



Pregnancy Tests

Frequently Asked Questions

Storage

How should pregnancy tests be stored?

Invitech's pregnancy test devices should be stored at room temperature (**between 4°C and 30°C**). They can also be refrigerated, but must then be warmed to room temperature before use. Storing the devices below 4°C or above 30°C will damage them, which may lead to incorrect results.

How long can the patient's sample be stored for?

Ideally, the sample should be tested as soon as possible. If it has to be stored, the sample can be refrigerated at 4°C for up to two days, or it can be frozen for longer term storage. In both cases, the sample must be warmed to room temperature before it is tested.

Sample

What type of sample should I use?

It is always preferable to test an **early morning urine sample**, particularly in very early pregnancy. If an ectopic pregnancy is suspected, use a serum test for human chorionic gonadotropin (hCG).

What type of container should I use for the sample?

A clean, plain (no preservative) universal container.

Test

How soon will the pregnancy test show a positive result?

The 10mIU/ml test can detect hCG the day the menstrual period is due and the 25mIU/ml test can detect hCG the day after the period is due.

Should I use the 10mIU/ml or the 25mIU/ml test?

The 10mIU/ml test is best for situations where pregnancy needs to be excluded e.g. prior to surgery or in the A&E department.

The 25mIU/ml test is better for confirming pregnancy.

How long does the test take?

The test should be interpreted at **five minutes**.

What should I do if the control line doesn't work?

If the control line doesn't appear, the test hasn't worked properly and must be repeated.

How should I interpret the result if the test line is weaker than the control line?

Any line in the test area of the device should be considered positive, even if it is much weaker than the control line.

Results

What can cause a false positive result (i.e. hCG is present in the sample but there is no viable pregnancy)?

Post pregnancy. The test will remain positive for some time after miscarriage, abortion and delivery. This means that Invitech's pregnancy tests cannot be used for detection or confirmation of miscarriage or successful termination, and care should be taken when using it to confirm an early subsequent pregnancy.

Early spontaneous abortion. Research has shown that up to half of all conceptions end in miscarriage. Due to the high sensitivity of Invitech's pregnancy tests (10mIU/ml and 25mIU/ml), fertilisation will cause a detectable level of hCG without a viable embryo.

Other sources of hCG. Certain drugs contain hCG e.g. infertility treatments. Some tumours, such as hydatidiform moles, may produce high levels of hCG, despite the absence of an embryo.

In addition, the β subunit of hCG is secreted by some cancers. For this reason a positive result in males can be an indication of cancer.

A small number of females have a very low background level of hCG, which can produce a weak positive result with the 10mIU/ml test.

What can cause a false negative result (i.e. no detectable hCG is present in the sample but there is a viable pregnancy)?

Testing too early. This can lead to a false negative result because, although the ovum is fertilised, the body has not started secreting enough hCG for the test to measure. It is important that you know the limitations of the test you are using.

Dilute urine. Early morning urine (EMU) is the best sample to test. If pregnancy is suspected and the test is negative, either the urine test must be repeated with an early morning sample, or a serum hCG test should be performed. **If an ectopic pregnancy is suspected, use a serum hCG test.**

Poor technique. If a dip stick test is used, it must **not** be immersed completely in the urine, but should only be dipped to the maximum line and held there for 10 seconds, to allow sufficient urine to travel up the stick. If a cassette test is used, ensure the correct number of drops (three to four) is applied to the sample window.

For accuracy, it is essential that the test is read at the stipulated time (five minutes). If a test is read too early, a weak positive result may be missed. If a test is left too long, the test membrane can dry out and lines from the manufacturing process may become visible.

Controls and External Quality Assurance (EQA)

Why should I run a control?

All of Invitech's pregnancy tests contain an internal control, and it is very important to check that the control line is present every time a test is performed. The presence of a control line indicates that the device has worked properly.

Some Trusts also like control samples to be run periodically – you can find out what the requirements of your Trust are by asking the point of care co-ordinator.

Why do I need to be part of an EQA scheme?

An EQA scheme allows your pregnancy test results to be checked against those from many other Trusts. Samples are sent out by the EQA scheme organiser to all of the participating sites. The samples are then tested as if they were patient samples and the results are sent back to the scheme organiser. The results from individual sites are then compared against each other.

If your results are at odds with everyone else, the scheme organiser will contact you to investigate the reason why. Participating in an EQA scheme helps ensure the quality of your pregnancy test results.

How long can I store EQA samples for?

EQA samples often have a short shelf life, so it's important to test them as soon as possible.