immo [redacted] -C IVD CE REF 003630-E

Rapid immunochromatographic assay for the qualitative detection of intact hHB (human hemoglobin) / fecal occult blood in stool specimens

Storage and Expiration Date

Store at 4-28°C (39-82°F). The expiration date is given on the box label, the buffer label and on the foil pouches.

ATTENTION – Sample stability:
The samples / specimens have to be returned to the physician / the laboratory immediately after completion of the test period. It is recommended to store the collection tube with the sample between 2 and 8 °C (35–46 °F) if a longer transportation time or temperatures above 25 °C (77 °F) are to be expected (also by the patient).

Contents and Additionally Required Materials

25 foil pouches each containing 1 test cassette and 1 desiccant
1 instruction for use

In a removable tray:
25 sample collection tubes with buffer and patient label
25 information sheets for the patients
5 plastic pouches

Additionally required materials:
a timer and a clean paper tissue

Warnings and Precautions

- In vitro diagnostic device for professional use
- For external use only
- Keep out of reach of children
- Do not use the tests after expiration date
- Read instructions for use carefully
- Open foil pouches just prior to use, use each test cassette just once
- Do not take apart test cassettes
- Do not ingest sample buffer (or other portions of the test)
- Patients' samples could be infected and as such should be handled and disposed of as potentially infectious
- Do not smoke, drink or eat while performing the test
- Wear gloves and wash hands after performing the test
- Avoid spilling, splashing, dissipation and the like
- Observe the given incubation times, otherwise the sensitivity or specificity of the test may be influenced
- The chosen test materials (e.g. antibodies) are potentially infectious materials; however, there is no danger provided that you use all test components according to the instructions for use

Usage

Specimen(s):
The specimen to be used is stool. Generally, the stool specimen will be collected by the patient himself (either at home or testing location). The sampling is to be performed according to the instructions included for the patient, which must be passed on to the patient. If the specimen is to be stored by the patient for any length of time before testing, please provide a plastic pouch for the hygienic storage of the sample tube.

ATTENTION:
Please inform the patient as to the quantity of specimen needed as too much can result in test performance problems.

Please note:
In order to increase the chance of detecting intermittent bleeding it is recommended to perform samplings over a course of 3 consecutive days respectively during 3 consecutive bowel movements. The 3 samples may be collected in 1 collection tube.
The performance evaluation of this test has been carried out for 1 time sampling only. To perform more samplings may result in an increased sensitivity but a decreased specificity.

Test Performance

1. Bring the specimen to 20-25°C (68-77°F)
2. Open foil pouch(es) just prior to use (discard attached desiccant)
3. Shake the sample collection tube in order to ensure proper mixing of the stool specimen with the sample buffer. Cover the tip of the cap with a clean paper tissue (to avoid splashing) and break off the tip.
4. Add 2 drops from the sample collection tube to the sample well "S" and avoid bubbles.
5. Then wait 5 minutes.

Reading the Results

The test should be considered **positive**, if **2 purple lines** (at "C" and "T") appear in the reaction field of the cassette **within 10 minutes** (Fig. A), also in the event of a faint line at "T".

If only **1 purple line** at "C" (Fig. B) is visible the test should be considered **negative**.

If only a purple line at "T" but not at "C" or if no purple line appears in the reaction field or the whole reaction field turns purple, the test should be considered **invalid** (Fig. C).

If there are still no clear results after 15 minutes, please use another test cassette to test the same specimen. In the event of another invalid result, please contact the manufacturer.

Fig. A POSITIVE | Fig. B NEGATIVE | Fig. C INVALID

Methods

Colon Cancer Prevention:[1]
The evidence of fecal occult blood has a particular role concerning prevention in a health system. Mortality rates due to colon carcinomas can, cost effectively be reduced significantly. Additionally other neoplasmic or inflammatory diseases may show up.
The major advantage of this immunological method is, that no dietary restrictions are necessary.

