**Introduction**

Colorectal cancer is one of the most commonly diagnosed cancers and a leading cause of cancer-related deaths in the United States. Screening for colorectal cancer is likely to improve the odds of detecting cancer at an early stage, reducing mortality.

Earlier commercially available FOB tests utilized a guaiac test, requiring specific dietary restrictions to minimize false positives and false negative results. The FOB Rapid Test Device (Feces) is designed especially to detect human hemoglobin in fecal samples using immunochromatographic methods, improving specificity for the detection of lower gastrointestinal pathologies, including colorectal cancers and adenomas, without the need for dietary restrictions.

**Principle**

The FOB Rapid Test Device (Feces) detects human hemoglobin through visual interpretation of color development on the internal strip. Anti-human hemoglobin antibodies are immobilized on the test region of the membrane. During the test, the analyte (hemoglobin) in the specimen is conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there are sufficient human hemoglobin in the specimen, a colored band will form at the test region of the membrane. The absence of a colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

**Specimen Collection and Pre-treatment**

1. Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the membrane. Collect specimens by inserting the applicator stock into at least 3 different sites of the feces.
2. Replace the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
3. Shake the specimen collection tube vigorously to mix the specimen and extraction buffer. Samples prepared in the specimen collection tube should be stored for 6 months at -20°C if not used within 1 hour after preparation.

**Testing**

1. Remove the test from its sealed pack, and place it on a clean, level surface. Label the test with the date and time. For best results, the analyte must be formed within 1 hour.
2. Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 3 drops of solution into the sample well(s) of the test device.
3. Avoid trapping air bubbles in the specimen well(s). Do not add any solution to the control region (C).
4. As the test begins to work, color will not diffuse across the membrane.
5. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

**Interpretation of Results**

**POSITIVE:** Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

**NEGATIVE:** Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

**INVALID:** Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedural technique with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

**Quality Control**

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal procedural control and indicates proper performance of the test. Absence of the control band indicates a procedural failure.

**Limitations of the Test**

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade or color of the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen. Insufficient specimen volume, incorrect operating procedure or expiration in the test are the most likely reasons for control band failure.

**Concentrations**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Concentration</th>
<th>Detection</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>2000mg/dL</td>
<td>95.96%</td>
<td>95.3%</td>
<td>95.7%</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>2000mg/dL</td>
<td>95.96%</td>
<td>95.3%</td>
<td>95.7%</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>2000mg/dL</td>
<td>95.96%</td>
<td>95.3%</td>
<td>95.7%</td>
</tr>
</tbody>
</table>

**Analytical Specificity:**

The test is specific for human hemoglobin and does not show any cross-reaction with hemoglobin from pig, bovine, chicken, goat, rabbit, horse, turkey at concentrations up to 1mg/mL.

**Interfering Substances**

No substances listed interference with the test.

**Literature References**