**MATERIALS**

**Inlet**
- Contains benzyl alcohol, ethanol (1%), heparin solution (from a baboon) and 0.01% sodium azide as preservative.

**Materials Required But Not Provided**
- Timer: To 5 minutes, with seconds.
- Disposable latex gloves.
- Protective eyewear including gowns.

**WARNINGS AND PRECAUTIONS**

**CAUTION**
- Observe universal safety precautions and other appropriate laboratory procedures when collecting and handling patient samples. All samples and materials that come in contact with them should be handled as potentially infectious.
- The areas for running External Quality Controls and the Test Procedure should be wiped down and cleaned to avoid contamination.
- Change gloves after handling tests 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 (microcellular portion). Handle the end opposite of the arrows at all times when holding the Test Strip.
- Use only inlet® Test Cards for QC (50 Test Cards) for preparing control test samples.
- DO NOT remove Test Strips from their foil pack or vial until ready for use.
- Use only inlet® Test Cards, Test Strips and Run Buffer after their labeled expiration dates.
- Use only inlet® Run Buffer to develop the Test Cards.
- DO NOT use any Run Buffer from a container that appears to have leaked.
- Avoid skin and eye contact. Refer to the SDS.
- The Test Strips must be used in a refrigerated environment. Use of reagent solutions containing azide can result in lower blood clotting times. When using specimens containing blood, do not use blood containing anticoagulants.
- The Test Strips may contain raw materials that may cause skin irritation. In case of contact, flush affected area with water for 15 minutes and consult a physician.

**STORAGE AND STABILITY**

Store Test Strips in their unopened foil pack or vial at 2–25 °C (72–77 °F). DO NOT FREEZE. When stored at temperatures exceeding 25 °C (77 °F) or three days after their expiration period, they may lose their test characteristics.

**Inlet® Run Buffer** should be stored at ≤ 28 °C (76 °C) until their labeled expiration date.

**PRESERVATIVE AND CONSERVATION**

Inlet® Test Strip samples contain a monoclonal anti-human hemoglobin Test Line and a conjugate of anti-human hemoglobin polyclonal antibodies bound to colored (colloidal gold) particles. Test Line and conjugate antibodies are produced in rabbits.

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**QUALITY CONTROL**

Controls Built into InSure® ONE™

This device contains built-in positive control features which consist of a Control Line and a negative background control area on the Test Strip. The presence of the Control Line indicates that an adequate amount of Run Buffer was used and migrated properly through the Test Card and Control Line. The Control Line contains immobilized conjugate-specific antibody. The presence of a Control Line indicates that the conjugate was properly controlled and that clinical negative or positive control samples should be observed for each patient test performed in order to monitor test validity. Patient test results should not be interpreted if the built-in controls indicate an invalid test.

**LIMITATIONS OF THE PROCEDURE**

Interpretation

The performance characteristics of InSure® ONE™ were assessed in a multi-center clinical trial involving over 400 laboratories. The InSure ONE™ assay was found to be highly specific and sensitive, and demonstrated excellent intra- and inter-laboratory variability.

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

<table>
<thead>
<tr>
<th>Category</th>
<th>InSure® ONE™</th>
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</tr>
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<tbody>
<tr>
<td>Agreement</td>
<td>100%</td>
<td>99.3%</td>
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<tr>
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**INTERPRETATION OF TEST RESULTS**

**PERFORMANCE CHARACTERISTICS**

**Analytical Performance Studies**

**Analytical Sensitivity**

In vitro studies demonstrated that following the recommended procedures for sample collection and storage, InSure® ONE™ will detect Hb 75 µg per HgHgb. Sensitivity is expressed as the lowest Hb concentration in µg HgHgb, ranging in at least 95% positive readings.

**Studies with hemoglobin (Hb) variants IDS (hemoglobinosis) and HbE (heterozygous) indicated that InSure® ONE™ was similarly as sensitive to these forms of hemoglobin as to normal hemoglobin. Other hemoglobin variants were not tested.**

**Precision Effect**

In vitro studies demonstrated that InSure® ONE™ sensitivity improved 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.

**Cross-Reactivity**

InSure® ONE™ was examined in vitro by adding samples of meat extract (myoglobin and hemoglobin) from beef, chicken, fish, pork, pig, rabbit, deer, sheep 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 for all cases when added with all of the blood, but was positive in all cases when human blood was present. In contrast, the meat extracts, when added without InSure® FIT™ (Hemoglobin), consistently gave positive results.

**Influence/Effect of Dietary Substances**

InSure® ONE™ does not require the patient to follow any special dietary restrictions. In vitro testing on meats and fish, as well as meat extracts, demonstrated that InSure® ONE™ reacted with all of the extracts, but was positive in all cases when human blood was present. Thus, no interference was evident with these substances. In contrast, the same substances when added to a guinea FHB (Hemoglobin) gave negative results. The studies confirmed that InSure® ONE™ performance remains unaffected by dietary substances.

### Interference by Tobacco Waters and Contaminants

The performance characteristics of InSure® ONE™ were assessed in a multi-center clinical trial involving over 400 laboratories. The InSure® ONE™ assay was found to be highly specific and sensitive, and demonstrated excellent intra- and inter-laboratory variability. The studies confirmed that InSure® ONE™ performance remains unaffected by dietary substances.

### Clinical Performance-METHOD COMPARISON

**Clinical Sensitivity**

The specificity of InSure® ONE™ for normal subjects with a negative colonoscopy in an elevated risk population of 10 individuals was 98.9% (95% CI, 98.4%-100%); the specificity of InSure® FIT™ was 99.9% (95% CI).

**Non-Neoplastic Finding**

In this study, the test-non-neoplastic findings, based on the histology reports from the pathologist included:

- **No abnormalities**
- **Diverticular Disease**
- **Hemorrhoids**
- **Hyperplastic Polyps (1 or 2)**
- **Inflammatory Bowel Disease**
- **Inflammatory Polyp**
- **Leiomyoma**
- **Malignant**
- **Mediastinal**
- **Varices**
- **Fibropolyph**
- **Uracellular Polyps**

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**Overall**

46 out of 63729 (89.4%) was 99.0% (96.7%).

**Cancer**

Overall 125 734 859

<table>
<thead>
<tr>
<th>Test</th>
<th>Pos</th>
<th>Pct</th>
<th>Overall</th>
<th>Cancer</th>
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<th>Positive</th>
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<tbody>
<tr>
<td>InSure® ONE™</td>
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<td>60</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>InSure® FIT™</td>
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<td>68</td>
<td>100</td>
<td>95</td>
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**Lower Gastrointestinal Sensitivity**

A study was performed on the suitability of InSure® ONE™ for the detection of lower gastrointestinal lesions, including normal bowel, inflammatory bowel disease, melena. The results showed that InSure® ONE™ was equally effective for the detection of lower gastrointestinal lesions as InSure® FIT™.

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**Wilson Score**

Wilson Score: 0.935, 95% CI (0.86, 0.96).