VISITECT® PREGNANCY Ref OD036/ OD056

Rapid test for detection of human Chorionic Gonadotrophin In Urine or Serum

Store at 4°C to 30°C. DO NOT FREEZE.

For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

Human chorionic gonadotrophin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy, is excreted in urine approximately 20 days after the last menstrual period. The levels of hCG rise rapidly reaching peak levels after 60-80 days.

The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation of pregnancy. However, elevated hCG levels is frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made

VISITECT PREGNANCY is a rapid, Point-of-Care, qualitative, two-site sandwich immunoassay for the determination of human chorionic gonadotrophin (hCG), a marker for pregnancy, in serum and urine specimens.
For professional use only.

PRINCIPLE OF THE TEST

VISITECT PREGNANCY utilises the principle of Immunochromatography, a unique two-site immunoassay on a membrane. As the test sample flows through the membrane assembly within the test device in place of the dipstick, the coloured monoclonal anti-hCG-colloidal gold conjugate complexes with the hCG in the sample. This complex moves further on the membrane to the test region where it is immobilised by the monoclonal anti-hCG coated on the membrane, leading to the formation of a pink coloured line which confirms a positive test result. Absence of this coloured line in the test region indicates a negative test result. The unreacted conjugate, unbound complex, if any, and the colloidal gold conjugated rabbit IgG moves further along the membrane and are subsequently immobilised by the goat anti-rabbit IgG coated on the control region forming a pink line. This control line serves to validate the test results.

VISITECT PREGNANCY detects the presence of hCG in serum and urine specimens, qualitatively, at concentrations as low as 10 mIU/ml in fifteen minutes using serum or five minutes using urine. Concentrations of about 100 mIU/ml of hCG are reached by the first day of the missed menstrual period in normal pregnancy. Thus **VISITECT PREGNANCY** is able to detect pregnancy at very early stages.

No cross reactions have been detected with LH at levels below 0.5 IU/ml – Normal level below 0.12 IU/ml.
No cross reactions have been detected with FSH at levels below 1 IU/ml – Normal level below 0.012 IU/ml.
No cross reactions have been detected with TSH at levels below 1 mIU/ml – Normal level below 7.1μIU/ml.

Calibrated against the WHO 4th International Std for Chorionic Gonadotropin 75/589.

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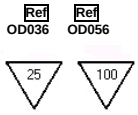


Test	Device

Comprising of membrane assembly predispensed with anti-hCG monoclonal antibodies conjugate to colloidal gold and colloidal gold conjugated rabbit IgG. Anti-hCG polyclonal antibodies on the test line and goat anti-rabbit IgG on the control line. Disposable plastic dropper (50μl drop size). Desiccant bag.

INSTRUCTION LEAFLET	1	1

PRECAUTIONS

VISITECT reagents do not contain dangerous substances as defined by current UK Chemicals (Hazardous Information and Packaging for Supply) regulations. All reagents should, however, be treated as potential biohazards in use and disposal. Final disposal must be in accordance with local legislation. Do not ingest.

STORAGE

Reagents must be stored at temperatures between 4°C to 30°C.

The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on kit and components. Expiry date is the last day of the month on the pouch and the kit label. Do not use reagents after the expiry date.

Exposure of reagents to excessive temperatures should be avoided. Do not expose to direct sunlight.

DO NOT FREEZE DEVICE as this will cause irreversible damage.

SPECIMEN COLLECTION AND PREPARATION

Serum: Obtain a sample of venous blood from the patient and allow a clot to form and retract. Centrifuge clotted blood sample and collect clear serum. Fresh serum samples are required.

Do not use haemolysed, contaminated or lipaemic serum for testing as this will adversly affect the results.

Serum may be stored at 2°C to 8°C for up to 48 hours prior to testing. If longer storage is required, store at –20°C for up to 6 weeks. Thawed samples must be mixed prior to testing.

Do not repeatedly freeze-thaw the specimens as this will cause false results.

Urine: Urine samples collected at any time may be used, however, it is recommended that to maximise hCG concentration, the first voided morning specimen should be used. The urine should be collected in a clean dry container (plastic or glass) which must be free from detergent. Urine specimens should be as fresh as possible and it is preferable to test within 24 hours of collection. The sample may be stored for longer periods (72 hours) prior to use, if stored, store at 2°C to 8°C.

Filtration or centrifugation is generally not necessary for urine used in the **VISITECT PREGNANCY** test, however, if a sample is very turbid, centrifugation or filtration may be necessary. (The use of supernatant from turbid samples allowed to sediment naturally prior to use may negate the need for sample preparation – this does not affect the hCG concentration.)

REAGENT PREPARATION

Devices and samples should be brought to room temperature (20°C to 25°C) and mixed gently prior to use.

In case the pouch has been stored at 4°C to 8°C, allow at least 30 minutes for the device to come to room temperature. Check the colour of the desiccant. It should be blue. If it has turned colourless or faint blue, discard the device and use another device.

LIMITATIONS OF USE

The use of samples other than serum or urine have not been validated in this test.

There is no reuse protocol for this product.

A low or suspected positive result should be re-assessed. Diagnosis should not be made solely on the findings of one clinical assay. When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

A number of conditions other than pregnancy, including trophoblastic and non-trophoblastic neoplasm such as hydatidiform choriocarcinoma etc cause elevated levels of hCG. Such clinical conditions must be ruled out before a diagnosis of pregnancy can be made.

Highly dilute urine specimens and specimens from very early pregnancy may not contain representative levels of hCG. If pregnancy is still suspected, repeat the test with first morning urine 48-72 hours after the initial test.

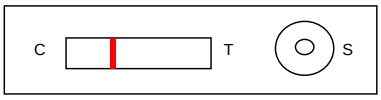
False positive and false negative pregnancy tests have been reported in tests of specimens from individuals taking a variety of drugs. The false reaction may be related to the donor and/or the drug. Whenever possible, it is best to test the specimen from donors who are not taking drugs.

ASSAY PROCEDURE

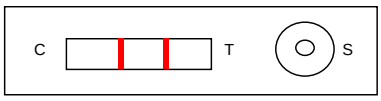
1. Open the pouch and remove the device. Once opened, the device must be used immediately.
2. Dispense two drops of urine or serum specimen into the sample well 'S' using the dropper provided.
3. Read the results at the end of fifteen minutes for serum or five minutes for urine.

RESULTS AND INTERPRETATION

Negative: Only one coloured line appears on the control region 'C' only.



Positive: A distinct coloured line appears on the control region 'C' and on the test region "T".



The test should be considered invalid if no line appears. Repeat the test with a new device.

Depending on the concentration of hCG in the specimen, positive results may appear as early as 30 seconds. Negative results must be confirmed only at the end of fifteen minutes for serum or five minutes for urine.

TROUBLESHOOTING

Use a separate disposable dropper for each sample to prevent cross contamination.

Prior to the start of the assay bring all reagents to room temperature (20°C to 25°C).

For use by operatives with at least a minimum of basic laboratory training.

Do not use damaged or contaminated kit components.

EVALUATION DATA

Reproducability of **VISITECT PREGNANCY** is 100% (+/- one double dilution).

	VISITECT PREGNANCY		Totals
	+	-	
hCG +	273	1	274
hCG -	1	948	949
	274	949	1223

Sensitivity 99.6%
Specificity 99.9%

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