ScheBo® • M2-PK Quick™

Stool test for colorectal cancer screening

Use

The ScheBo® • M2-PK Quick™ stool test is a visual immunochromatographic rapid test for the qualitative detection of M2-PK in stool samples. It is an in-vitro diagnostic test exclusively for professional use. The test is used for colorectal cancer screening and indicates colorectal polyps, colorectal cancer, acute and chronic inflammatory bowel disease and other diseases of the digestive tract.
The test result is not affected by any foods, so no dietary restrictions are necessary before taking the stool sample. It does not measure blood in the stool but instead it recognizes the enzyme M2-PK (M2-pyruvate-kinase). The ScheBo® • M2-PK Quick™ stool test can detect bleeding and non-bleeding colorectal polyps and tumors.

Table: Sensitivity and Specificity of M2-PK

	Sensitivity	Specificity
Colorectal Cancer*	93%	97,5%
Polyps**	55,6%	89,5%

* Adapted from: Sithambaram, S., Hilmi, I., Goh, K.-L. The Diagnostic Accuracy of the M2 Pyruvate Kinase Quick Stool Test - A Rapid Office Based Assay Test for the Detection of Colorectal Cancer. PLoS ONE 10(7): e0131616. doi:10.1371/journal.pone.0131616 (2015)

** Adapted from: Cho, C.H., Lee, B.J., Lim, C.S. Evaluation of the Performance of Fecal Tumor M2-PK Rapid Kit for Screening Colorectal Tumors Using Stool Specimens, Poster from the 54rd Congress of The Korean Society of Laboratory Medicine (KSLM) (2014)

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Test principle

Pyruvate kinase is a key enzyme in glucose metabolism and exists in various isoforms. In its active form, it consists of four equal subunits (tetramer). When a tumor develops, the tissue-specific isoenzymes are lost and expression of the M2 form of isoenzyme occurs. The amount of M2-PK increases and the isoenzyme that originally consisted of four subunits is split into a low-activity form consisting of two subunits (dimer). The dimeric form is generally detectable in large amounts in tumor cells.

The ScheBo® • M2-PK Quick™ stool test is based on an immunochromatographic method. The M2-PK is detected by two specific monoclonal antibodies. M2-PK in the stool sample reacts with a monoclonal antibody bound to gold particles. This complex migrates along the membrane and reaches the test line (T) which has a second monoclonal antibody against M2-PK attached.

When the result is positive, the gold-labeled antibody-M2-PK complex binds to the test line (T) and a pink color develops. When the result is negative, the sample does not contain any antibody-M2-PK complex that can bind to the test band (T) so no color becomes visible. Development of a pink control line (C) guarantees that sample application and migration have taken place correctly and that the test was properly performed.

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Storage and shelf life

Test

The test must be stored at +4°C to +27°C, and then brought to room temperature just prior to use if necessary.

Stool sample

The stool sample should preferably be stored refrigerated or at room temperature. After taking the stool sample it can be stored for no longer than 48 hours. Within these 48 hours, either the rest must be performed or the sample frozen at -20°C for longer-term storage. The deep frozen sample is stable for up to 1 year. Performance characteristics have not been established for other types of samples.

Interference

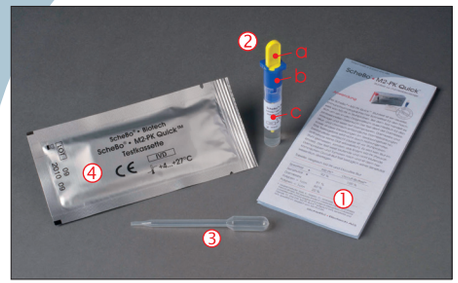
Very watery stools can lead to a false-negative result because of a dilution effect.

