PHARMA *SOUTHERN AFRICA*

BABYCHECK-1® WB

Ref. 3184/ZA

Finger prick whole blood pregnancy self-diagnostic device.

GENERAL POINTS

BABYCHECK-1® WB is a self-diagnostic rapid test for the determination of the hCG (human Chorionic Gonadotropin) in whole blood sample for the diagnosis of pregnancy. While pregnancy can be detected in urine about 1 week **after a missed period**, whole blood testing can detect pregnancy as early as a few days **after impregnation**.
Pregnancy whole blood tests are also known to be more accurate than urine tests. This is the reason why whole blood/serum pregnancy tests are widely used in laboratories/hospitals. In addition, the volume of ingested liquids which may affect the urine test results (dilution of hCG) is not affecting whole blood test.
The test accuracy is indeed very important as a pregnancy necessarily implies precautions as well as a change in lifestyle such as stopping smoking or drinking alcohol, reducing or even eliminating medications as well as certain foods.
BABYCHECK-1® WB is a rapid qualitative test for the detection of the hCG in whole blood. In only 5 minutes, it is possible to detect an hCG concentration of 25 IU/L.

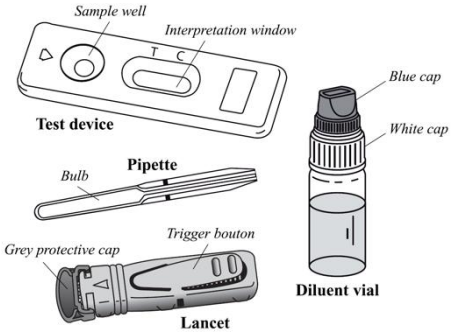
PRESENTATION

The box contains all the material necessary to perform a test:

- 1 sealed aluminium pouch containing:
1 test device, 1 plastic pipette and 1desiccant pouch.

Only open the protective pouch when you are ready to perform the test. The desiccant bag should not be used.

- 1 sterile lancet for blood sampling.
- 1 dropper vial containing 1 mL of diluent. DIL
- 1 instruction manual.
- 1 alcohol pad.



Material required but not provided: Timer

PRECAUTIONS

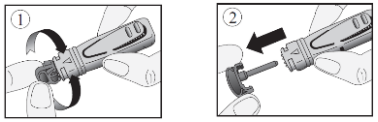
1. This test is exclusively intended for *in vitro* diagnostic. External use only. DO NOT SWALLOW.
2. Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected. Follow strictly the indicated time, blood and diluent quantities.
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
5. Do not re-use **BABYCHECK-1® WB**
6. **Keep out of the reach of children**
7. After use, all components can be discarded in a dustbin.

PROCEDURE

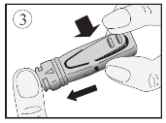
Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

1. Wash your hands thoroughly. Use soap and warm water. Dry your hand with clean towel.

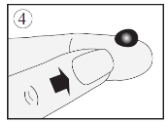
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant pouch.
3. **Prepare the lancet.** Hold the lancet **without touching the trigger button.** Unlock the lancet cap twisting it off ¼ turn until you feel it separates from the lancet and then continue twisting it (2-3 rotations). **Don't pull just twist** and discard the cap when finished ① & ②.



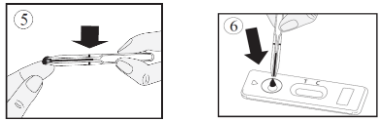
4. Clean the end of the middle finger or ring finger with the alcohol pad.
Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. **Press platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button**③.



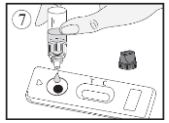
6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample.④.



8. Without pressing the bulb, put in contact the plastic pipette with the blood sample⑤. The blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb⑥.



10. Wait 30-40 sec for the blood being totally absorbed into the sample well. **Unscrew the blue cap** of the diluent dropper vial (leave the white cap tightly screwed) and add the diluent as follows:
Hold the diluent dropper vial vertically and slowly add exactly 4 drops in the sample well of the device⑦ with an interval of 2-3 seconds between each drop.



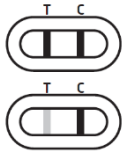
11. Read the result within 5 minutes to 10 minutes. Do not interpret after 10 minutes.

RESULTS INTERPRETATION

The colour and intensity of the lines do not have any importance for the interpretation of the test results.

