SSENTIFIT® - FOB Gold® latex Fecal Immunoassay Test (FIT) evaluation on SENTIFIT® 270 analyzer.

M. Correale, T. Pinto, F. Bellini, F. Sportelli
Lab. of Clinical Pathology - National Institute for Digestive Diseases IRCCS S. De Bellis - Castellana G. (BA), Italy

Background
Fecal Immunoassay Testing is recommended by European Guidelines to be introduced in screening programs for colorectal cancer. Scope of this study is the analytical evaluation of SENTIFIT® 270, the new dedicated analyzer for Fecal Immunoassay Testing (FIT) for Hemoglobin from Sentinel CH.

Materials

Instrument
- Sentinel SENTIFIT® 270

The SENTIFIT® 270 system is an automatic analyzer dedicated to detecting fecal occult blood using the SENTIFIT® - FOB® Gold latex quantitative immunochromatological method.

Reagents
- Ref. 115602 SENTIFIT® - FOB Gold® latex

The SENTIFIT® - FOB Gold® latex test is an immunodiagnostic kit developed for providing sensitive, accurate and reproducible measurements of human, haemoglobin levels in feces specimens on SENTIFIT® 270 analyzer. It is based on an antigen-antibody agglutination reaction between the human hemoglobin contained in the sample and the polyclonal antibodies anti-human hemoglobin coated on polystyrene particles. The reagent can be used for screening many low gastrointestinal tract conditions associated with bleeding such as colorectal carcinoma, colon polyps, Crohn's disease and ulcerative colitis. The method is specific for human hemoglobin and no restricted diet (meat-free or paroxetine-free diet) is required.

- Ref. 11574 FOB Gold® Calibrator Set H

6 liquids levels prepared by human haemoglobin and stabilized by adding preservatives.

- Ref. 11571 FOB Gold® Control Set H

2 liquids levels prepared by human haemoglobin and stabilized by adding preservatives.

- Ref. 1156188 SENTIFIT® pierceTube

Collection tube dedicated for SENTIFIT® 270 analyzer. The human hemoglobin extracted from the feces sample and obtained according to the recommended collection procedure is stable for 14 days at 2-8 °C or 7 days at 15-30 °C if protected from direct light. The collection tube ensures maximum safety for the operator in addition to sample integrity as there is only one patient opening side. The analyzer opening side is sealed by a film, which is pierced by the instrument's sample needle. There can therefore be no accidental sample loss caused by the incorrectly tube opening.

- Ref. 1157501 FOB Gold® Screen Diluent

FOB Gold® Screen Diluent is a liquid material stabilized by adding preservatives.

Methods

Methods and results for SENTIFIT® 270 analyzer
1. One week familiarization: familiarization was done successfully: SENTIFIT® 270 is user friendly and reliable.
2. Evaluation of piercing: piercing 120 tubes without problems.
3. Sample barcode reading: sample barcode reading always OK.
4. Timing: time to first result: 14 minutes.

Results

Sentinel SENTIFIT® 270

■ Limit of Blank (LOB): 3.9 ng/mL
■ Limit of Quantitation (LOQ): 14.8 ng/mL

■ Imprecision: CV = 4.8% ≤ 5.2% ± 2.7% ± 3.8% ± 7.0% ≤ 9.0% ≤ 9.0% ≤ 4.5%

■ Linearity: EP-A values ≤ ± 10 ng/mL, or bias ≤ 10%

■ Prozone: check and flag up to 50,000 ng/mL.

■ Reagents on board and calibration stability: 33 days.

Limit of Blank (EP17-A)
The limit of blank is the highest measurement result that is likely to be observed (with a stated probability) for a blank sample.

Procedure: 20 samples x 3 runs

<table>
<thead>
<tr>
<th>Acceptance criteria</th>
<th>Evaluation results</th>
<th>Claim on IFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10 ng/mL</td>
<td>3.9 ng/mL</td>
<td>&lt; 10 ng/mL</td>
</tr>
</tbody>
</table>

Limit of Quantitation (EP17-A)
The Limit of Quantitation is the lowest amount of analyte in a sample that can be unequivocally determined with stated acceptable precision and trueness, under stated experimental conditions.

Procedure: 12 samples x 10 exps

<table>
<thead>
<tr>
<th>Dilution (ng/mL)</th>
<th>CV (%)</th>
<th>Mean (ng/mL)</th>
<th>Theor. Conc. (ng/mL)</th>
<th>Claim on IFU (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>28.1</td>
<td>8.8</td>
<td>9.1</td>
<td>NA</td>
</tr>
<tr>
<td>15%</td>
<td>16.5</td>
<td>14.8</td>
<td>15.3</td>
<td>10</td>
</tr>
<tr>
<td>20%</td>
<td>12.6</td>
<td>23.2</td>
<td>21.5</td>
<td>NA</td>
</tr>
</tbody>
</table>

Imprecision (EPS-A2)
Dispersion of independent results of measurement obtained under specified conditions

Procedure: 21 days x 2 runs x 2 exps x 3 levels

<table>
<thead>
<tr>
<th>Acceptance criteria</th>
<th>Claim on IFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>values ≤ 95 ng/mL</td>
<td>CV ≤ 7.0% ± 5.0% ± 6.0 ng/mL</td>
</tr>
<tr>
<td>values ≤ 85 ng/mL</td>
<td>CV ≤ 5.0%</td>
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Reagent and Calibration stability (EPS25-A)

Calibration interval: period of time following a calibration during which an IVD reagent under specified conditions demonstrates apparent change in measured content within the allowable drift limit an all stability-related criteria are met. Reagent in use stability: duration of time over which the performance of an IVD reagent within its expiration date remains within specified limits after opening container system supplied by the manufacturer, and put into use under standard operating conditions (e.g., storage on the instrument).

Procedure: 11 days x 2 runs x 2 exps x 3 levels

<table>
<thead>
<tr>
<th>Acceptance criteria</th>
<th>Claim on IFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>values ≤ 10% compared to the initial value</td>
<td>30 days</td>
</tr>
</tbody>
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Bibliography

Conclusion
This evaluation confirms the claims declared from Sentinel CH for SENTIFIT® - FOB Gold® latex on SENTIFIT® 270 system. The instrument is friendly and easy to use with automatic dilution capability and automatically daily and weekly maintenance managed by software, reducing the operation by end user. The new pieceable tube increases the safety, reduces the workability and makes this system completely automatic and dedicated for Fecal Immunochromatological Testing.