Test principle:
After application of the sample it moves to a pad coated with antibody-colloidal-gold-conjugates by capillary action. In the event of a positive sample the hHB binds to the corresponding anti-β-hHB antibody colloidal gold conjugate and the complex moves on to a line constituting immobilised anti-α-hHB antibodies. In the presence of hHB a purple line appears in the reaction area at "T". As an internal positive control at the pad of antibody-colloidal-gold-conjugates another independent antibody-colloidal-gold-conjugate is mobilised and independent of the presence of hHB moves to another immobilised antibody. This results in a purple color line at "C" and serves as a control for the correct test performance.

Evaluation:[1]
The following guidelines apply to fecal occult blood tests: A negative test does not rule out a carcinoma; a positive test need not be verified by another positive test. Ongoing suspect clinical data justifies further diagnostic measurements and methods that should be taken quickly.
A positive test result for fecal occult blood must be re-checked until the bleeding source is detected / localised.

Limitations of the Test

- A number of medications like acetylsalicylic acid, glucocorticoids, non-steroid antiphlogistica / anti-rheumatica or cumarin-derivates may lead to gastrointestinal bleeding. Therefore a test for fecal occult blood should only be started a few days after such medication has been stopped.
- It may occur that too much stool was mixed into the buffer by the patient. Excessive stool may lead to false positive results (10 ng hHB/10 mg stool = 4 ng hHB/ml buffer = negative, BUT 200 ng hHB/200 mg stool = 80 ng hHB/ml buffer = weak positive). If the buffer with the stool sample inside appears dark, viscous or if

sedimentation of the stool can be observed, the specimen should be diluted. Sample bottles with buffer for dilution can be purchased at CARE diagnostica (per 50 pcs.).

Quality Controls

1. **Internal controls:**
   immoCARE-C tests have a built in quality control. The appearance of a purple line at "C" shows, that the sample has been absorbed properly and that the antibodies possess enough activity.
2. **External controls:**
   "Good laboratory practice"" ("GLP") recommends the usage of external controls. Positive and negative controls are available from CARE diagnostica upon request. The test should be performed as described in the instructions for use. With the use of controls, corresponding results can be expected.

Performance Evaluations

Analytical sensitivity:
ImmoCARE-C – tests show a positive result starting with an hHB concentration of 0.05 µg/mL (corresponds to about 0.03 mg/g stool). Also a very faint line at "T" has to be judged as positive result.

Specificity / Cross-reactions
ImmoCARE-C is specific for human hemoglobin.
The following substances do not influence the test results:

Substance	Concentration
Chicken – Hemoglobin	500 µg/mL
Pig – Hemoglobin	500 µg/mL
Beef – Hemoglobin	2000 µg/mL
Sheep – Hemoglobin	500 µg/mL
Horse – Hemoglobin	500 µg/mL
Horseradish – Peroxdiase	2000 µg/mL

Clinical Studies:[7]
The immunological immoCARE-C test was evaluated during a clinical study covering 253 symptomatic patients (131 women and 122 men, average age 52.6 years, 19-88 years) in Prague.
The following parameters have been calculated in comparison to colonoscopies:

Diagn. Sensitivity: 62.1 %	**Pos. praedicative value:** 88 %
Diagn. Specificity: 95 %	**Neg. praedicative value:** 81 %

Composition

Active Reagents:
Monoclonal mouse-anti-β-hHB antibodies colloidal gold conjugate
Monoclonal mouse anti-α-hHB antibody
Polyclonal rabbit IgG antibody colloidal gold conjugate
Polyclonal sheep anti-rabbit IgG antibody
Stabiliser: Sodium Acide

Explanation of Symbols

IVD "In-vitro-diagnostic device"

REF "Order number, catalogue number"

"Read instructions carefully before use"

"Use only once"

"use before", "expiration date"

LOT "LOT number"

CE "CE Symbol" – this product fulfils the requirements of directive 98/79/EC on in vitro diagnostic medical devices

Literature

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