1. Positive result

Two coloured lines appear in the window under the marks T (Test) and C (Control). The colour intensity of the T line may be clearer than the intensity of the C line. **The test is positive indicating that the hCG level is than 25 IU/L or higher and that you are pregnant**.

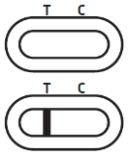


2. Negative result

Only one coloured line appears under the mark C (Control). **The test is negative indicating that the hCG level is below 25 IU/L.**

3. Invalid result

No line appears or a coloured line appears under the mark T (Test) without any line under the mark C. In this case, it is not possible to interpret the test, which must be considered as invalid. It is recommended to repeat the test with another **BABYCHECK-1® WB** and new blood sample.



QUESTIONS AND ANSWERS

How does BABYCHECK-1® WB work?

When a woman becomes pregnant, her body begins to produce a hormone, human chorionic gonadotropin (hCG), which is released in the blood where its concentration rises over time. **BABYCHECK-1® WB (**Pregnancy test) detects the hCG hormone in whole blood. The BABYCHECK-1® uses a specific pair of antibodies detecting the hCG hormone in whole blood when the hormone level is, at least, 25 IU/L (determined against W.H.O.* reference) or greater.

World Health Organization

When should the test be performed?

You can use the **BABYCHECK-1® WB (**Pregnancy test) at any time of day or night. **BABYCHECK-1® WB** can detect pregnancy earlier than a classical urine test because the hCG hormone produced in the placenta is first released in the blood flow and then into the urine. Therefore, there is no more limitation to collect the morning first urine in order to increase the probability of an early pregnancy detection.

Can the results be incorrect?

The results are accurate as long as the instructions are carefully respected. Nevertheless, the result can be incorrect if the **BABYCHECK-1® WB** gets wet before performing the test or if the quantity of whole blood dispensed in the sample well is not correct. The plastic pipette provided in the box makes sure the collected whole blood volume is correct.

Certain drugs containing hCG or which are used in combination with hCG (such as Pregnyl, Porfasi, Pergonal) and rare medical conditions may lead to a false positive result. Alcohol, analgesics, antibiotics, birth control pills, hormone therapies containing clomiphene citrate (such as Clomid, Serophen) or painkillers should not affect the test result.

The test may show a false positive result if you have had a miscarriage, abortion or have given birth within the past 8 weeks.

This is due to the test detecting hCG still present in your body.

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

The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and complete. The test should be considered as positive whatever the color intensity of the test line (T), even weak.

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

When this line appears, it only means that the test has been performed well.

If I read the result after 10 minutes, will the result be reliable?

No. The result should be read within 5 minutes after adding the diluent. The result is reliable up to 10 minutes.

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

If the result is positive, **you should consult your general practitioner and/or gynecologist** to discuss about your pregnancy and next steps. Early prenatal care is important for a safe follow up of pregnancy.

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

If the test is negative, it is most likely that your blood does either not contain hCG or very low levels of hCG (the test detects hCG concentration as low as 25 IU/L) and that you are most probably not pregnant. However, you may have miscalculated the date of your period, especially if you have irregular periods. If your period does not start within a week, repeat the test. If you still get a negative result and your period has not started, **you should consult your general practitioner or gynecologist**. This delay could be caused by other reasons.

What is the accuracy of BABYCHECK-1® WB?

The **BABYCHECK-1® WB** is accurate. Evaluation reports show an overall agreement higher than 98% [95.2 - 99.5**] with reference methods. Although this test is reliable, false positive or false negative results could be obtained.

***** CI 95%: 95% Confidence Interval.***

Information on pregnancy

1. Michie, L. and Cameron, S.T. Contraception (Elsevier). 2014, 89: 440.

2. Web information: https://www.health.harvard.edu/topics/womens-health

3. Web information : https://wehavekids.com/having-baby/How-Soon-Can-a-Blood-Test-Detect-Pregnancy (2018).

Sterile lancet: STERILE R CE 1639

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EC REP GERMANY

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IVD	For in vitro diagnostic use	LOT	Batch number		Store between +4°C and +30°C
	Read the instructions before use		Expiration date		Do not reuse
DIL	Diluent vial		Manufacturer	EC REP	Authorized EU representative

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CE 0483

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
Administrative Change	Addition of alcohol pad in components and procedures

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

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