PHARMA *SOUTHERN AFRICA*

POLY-CHECK®

Ref. 4084/ZA

Self Diagnostic Test for the detection of blood in faeces

GENERAL POINTS

Faecal blood can indicate different gastrointestinal disorders. These disorders can be as different as ulcers, polyps, colitis, fissures and colorectal cancer. These diseases cannot be detected only by visual examination and symptoms are often silent. Only the detection of blood in faeces can indicate a gastrointestinal disorder. Faecal occult blood in stool should be screened at least yearly starting with the age of 45 years

Poly-Test is a highly specific immunological rapid test. POLY-CHECK does not require a diet period as current guaiac tests.

It is known that polyps are, in most of the cases for early stage of diseases, not bleeding all the time but only intermittently. Stool sampling must therefore be collected for three consecutive days to increase the probability to detect intermittent bleedings for safer patient information.

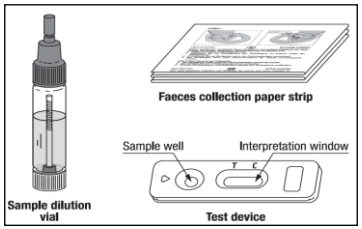
PRESENTATION

The box contains the material necessary to perform a test:

- 1 sealed aluminium pouch containing:
1 test device, 1 desiccant pouch

Only open the protective pouch and use the test after you have collected the faeces samples during 3 days. The desiccant bag should not be used.

- 3 paper faecal sample collection strips.
- 1 syringe containing 2 mL of extraction solution in a protective plastic bag.
- 1 instruction leaflet.



PRECAUTIONS

1. This test is exclusively intended to *in vitro* diagnostic. External use only. DO NOT SWALLOW.
2. Carefully read the instructions before performing the test.
3. The test is only reliable if the instructions are carefully respected. Respect the indicated number of drops and times.
3. Keep stored between +4°C and +30°C. Do not freeze the test.
4. Do not use after the expiry date indicated on the label and the pouch. Do not use the test if the protective aluminium pouch is damaged.
5. Do not re-use POLY-CHECK.
6. Keep out of the reach of children.
7. <u>Important:</u> Women must not perform the test during menstrual periods to avoid false positive results due to menses blood.
8. After use, all the components can be discarded in a dustbin.

PROCEDURE

Before performing the test, stool samples must be collected following the instructions below and be repeated during three (3) days:

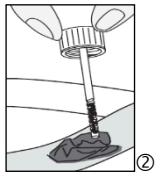
A – Sample collection
First Day

1. Wash your hands with soap and rinse with clear water. Dry your hands with a clean towel.

2. The faeces are collected on the special paper strip supplied in the box (see figure 1). Use one paper for each day.

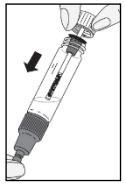
①

3. Unscrew the **white cap** of the sample dilution vial having the collection tip attached on it. and dip the tip (about 2 cm) in the faeces sample at 3 different locations (see figure 2).



②

4. Put the white cap containing the faeces sample back in place onto the dilution vial. Screw it firmly and shake well to resuspend the faeces sample (see figure 3). Put the sample dilution vial back into the plastic bag and keep it in the refrigerator between each collection step.



③

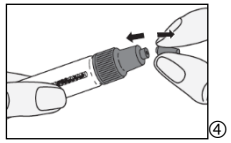
5. Remove the collection paper strip and dispose it in the toilets.

Second Day
Repeat steps 1 to 5.
Third Day
Repeat steps 1 to 5.

B- Test realization after the 3 days collection period of samples

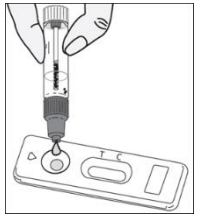
6. Tear the protective pouch (from the notch) and only get out the device. Discard the small desiccant pouch.

7. <u>Wait for the sample dilution vial to be at room temperature before performing the test.</u> Break the **purple** tip (see figure 4).



