

INTRODUCTION

checkToP® test is not a classical pregnancy test. **checkToP®** is a low sensitive urinary rapid test for the determination of the hCG (human Chorionic Gonadotropin) level in urine for home use, to determine the outcome after a previously confirmed Termination of intrauterine Pregnancy (ToP) up to 9 Weeks of Amenorrhea (9 WA) and miscarriage.

Your Health Care Professional will explain you if and how to use this test.

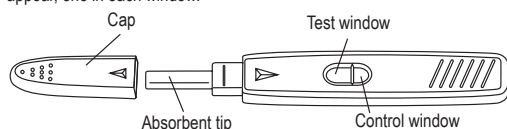
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Ref. 3066-1000AI: Each pack contains one (1) instruction for use and one (1) **checkToP®** test packaged in a hermetically sealed aluminium pouch containing one desiccant sachet.

Ref. 3067-1000AI: Each pack contains twenty (20) instructions for use and twenty (20) **checkToP®** tests packaged in a hermetically sealed aluminium pouch containing one desiccant sachet.

PRINCIPLE OF THE TEST

checkToP® is a rapid qualitative test for the presence of hCG in urine. In 5 to 10 minutes, it will detect an hCG level of 1000 mIU/mL or more. When the hCG level is below 1000 mIU/mL, only one coloured band appears in the control window but no coloured band appears in the test window. When the hCG level is above 1000 mIU/mL two coloured bands appear, one in each window.



PRECAUTIONS

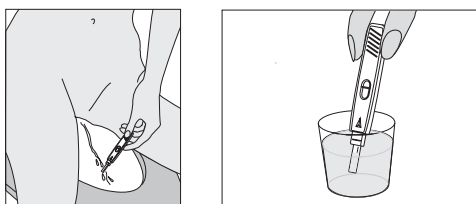
1. This test is exclusively intended for external use only (in vitro diagnostic use). Do not swallow.
2. Carefully read the instructions before carrying out the test. The test is not reliable unless the instructions are strictly followed.
3. Store between +4°C to +30°C. **Do not freeze.**
4. Do not use after the expiry date. The expiry date is printed on each of the aluminium pouches and is also printed on the external package. Do not use if the aluminium pouch has been damaged.
5. Do not reuse **checkToP®**.
6. Keep out of reach of children.
7. After use please dispose of all kit components into domestic waste.

PROCEDURE

The test must be performed after Termination of Pregnancy at a time indicated by your gynaecologist, usually between 10 to 20 days after

- the first drug intake in Medical ToP up to 9 WA
- miscarriage

1. Remove the **checkToP®** test device from the aluminium foil pouch. Discard the small sachet.
2. Remove the cap and either:



- hold the absorbent tip directly in your urine stream for 5-10 seconds. **Take care no urine enters the test window.**
- or collect your urine in a clean and dry container and dip the absorbent tip into the urine for at least 5 to 10 seconds in order for it to be completely soaked.

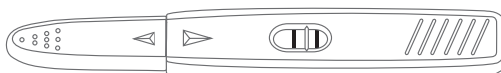
3. **Replace the cap** on the test device.
4. Lay the test device on a dry flat surface with the two windows facing up. Results will be shown in the windows and can be read between 5 to 10 minutes. Do not read the test after 10 minutes.

RESULT INTERPRETATION

Wait between 5 to 10 minutes to read the test results. Between 5 to 10 minutes a line will appear in the control window (the smaller window).

Important: Do not read before 5 minutes or after 10 minutes.

