**INTENDED USE**

**CANCHECK-FOBT** is a rapid, qualitative, two-site sandwich immunoassay for the detection of Faecal Occult Blood concentration in human faeces.

**SUMMARY**

Colorectal cancer (CRC) is a major cause of death from cancer. The risk of CRC increases with age, with an approximate doubling of the incidence in each decade from 40 to 80 yrs of age. It has been estimated that the lifetime risk of developing CRC is 1:50.

Faecal Occult Blood Test (FOBT) provides the most cost-effective way to screen for CRC. It has been reported that screening for CRC by FOBT decreases CRC mortality by 15-33%.

FOBT is the test to detect the presence of occult blood in the faeces. Small amounts of blood are present in the faeces of normal healthy individuals due to bleeding from the gastrointestinal tract like bleeding gums and bleeding from minor abrasions. The presence of small amounts of blood in faeces may not alter the colour or appearance of the stool. The detection of faecal occult blood can be useful in detecting bleeding resulting from gastrointestinal disorders such as colitis, polyps, colorectal carcinomas and diverticulitis.

Benzidine and guaiac tests for faecal occult blood detect the peroxidase activity of haeme, either as intact haemoglobin or as free haeme. Hence, to avoid false positives, for the week before the test, patients need to follow a diet that excludes red meat, turkeys, horseflesh, broccoli, radishes, cauliflower, cantaloupes and other melons and supplemental vitamin C. Unlike Guaiac tests, **CANCHECK-FOBT** is a 3rd generation immunochromatographic test that is not affected by peroxidase activity.

**PRINCIPLE**

**CANCHECK-FOBT** utilizes the principle of agglutination of antibodies/antiserum with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad contains two components - Agglutinating sera for human haemoglobin conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the highly specific Agglutinating sera for human haemoglobin - colloidal gold conjugate complexes with the human haemoglobin in the specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is immobilized by another specific Agglutinating sera for human haemoglobin coated on the membrane leading to formation of a coloured band. If occult blood level is equal to or higher than the 200 µg of faeces suspension, the test is positive. The absence of this coloured band in the test region indicates a negative test result. The rabbit globulin - colloidal gold conjugate and unbound complex, if any, move further on the membrane and are subsequently immobilized by the Agglutinating sera for Rabbit globulin coated on the membrane at the control region (C), forming a coloured band. The control band formation is based on the ‘Rabbit’ Agglutinating sera for Rabbit globulin’ system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band acts as a procedural control and serves to validate the test results.

**REAGENTS AND MATERIALS SUPPLIED**

**CANCHECK-FOBT** kit contains:

A. Individual pouches, each containing:
   1. **DEVICE**:
      Membrane assembly pre-dispersed with Agglutinating sera for human haemoglobin - colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, Agglutinating sera for human haemoglobin and Agglutinating sera for rabbit globulin coated at the respective regions.
   2. Desiccant pouch.
B. **BUFF**:
   Specimen Extraction Buffer in a dropper bottle.
C. Package Insert.

<table>
<thead>
<tr>
<th>REF.</th>
<th>507040010</th>
<th>507040025</th>
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<tbody>
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<td></td>
<td>10</td>
<td>25</td>
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</table>

**STORAGE AND STABILITY**

The sealed pouches in the test kit and the kit components may be stored between 4°C to 30°C for the duration of shelf life as indicated on the pouch/carton. DO NOT FREEZE.
NOTES
1. Read the instructions carefully before performing the test.
2. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
3. Do not use the kit beyond expiry date and do not re-use the test device.
4. Do not intermix reagents from different lots.
5. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-3)
   should be kept to a minimum. Inhalation/swallowing may cause harm.
6. Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
7. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
8. Specimen extraction buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal azide. Flush with large volumes of water to prevent azide build-up in the plumbing.

