





PREGNANCY TEST: INSTRUCTIONS FOR PARTICIPANTS

If you are a woman of child-bearing potential who is capable of becoming pregnant and have been allocated to certain medication, you will have been provided with a pregnancy test in your trial pack.

Please take the test provided as soon as possible and before starting your first dose of trial medication.

The trial team will contact you shortly to ask for your test result.

Please do not start your trial medication until you have confirmed a negative pregnancy test result. This is important to ensure your safety since there is limited human research for this medication for pregnancy and breastfeeding.

If your test is positive, or you decide not to take the test, you will be withdrawn from the trial and will need to return your trial medication in the envelope provided, free of charge.

Contact us

If you have any questions about taking the pregnancy test, please contact us on:

E-mail: principle@phc.ox.ac.uk

Telephone: 0800 138 0880

PRINCIPLE Pregnancy Test Instructions v1.0 15Oct2021 IRAS ID: 281958 REC: 20/SC/0158

Directions for use:

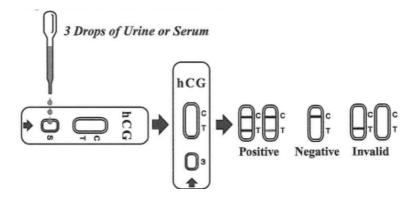
The test detects the presence of Human Chorionic gonadotropin (HCG), which appears in urine early during pregnancy.

Do not use the pregnancy test after the expiration date.

Keep the test in the sealed pouch at room temperature until ready to use.

The test kit cannot be used more than once. Please discard after use.

- 1. When you are ready to test, remove the test device from the sealed pouch and use it as soon as possible.
- Collect a sample of your urine in a clean and dry container. A first morning urine specimen is preferred however, urine specimens collected at any time of the day may be used.
- 3. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 drops of urine to the specimen well **(S)** of the test device and start the timer. Please see illustration below.
- 4. Wait for the coloured line(s) to appear.



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Read the result at 3 minutes. Do not interpret the result after the recommended read time. It is important that the background is clear before the test result is read.

How to interpret the results (please refer to illustration above):

POSITIVE (pregnant): *Two distinct coloured lines appear. One line should be in the control line region (C), and another line should be in the test line region (T).

*NOTE: A sample hCG concentration below the cut-off level of this test might result in the test region (T) seen after the read time and could indicate a low hCG level in the sample. If such results are seen, it is recommended that you repeat the test with a new sample of urine in 48-72 hours. If this occurs, please contact the trial team for a new test.

NEGATIVE (not pregnant): One coloured line appears in the control line region (C). No apparent coloured line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. If this occurs, please contact the trial team immediately to request a new test using the contact details found on the first page of these instructions.

If for any reason you require a new test kit to be sent out to you, the delay incurred may result in you becoming ineligible for the trial. If this occurs, you will be withdrawn from the trial and asked to return your trial medication.

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