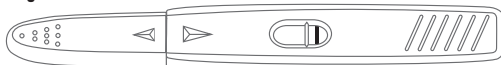
Positive test result:



If two pink coloured bands appear within 10 minutes : one band in the test window and one in the control window, the test is positive. Your hCG level may be above 1000 mIU/mL. This could mean that the treatment for Termination of Pregnancy may not have worked or is not complete, or that miscarriage has not occurred. **In any case you should consult your gynaecologist.**

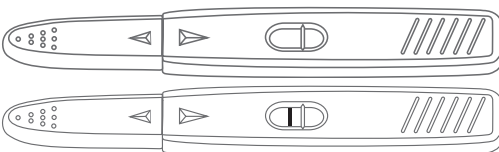
Note: One band can be darker than the other. The two bands can be any shade of pink-purple and can be lighter or darker than the control. However, you should see two clear parallel bands.

Negative test result:



If only one pink coloured band appears in the control window (the smaller window) and no band appears in the test window (the largest window), the test is negative. Termination of Pregnancy or miscarriage is confirmed.

Inconclusive:



The test is inconclusive if there is no coloured band in the control window of the test. Even if there is a coloured band in the test window, it is recommended that the test be repeated with a new **checkToP®** and tested on a fresh urine sample that has been obtained 24 hours later after the inconclusive test.

QUESTIONS AND ANSWERS

How does the **checkToP®** test work ?

When a woman becomes pregnant, her body begins to produce a hormone, human Chorionic Gonadotropin (hCG), which is excreted in the urine where its concentration rises over time. The **checkToP®** test detects the hCG hormone in urine if the hormone level is 1000 mIU/mL or greater. If treatment for Termination of Pregnancy has been effective or miscarriage has occurred then the hCG level should drop below 1000 mIU/mL within 10 to 20 days. **checkToP®** will not detect hCG levels lower than 1000 mIU/mL while classical pregnancy tests will be positive.

Should I test at a certain time of day ?

Yes, we recommend testing **checkToP®** on the first morning urine that should be more concentrated.

Will the quantity of fluids I have drunk affect the result ?

Yes, a high fluids intake may dilute the urine and make the hCG detection more difficult. Abnormal fluid intake is therefore not recommended.

What if I am unsure about the result of the test ?

If you are unable to determine whether or not a line is present in the oval test window, repeat the test after 1 day with a new **checkToP®** Test. If you follow the instructions, you should get accurate results. Certain drugs which contain hCG or that are used in combination with hCG (such as Pregnyl, Profasi, Pergonal) and rare medical conditions may give 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.

I left the absorbent tip in my urine for more than 10 seconds. Will I still obtain a correct result ?

Yes. A few extra seconds will not affect the results.

I left the absorbent tip in my urine for less than 5 seconds. Will I still obtain a correct result ?

No, because the urine sample volume may be too small.

What if the line in the test window is darker than the line in the control window or the line in the test window is lighter than the line in the control window?

As long as you see a line in each window, the test result is positive.

What should I do when I have the result ?

You must follow the advice given by the medical staff managing you.

What if I don't wait the full 5 minutes before reading the test ?

If you read the test before 5 minutes, you may not give the test enough time to work, and the test result may not be accurate. **DO NOT INTERPRET** the results if 10 minutes have elapsed after having brought the absorbent tip into contact with urine.

How accurate is the test?

The **checkToP®** is very accurate and has been used by health care professionals to confirm the success of Medical Termination of Pregnancy up to 9 WA (hospitals and laboratories). Evaluation reports show that **checkToP®** can detect hCG above 1000mIU/mL in over 99% of cases. No test is perfect and even if the test is negative, you should still contact your health care provider if you have symptoms of pregnancy such as scanty bleeding, no period at the expected time, tender breasts, feeling sick, and tummy growing.

Can I use **checkToP®** to diagnose a pregnancy?

Yes but **checkToP®** is not able to detect very early pregnancies and only shows positive if the hCG hormone is more than 1000 mIU/mL.

Other pregnancy tests are more sensitive and give a positive result starting from 5 to 25 mIU/mL.

WARNINGS

- **checkToP®** cannot be used for pregnancies where the initial hCG was lower than 1000mIU/mL.
- Use **checkToP®** only within a medical treatment ordered by your treating doctor. The clinical interpretation of the test has to be done with or according to the medical staff managing you.

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