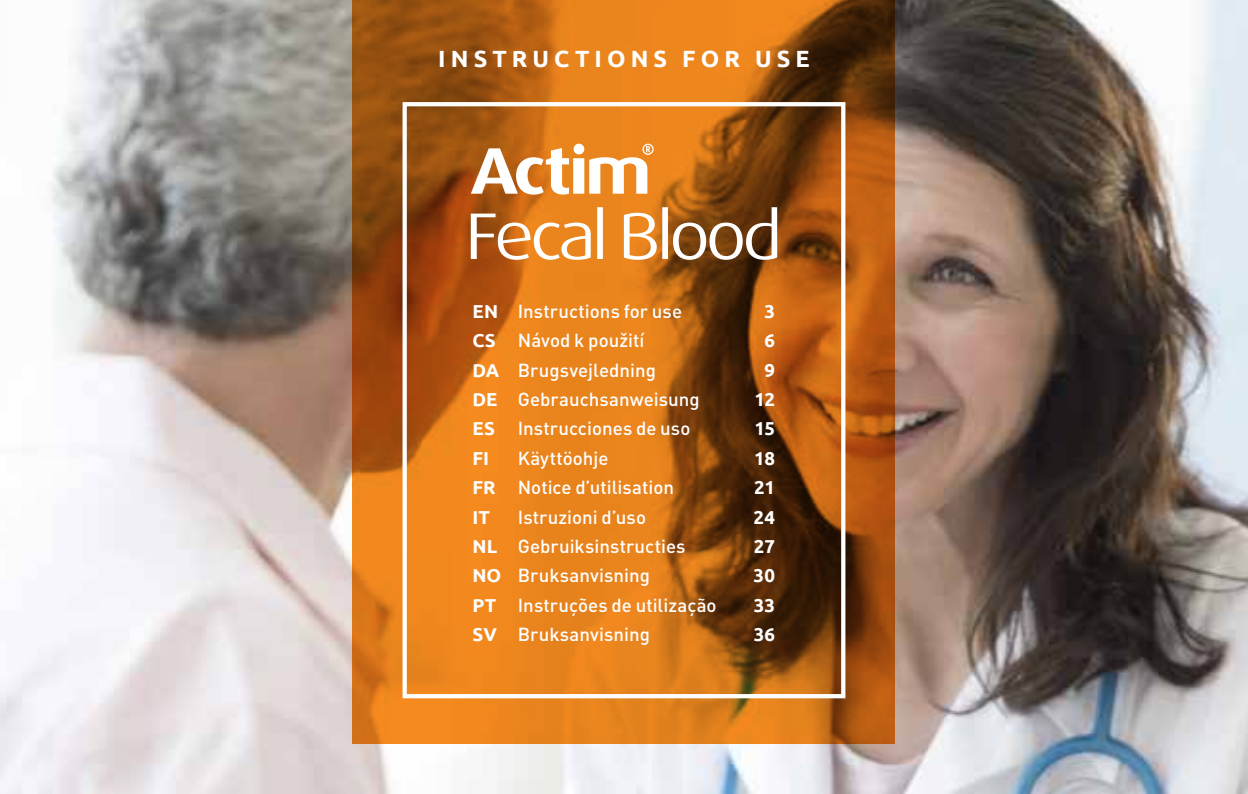
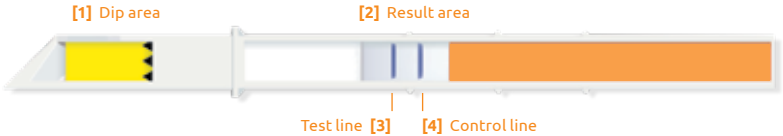


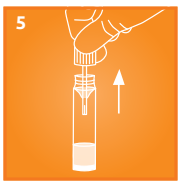
INSTRUCTIONS FOR USE

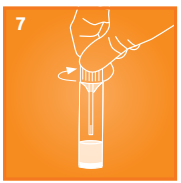
Actim® Fecal Blood

Structure of dipstick

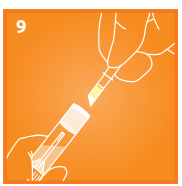


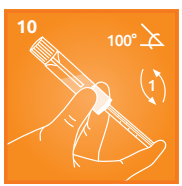
Specimen collection

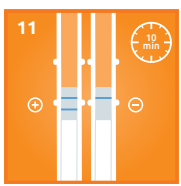


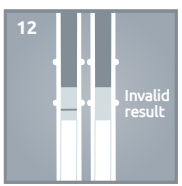


Test procedure and results









Instructions for use

Numbers **[1]** - **[12]** refer to illustrations on inner cover.

