Rapid chromatographic immunoassay (non-invasive assay) for the qualitative detection of human haemoglobin and transferrin in human faeces specimens.
1. What is Fecal Occult Blood (FOB) and Transferrin?

In medicine, **FOB (fecal occult blood) test** is a check for hidden (occult) blood in the stool (feces). Fecal occult blood testing can provide clues as to subtle blood loss in the gastrointestinal tract. Positive tests ("positive stool") warrant further investigation for a malignancy such as colorectal cancer (that is one of the leading causes of illness and death in the Western world) or gastric cancer.

The presence of human haemoglobin in faeces is inadequate as a screening test for stomach cancer (upper gastrointestinal disorders), because of human haemoglobin derived from the upper digestive tract is broken down in the intestinal tract (the antigenicity is lost). Detection of fecal **Transferrin**, which is more resistant to the metabolism in the intestine than that of the Haemoglobin, provides the best complementary way of diagnosing the disease in the upper digestive tract.

**Transferrin** is a blood plasma protein for iron ion delivery. Although iron bound to transferrin is less than 0.1% (4 mg) of the total body iron, it is the most important iron pool with the highest rate of turnover (25 mg/24 h).

Transferrin imbalance can have serious health effects for those with high serum transferrin levels. A patient with an increased serum transferrin level suffers from iron deficiency anemia that is one of the most important symptoms when a tumor has caused chronic occult bleeding.

2. What is H&R FOB-Transferrin test?

The **H&R FOB-Transferrin** test is a rapid chromatographic immunoassay (non-invasive assay) for the qualitative detection of human haemoglobin and transferrin in human faeces specimens, which might be useful for the diagnosis of bleeding gastrointestinal disorders.

3. How is H&R H.pylori test performed?

a. Collect sufficient quantity of faeces.
b. Unscrew the cap of the vial and introduce the stick into the faecal specimen to pick up enough sample.
c. Introduce the stick with the sample into the vial and shake it in order to assure good sample dispersion.
d. Break off the tip of the vial and open the pouche to take the H&R FOB-Transferrin test device.
e. Dispense 5 drops or 100 µL into the cassette and wait 10 minutes for the result.

3. Interpretation of results

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<th>Tf POSITIVE</th>
<th>Hb POSITIVE</th>
<th>Tf-Hb POSITIVE</th>
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**Digestive tract: haemorrhage level**

- upper/lower: acute blood loss
- upper part: acute blood loss
- lower part: slight blood loss
- No GI bleeding

4. Performance Data

a. **Sensitivity** is >99% compared to another commercial rapid test (ImmunoTech OcculTech and Human Hexagon OBTI) and the results of that guaiac assay.
b. **Specificity** is >99% compared to another commercial rapid test (ImmunoTech OcculTech and Human Hexagon OBTI) and the results of that guaiac assay.
c. **No special diet** is recommended prior to testing. There are not interferences with any foods (vitamin C, broccoli, carrots...) and supplements (iron).
d. **Cross reactivity**: there is not cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in feces: Rotavirus, Astrovirus, Campylobacter, Adenovirus, Escherichia coli, Giardia, Lactoferrin.