⚠ In vitro diagnostic test for professional use only

Not for re-use

- Do not use the test after the expiry date.
- Do not use reagents from different lots.
- Only open the test cassette's packaging shortly before performing the test.
- Make sure the foil bag containing the test cassette is undamaged.
- All patients' samples should be regarded as potentially infectious. Therefore, wear disposable gloves when conducting the test and dispose of the samples, extracts and test cassettes accordingly.
- The extraction buffer contains small quantities of sodium azide.

Contents of the doctor's carton



① 1 Instruction for use

② 10 ScheBo® • M2-PK Quick™ ready-to-use stool extraction systems consisting of:
- a yellow dosing tip
- b blue cone
- c pre-filled tube

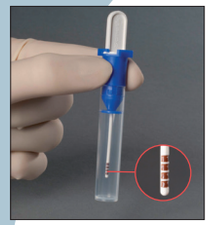
(extraction buffer: phosphate-buffered saline with detergent (<0.5%) and sodium azide (<0.05%))

③ 10 Pipettes

④ 10 ScheBo® • M2-PK Quick™ cassettes (individually packed in aluminium sachets)

CE

Test procedure



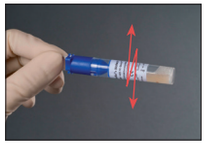
1. **Before starting the test, check that all the notches in the white dosing tip in the patient's tube are filled with stool.**

2. Turn the **yellow** dosing tip of the **extraction system** (tube containing buffer) anti-clockwise and with-draw it from the blue cone. Throw away the yellow dosing tip.

3. Turn the **white** dosing tip of the **patient tube** anti-clockwise and withdraw the tip with the stool through the blue cone.

Test procedure

4. Insert the **white** dosing tip with the patient's stool through the blue cone and into the **extraction system** and turn the tip clockwise to close it.



5. Shake well and tap the tube if needed until **all** the stool has been removed from **all** the notches in the dosing tip.

10min

6. Leave to stand for 10 minutes

7. Give the tube a final shake.
Caution: no stool should remain attached to the **white** dosing tip. If stool still remains stuck to the dosing tip, the extraction system can be left to stand for up to an hour in order to free the stool by repeated shaking.

8. Tear open the aluminium packaging and remove the test cassette.

9. Remove stool sample extract from the extraction system with a pipette.

10. Using the pipette apply 4 drops of stool extract into the circular sample well on the cassette.

5min

11. **Wait exactly 5 minutes** and then **read the result**. Results which are read later may become false positives!

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Interpretation of the test results

Quality control: the test contains an inbuilt control. When a pink band forms in the control region (C) the test has been performed correctly.

Negative a pink band appears in the control region (C) only. No band develops in the test region (T).

Positive two pink bands develop, one in the control region (C) and one in the test region (T). The test stripe (T) must be clearly recognizable as a line, although it may be weaker than that of the control (C).

Invalid if no pink band appears, the test has not worked.

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Application and test interpretation

The test is used for the qualitative measurement of M2-PK in stool samples. A positive result is obtained when a raised M2-PK concentration is present in the sample.

Negative test result

A raised fecal level of M2-PK **was not found** at the time the test was performed. When the test result is negative but there are disease symptoms (such as frequent lower abdominal pain, irregular bowel movements, weight loss or visible blood in the stools), you should arrange further diagnostic investigations. The test is not a substitute for colonoscopy.

Positive test result

A raised fecal level of M2-PK **was found** at the time the test was performed. A raised level of M2-PK in the stool can be an indicator of colorectal polyps or colorectal cancer. Raised levels can also occur in acute and chronic inflammatory bowel disease and other diseases of the digestive tract. Further appropriate investigations (e.g. colonoscopy, CT or ultrasound) should always be performed to confirm the pathological result or clinical suspicion of cancer or its precursors. The test is not a substitute for colonoscopy.

Performance

The ScheBo® • M2-PK Quick™ test uses monoclonal antibodies specifically targeted at dimeric M2-PK. The cut-off of the test is 4 U/ml.

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