Structure of dipstick

[1] Dip area **[2]** Result area **[3]** Test line **[4]** Control line

Intended use

The Actim® Fecal Blood test is a visually interpreted, qualitative immunochromatographic dipstick test for detecting occult blood in feces. The Actim Fecal Blood test detects human hemoglobin in a feces suspension. The test is intended for professional use to help diagnose gastrointestinal bleeding.

Kit components

The components of the Actim Fecal Blood test are:

- Actim Fecal Blood dipstick in a perforating device. The dipsticks (10) are packed in an aluminum container (30361ETAC).
- Specimen Dilution Buffer (3 ml). This phosphatebuffered solution contains bovine serum albumin (BSA), protease inhibitors and <0.1 % (w/v) sodium azide (NaN3). One sampling stick is attached to the cap of each tube.

The kit 30331ETAC contains 2 aluminum tubes of dipsticks (30361ETAC) and 20 Specimen Dilution Buffer tubes (30371ETAC). The Actim Fecal Blood Buffer kit (30372ETAC) contains 20 Specimen Dilution Buffer tubes (30371ETAC).

An instructions for use leaflet is included in all product formats. Toilet paper or a clean disposable container is needed for sampling (not provided with the test).

Storage

Store the dipsticks and the Specimen Dilution Buffer tubes at +2...+30 °C. Stored unopened, each component can be used until the expiry date marked on the component. After opening the aluminum container first time, the dipsticks can be stored for 4 months at +2...+30 °C. However, the expiry date must not be exceeded.

Specimen collection

The specimen is feces suspension that is prepared as soon as possible after sample collection. The original feces sample can be stored for 3 days at +2...+8 °C.

Unscrew the cap of the Specimen Dilution Buffer tube **[5]**. Collect the feces sample by using the sampling stick attached to the screw cap. There are two small slits in the head of each stick. Twist the stick randomly in several different places in the feces sample so that both slits become filled with feces **[6]**. In case of liquid samples, dry the stick by wiping it with a piece of e.g. toilet paper before sticking it into the sample. The slits of the stick will be filled with the liquid feces.

Put the sampling stick into the Specimen Dilution Buffer tube by pushing the stick through the cone. Close the cap tightly **[7]** and shake the tube to suspend the feces in the buffer **[8]**. The specimen suspension is now ready for testing. The suspension can be stored for one week at +2...+25 °C (+2...+8 °C is recommended).

Test procedure and interpretation of the results

1. If stored refrigerated, allow the aluminum container of dipsticks and the buffer tube to reach room temperature before opening. Remove the required number of perforating devices (each containing a dipstick) from the container just prior to use and close the container immediately. Do not touch the yellow dip area at the lower ends of the dipsticks. Do not touch the part of the perforating device below the stopper, as this area will come into contact with the sample. Identifying marks may be written on the upper orange parts of the dipsticks.
2. The specimen should be at room temperature upon testing. Use the sharp tip of the perforating device to puncture the perforation area in the bottom of the buffer tube **then push the device into the tube until the stopper prevents it going further [9]**.
3. Slowly invert the tube (not fully upside down) once and immediately place the tube on the table in an upright position **[10]**. **NOTE! It is important that the inverting movement is not too abrupt, a peaceful inversion is vital for the correct performance of the test.**
4. The result can be interpreted as positive as soon as two blue lines become visible in the result area. The negative result should be read at **10 minutes** after the liquid front has reached the lower part of the result area **[11]**. **Do not pay attention to any lines appearing later than 10 minutes**.
5. If **two blue lines, the test line and the control line**, appear, the test result is **positive**. If **one blue line, the control line**, appears, the test result is **negative**.

If **the control line does not appear**, the test is **invalid [12]**.

In case of a missing control line, please see the Notes section for troubleshooting.

Disposal of the test device

The contact between the Specimen Dilution Buffer tube cap and the perforating device is so close that the test device can be disposed of directly after the result has been read. Do not remove the perforating device from the tube.

Limitations of the test

The test is intended for *in vitro* diagnostic use only.

