

# TestPack® hCG Combo (505805)

## Frequently Asked Questions

The TestPack® hCG Combo detection test is a rapid diagnostic device for the qualitative detection of human chorionic gonadotrophin (hCG) in urine and serum.

### **How sensitive is TestPack hCG Combo?**

TestPack hCG Combo is sensitive to 25 mIU/ml hCG in urine or serum.

### **How accurate is the test?**

TestPack hCG Combo has been shown to be > 99% accurate in clinical trials.

### **Can plasma be used with the TestPack hCG Combo test?**

No. The test has only been validated for urine and serum samples only.

### **Can urine and serum samples be stored in the fridge/ freezer?**

Yes. Both urine and serum samples can be stored for up to 48 hours between 2°C and 8°C or up to 3 months if frozen at -20°C. However, samples must always be brought to room temperature prior to use.

### **Can the test be used directly from the fridge?**

No, although the kit can be stored at 2 - 30°C, it must be allowed to equilibrate at 18 - 30°C for a minimum of 30 minutes before use.

### **Do urine samples need to be collected in containers containing preservatives?**

No. You do not need to add preservatives to the urine sample. If you want to use a preservative TestPack hCG Combo has been validated for use with samples containing 0.1% sodium azide only.

### **How soon can TestPack hCG Combo be used?**

TestPack hCG Combo can detect hCG in urine at concentrations  $\geq 25$  mIU/ml. On the first day of the expected period the level of hCG in the urine and serum of a pregnant woman is expected to range between 50 – 250 mIU/ml.

### **When is the best time of day to test?**

It is possible to use TestPack hCG Combo with a urine or serum sample collected at any time of day. However, a first morning urine sample will usually contain the highest level of hCG.

### **How critical is the timing and are the results stable?**

The result must be read 5 minutes after the sample has been applied to the Sample Well of the reaction disc, after which time the test should be discarded.

### **The Patient Bar is very faint, what does this mean?**

Samples containing 5 - 25mIU/ml hCG may produce weak positive results. In such cases a repeat test is recommended 48 to 72 hours later. However, provided the Minus Bar is present a weak positive should be recorded as a valid positive result.

### **Sometimes the Patient Bar can be fainter or darker than the Minus Bar. How should this result be interpreted?**

The presence of the Patient Bar in the Result Window indicates a positive result, regardless of its intensity compared to the Minus Bar.

# TestPack® Plus hCG Combo (505805) Frequently Asked Questions Ctd.

## **What is the purpose of the Positive On Board Control?**

The Positive On Board Control demonstrates the functionality of the antibodies that detect hCG. It will always be produced in a valid test whether or not hCG is present in the sample.

## **No Minus Bar has appeared in the Result Window, what does this mean?**

The test has not run correctly. This may occur if the pouch has been opened for too long prior to the test being carried out. It could also be a consequence of adding insufficient or excessive sample to the test.

## **Will fertility drugs affect the test result?**

Fertility drugs containing hCG can give misleading results. We recommend that a pregnancy test is not carried out until at least 14 days have passed since the administration of these drugs, testing too soon may give a false positive result.

## **Do hormonal contraceptives affect the test?**

No. However if a woman has recently discontinued the use of hormonal contraceptives her periods may not be regular. In such cases we recommend testing 19 days after the last unprotected sexual intercourse.

## **Can TestPack hCG Combo be used to detect ectopic pregnancy?**

TestPack hCG Combo can be a useful aid in the diagnosis of ectopic pregnancy, although it cannot distinguish ectopic pregnancies from normal pregnancies, and since ectopic pregnancies may produce lower levels of hCG than normal pregnancies, a positive result may not be seen as early. If an ectopic pregnancy is suspected, it should always be followed up with a suitable confirmatory method.

*Please see instructions for use for full information.*

*If you have any further questions please contact us via the enquiry button on the product page.*

*For reference hCG positive and negative controls are available (510068). Please evaluate these in-house.*