④

8. Put the test device on a flat surface (a table for instance) and press the vial body to add exactly 5 drops of the extract with an interval of 2-3 seconds between each drop in the sample well (see figure 5).



⑤

9. Read the result at 10 minutes. Do not interpret after 15 minutes.

RESULT INTERPRETATION

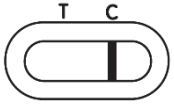
The intensity of the line colour does not have any importance for the interpretation of the test result.

1. Positive result

Two coloured lines appear in the window under the marks T (Test) and C (Control). The intensity of the line T may be clearer than the intensity of the line C. This result means that blood is present in the faeces and **that you should consult a doctor.**

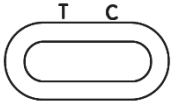
2. Negative result

Only one coloured line appears under the mark C (Control). This result means that no blood is detectable in the faeces sample.



3. Non valid result

No line appears or a coloured lin appears under the mark T (Test) without out any line under the mark C.



In this case, it is not possible to interpret the test, test which must be considered as non valid. It is recommended to repeat the test with a new POLY Check test and a fresh sample of faeces.

QUESTIONS AND ANSWERS

How does POLY-CHECK work?

Gastro-intestinal lesions are often bleeding. The blood can be detected specifically by POLY-CHECK in the faeces when concentration is higher than 10 ng/mL. The presence of blood can be explained by several causes: ulcers, haemorrhoids, colorectal cancer. The probability for intermittent bleeding to be detected is increased by the procedure of sample collection over 3 running days.

This procedure allows a more accurate test result for the patient especially for early stages of diseases and, therefore, greater probability to cure them.

When can this test be used?

POLY-CHECK can be performed at any time of the day when having a bowel movement.

Can the results be incorrect?

The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be falsified if Poly-Check gets wet before test performing or stool collecting steps are not correctly performed or if the sample is contaminated with blood from other origins than faeces (cuts, haemorrhoids, menses etc…) or if an incorrect number of drops is dispensed in the sample well.

How to interpret the test if the colour and the intensity of the lines are different?

The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogenous and full.

What is the line that appears under the mark C (Control) for?

When this line appears, it only means that the test correctly worked, but it does not play any role in result interpretation.

If I read the result after 15 minutes, will the result be reliable?

No. The test should be read after 10 minutes and before 15 minutes after having added the extract. The results are reliable up to 15 minutes.

What do I have to do if the result is positive?

If the result is positive, it means that blood has been detected in the stool sample and that you should consult a doctor to show the test results. Then, the doctor will decide what you have to do.

What do I have to do if the result is negative?

If the result is negative, it means that the test could not detect blood in stool sample. Meanwhile for the patients aged of 45 years and over or having relatives suffering from colorectal cancer, it is recommended to perform a test every year.

What is the accuracy of POLY-CHECK?

The Poly-Check is accurate and has been used for more than 10 years by professionals in the field.

Evaluation reports show an overall agreement of at least 93% ([86.78 – 97.17*]) with different reference methods. Although this test is reliable, false positive or false negative results could be obtained.

*CI 95%: 95% confidence interval

Information on faecal occult blood and its clinical significance:

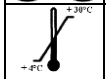
https://www.mayoclinic.org/tests-procedures/fecal-occult-blood-test/about/pac-20394112

https://medlineplus.gov/lab-tests/fecal-occult-blood-test-fobt/

https://www.unisante.ch/fr/promotion-prevention/depistage/programmes-vaudois-depistage-du-cancer/depistage-du-cancer-du-0

https://www.biron.com/fr/centre-du-savoir/parole-de-specialiste/sang-dans-les-selles/

https://www.biron.com/en/education-center/specialist-advice/blood-in-the-stool/

	Read the instructions before use	IVD	For *in vitro* diagnostic use		Do not reuse
	Store between +4°C and +30°C	LOT	Batch number		Expiry date
	Manufacturer				

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CHANGES DESCRIPTION

Changes type:

- N/A Not Applicable (creation)
- Technical change Addition, revision and/or removal of information related to the product.
- Administrative Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
N/A	Creation

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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