Notes

- The test results are qualitative. No quantitative interpretation should be made based on the test results.
- Do not use a dipstick that has become wet before use, because moisture damages the dipstick.
- Do not use a dipstick if you notice a blue coloring in the result area before testing.
- Take care that any part of the test device that will be in contact with the sample tube do not become contaminated by external blood, e.g. from a cut finger. Do not touch the dip area of the dipstick or the area of the perforating device below the stopper.
- When inverting the sample tube to allow the dipstick to absorb sample, do not invert the tube too fast, or for too long. The test will not work properly if the amount absorbed is too small or too large.
- If the control line does not appear, the inversion of the sample tube may have been performed too abruptly. Take a new dipstick and repeat the inversion in a controlled way.
- Improper sampling may lead to false result.
- Occult blood is not uniformly distributed in the feces sample. Therefore, it is important to dip the sampling stick randomly in several places in the feces sample.
- The test line is in the lower half, the control line in the upper half of the result area of the dipstick. Appearance of a control line confirms correct performance of the test. If a control line does not appear the test is invalid, and should be repeated using another dipstick.
- If the test result cannot be interpreted clearly (e.g. if the lines are blotched or uneven) it is recommended that the test be repeated with another dipstick.
- At ten minutes the appearance of any faint-to-dark blue test line along with a control line indicates a positive result. However, do not pay attention to any lines appearing after 10 minutes.
- If only the control line is visible, the test result should be interpreted as negative only after 10 minutes have elapsed.
- If the color of the test line is not blue, the result should be interpreted as invalid and the test should be repeated with a new feces sample.
- Patients with the following conditions should not be considered for testing, as these conditions may interfere with test results: bleeding hemorrhoids, constipation bleeding, menstrual bleeding and urinary bleeding. However, these patients may be considered for testing after such bleeding ceases.
- As with all diagnostic tests, results must be interpreted in the light of other clinical findings.
- All biological specimens and materials must be treated as potentially hazardous, and disposed of in accordance with local authority guidelines.

Principle of the test

Feces do not normally contain measurable amounts of blood. The presence of hemoglobin in feces implies that there may be bleeding in the gastrointestinal tract.

The test is based on immunochromatography. It involves two monoclonal antibodies to human hemoglobin. One is bound to blue latex particles (the detecting label). The other is immobilized on a carrier membrane to catch labeled particles and indicate a positive result. When the feces suspension comes into contact with the dip area of the dipstick, the dipstick absorbs liquid, which starts to flow up the dipstick. If the sample contains hemoglobin, it binds to the antibodies attached to the latex particles. The particles are carried by the liquid flow and, if hemoglobin is bound to them, they bind to the catching antibodies. A blue line (test line) will appear in the result area if the concentration of hemoglobin in the sample exceeds the detection limit of the test. A second blue line (control line) confirms correct performance of the test.

Performance of the test

Analytical Sensitivity

The analytical sensitivity, detection limit, of the Actim Fecal Blood test was evaluated using samples with different concentrations of human hemoglobin on three different lots of Actim Fecal Blood test. The detection limit of the Actim Fecal Blood test is approximately 50 µg/l of human hemoglobin in the sample and the results remain positive at least to 500 000 µg/l. A feces suspension with 50 µg of hemoglobin/l corresponds to 25 µg of hemoglobin/g of feces.

Repeatability and reproducibility

Intra- (repeatability) and inter- (reproducibility) assay precision were evaluated using samples containing 0 – 2000 µg/l of human hemoglobin in feces suspensions. For repeatability the samples were tested on the same day using 10 replicates per sample on three different lots of Actim Fecal Blood test, the total amount being 180 tests in one day. For reproducibility the samples were tested on the five consecutive workdays using two replicates per sample on three different lots of Actim Fecal Blood test, the total amount being 180 tests in five days. Repeatable and reproducible results were obtained.

Analytical specificity, Cross-reactivity

The Actim Fecal Blood test was tested with following animal hemoglobin: Bovine, Equine, Porcine, Rabbit, Sheep, Goat and Dog. No cross-reactivity was observed. The Actim Fecal Blood test is specific for the human hemoglobin.

Interference testing

Interference of dietary iron supplement and dietary C-vitamin supplement in the Actim Fecal Blood test was examined. The feces samples were collected before medication and during the medication. No interference of the tested substances was observed with the performance of the Actim Fecal Blood test.

Diagnostic performance

Actim Fecal Blood test was evaluated for diagnosing colorectal disease at Ústav klinické biochemie a 4. interí klinika VFN a1.LF UK Prague, Czech Republic. The results are shown in FIG 1 on the inner back cover.

Method comparison

The function of Actim Fecal Blood test was compared using the new and old Specimen Dilution Buffer tube. The agreement with the two methods was 100 %.

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