrointestinal bleeding.

PERFORMANCE CHARACTERISTICS

Analytical Performance Studies

ANALYTICAL SENSITIVITY

In vitro studies demonstrated that by following the recommended procedures for sample collection and storage, InSure® ONE™ was reliably detected up to 10 μg hemoglobin/μL (100 μg hemoglobin/g stool). Sensitivity is expressed as the lowest Hb concentration in μg Hb/g feces, resulting in at least 95% positive readings. Studies with hemoglobin (Hb) variants HBS (hemoglobin S) and HBE (hemoglobin E) indicated that InSure® ONE™ was similarly sensitive to these forms of hemoglobin as to normal hemoglobin. Other hemoglobinopathies were not tested.

Precise Effect

In vitro studies demonstrated that InSure® ONE™ reliability detected up to 21 ml of added blood per 100 g of feces (30 mg hemoglobin per g of stool). At this level the blood is generally visible.

Crosstalk

InSure® ONE™ was examined in vitro by adding samples of meat extract (myoglobin and hemoglobin) from beef, chicken, fish, pork, turkey, rabbit, deer, and kangaroo to the Test Card to determine whether meat extracts cross-react with the test. The samples were added with and without diluted human blood and the cards dried overnight. InSure® ONE™ gave negative results in all cases where it was positive in all cases when human blood was present. In contrast, the meat extracts, when added to the Test Card, produced a positive line. This is consistent with the positive results obtained with the InSure® ONE™ test.

Influence of Syringe Additives and Contaminants

Studies demonstrated that InSure® ONE™ was reliably detected up to 21 ml of added blood per 100 g of feces (30 mg hemoglobin per g of stool). At this level the blood is generally visible.

Non-Neoplastic Finding

In this study, the test–non-test–findings, by the histopathology reports from the pathologist included:

- Anemia
- Diverticular Disease
- Hemorrhoids
- Hyperplastic Polyps (1 or 2)
- Infiltrative Blister Disease
- Inflammatory Bowel Disease
- Leiomyosarcoma
- Melanoma
- Medulloblastoma
- Rare Tumors
- Fibrosarcoma
- Pleomorphic Sarcoma

VARIANCE IN TEST RESULTS

The performance of InSure® ONE™ was assessed in a mixed population of 893 subjects with elevated risk and with normal subjects requiring a colonscopy. No dietary restrictions were required. Those who had an incomplete colonoscopy or self-reported testing more than once lifetime fecal samples were included. Statistical analysis of the test results based on clinical positive percent agreement (PPA) and negative percent agreement (NPA) showed that the InSure® ONE™ test results have acceptable overall agreement with InSure® FIT™ test results. See Summary of Agreements Table.

CLINICAL PERFORMANCE-METHOD COMPARISON

Clinical Sensitivity

The specificity of InSure® ONE™ for normal subjects with a negative colonoscopy in an elevated risk population of 1019 individuals was 98.9% [95% CI, 95.8%-99.0%]. The specificity of InSure® FIT™ in the same study was 99.6% [98.8%-99.8%].

Interference/Toxicity

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Summary of Agreements Between InSure® FIT™ and InSure® ONE™

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<th>InSure® FIT™</th>
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</tr>
<tr>
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<td>98 98%</td>
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</tr>
</tbody>
</table>

Comparison of Sensitivity, Specificity, PPV, and NPV

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