SPECIMEN COLLECTION AND PREPARATION
1. **CANCHECK®-FOBT** uses human faeces as specimen.
2. Collect faeces in a clean dry container.
3. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2°C to 8°C for maximum up to 24 hrs.
4. Refrigerated specimens must be brought to room temperature prior to testing.
5. Label the specimen collection bottle with specimen identity.
6. Unscrew and remove the cap (with attached sampling stick) of the specimen collection bottle ensuring that the extraction buffer is not split.
7. Take representative amounts of faeces specimen from different portions of the sample by introducing the sampling stick at 3-4 different places in the faeces specimen.
8. Wipe the sampling stick with an absorbent or tissue paper. The sample taken up by the grooves is sufficient for the test.
9. Reinsert the sampling stick into the bottle and screw the cap tightly.
10. Shake the specimen collection bottle so that there is proper homogenisation of faeces in buffer solution.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS
1. Bring the kit components of **CANCHECK®-FOBT** device to room temperature prior to testing.
2. Open a foil pouch by tearing along the “notch”.
3. Remove the testing device. **Once opened, the device must be used immediately**.
4. Label the device with specimen identification.
5. Place the testing device on a flat horizontal surface.
6. Hold the specimen collection bottle in an upward position and break the tip off.
7. Invert the bottle and holding the dropper vertically, carefully dispense exactly two drops of specimen-buffer mixture into the specimen port.
8. Observe the development of visible coloured band at Test region (T).
9. Positive results may be observed within 5 minutes, depending on the concentration of occult blood in the tested specimen.
10. Do not read and interpret after 5 minutes.
11. In negative specimens only the control band(C) would develop.

**Negative Result**
Presence of one coloured band at Control (C) region indicates absence of OCCULT BLOOD or the concentration of OCCULT BLOOD in the specimen is below the detection limit of 200 µg/l of faeces suspension.
**Positive Result**
If concentration of OCCULT BLOOD in specimen is above 200µg/ml of faeces suspension, two coloured bands appear at Test (T) and Control (C) regions. The intensity of the test band may be more or less than the Control band, depending upon the concentration of OCCULT BLOOD in specimen.

**Invalid Result**
The test is invalid if no band is visible at five minutes. The test should also be considered invalid if only the test band appears and no control band appears. Verify the test procedure and repeat the test with a new CANCHECK™-FOBT device.

**PERFORMANCE CHARACTERISTICS**
The detection limit of CANCHECK™-FOBT is up to 200µg/ml of faeces suspension i.e. equivalent to 100-200 µg/gm of faeces.

**Sensitivity**
The detection limit of CANCHECK™-FOBT device is up to 200µg/ml faeces suspension (calibrated against Sigma Human Hemoglobin Cat No. H-7309). This corresponds to a concentration of 100 to 200 µg/gm hemoglobin/gm of faeces. No Prozone Effect up to a hemoglobin concentration of 1000µg/ml has been observed.

**Specificity**
CANCHECK™-FOBT is highly specific to human hemoglobin and does not cross react with the following:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
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<tr>
<td>Chicken hemoglobin</td>
<td>500µg/ml</td>
</tr>
<tr>
<td>Pork hemoglobin</td>
<td>500µg/ml</td>
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<tr>
<td>Beef hemoglobin</td>
<td>500µg/ml</td>
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<tr>
<td>Goat hemoglobin</td>
<td>500µg/ml</td>
</tr>
<tr>
<td>Rabbit hemoglobin</td>
<td>500µg/ml</td>
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<tr>
<td>Horseradish peroxidase</td>
<td>2000µg/ml</td>
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**LIMITATIONS OF THE TEST**
1. **CANCHECK™-FOBT** is a highly sensitive and specific test for human haemoglobin in faeces. Nonetheless, as with any in-vitro diagnostic test, occasional false positive and negatives may occur.
2. False negatives may occur due to improper faeces suspension preparation or the lesion did not bleed or bleed sufficiently to produce a positive result.
3. Blood secondary to aspirin use or use of other non-steroidal anti-inflammatory agents may cause GI bleeding and show false positive results.
4. Stool samples collected during menstrual bleeding, constipation induced bleeding, bleeding hemorrhoids and rectal medication may also cause false positive results.
5. Gloves, collection container and test area should be kept free of blood to avoid false positive results.
6. Since benzidine & guaiac-based tests suffer from non-specific interference of peroxidase activity, exact one-to-one correlation of the results of such tests with a 3rd Generation Immunochromatographic test like CANCHECK™-FOBT may not be observed.
7. **CANCHECK™-FOBT** should only be used as a screening test. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

**WARRANTY**
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.
BIBLIOGRAPHY

SYMBOL KEYS
- Temperature Limitation
- Conseil Instructions for use
- Date of Manufacture
- Do not reuse
- Manufacturer
- IVD
- In-vitro Diagnostic Medical Device
- This side up
- Use by
- REF
- Catalogue Number
- DEVICE
- Device
- Contains sufficient for N tests
- LOT
- Batch Number / Lot Number
- BUF
- Specimen Extraction Buffer

Manufactured by:
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CMC Medical Devices & Drugs S.L., Spain.