hCG One Step Pregnancy Test Cassette
(Urine/Serum)

IVD CE

PRODUCT CODE
RT001

INTENDED USE
hCG One Step Pregnancy Test Cassette(Urine/Serum) is an immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine and serum. The test is used to obtain a visual qualitative result. It is for professional in vitro diagnostic use only.

PRINCIPLE
Human chorionic gonadotropin (hCG) is a hormone, produced by the developing placenta shortly after the conception and secreted into the urine and serum. The pregnancy test contains antibodies which specifically react with this hormone. When the specimen is dropped into the sample well of the device, capillary action carries the specimen to migrate along the membrane. Holding a Sample Dropper vertically, add exactly urine or serum specimen to the sample well marked S. When hCG in the sample reaches the Test Zone region of the membrane, it will form a colored line. Absence of this colored line suggests a negative result. To serve as a procedure control, a colored line will appear at the control zone region, if the test has been performed properly.

MATERIALS SUPPLIED
1. Test Cassette 2.Desiccant 3.Package Insert 4.Dropper

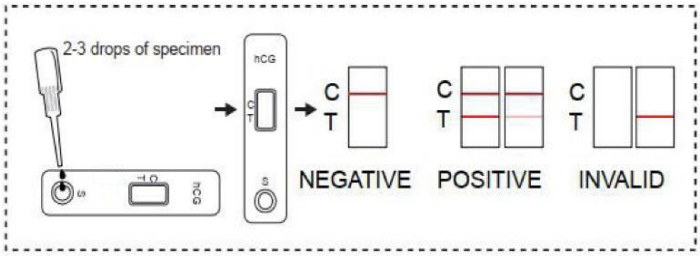
ADDITIONAL REQUIREMENTS
1. Clock or Timer
2. Specimen collection containers.

REAGENT STORAGE AND STABILITY
1. Store at 2℃ to 30℃ in the sealed pouch up to the expiration date. If stored at 2℃-8℃ ensure that the test device is brought to room temperature before opening.
2. Keep away from sunlight, moisture and heat.
3. DO NOT FREEZE.
4. Preferably open the pouch shortly before the test.

The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30℃.

SPECIMEN AND SAMPLE PREPARATION
1. Any urine specimen is appropriate for pregnancy testing but the first morning urine specimen is optimal because of its highest concentration of hCG.
2. Separate the serum from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below - 20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

PROCEDURE
1. Remove the Test Device from the foil pouch by tearing at the notch and place it on a level surface.
2. Holding a Sample Dropper vertically, add exactly 2-3 drops of specimen to the sample marked S.
3. Read results in 5 minutes. Do not read results after more than 5 minutes.



RESULTS
Positive: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
Negative: One red line appears in the control region (C).No apparent red or pink line appears in the test region (T).
Invalid: The result is invalid if no red line appears in the control region (C), even if a line appears in the test region (T). You should repeat the test with a new test.
NOTE: if the test line is weak, it is recommended that the test be repeated in 48 hours

SYMBOLS OB LABEL

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCE

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4. Lenton EA, LM Neal, R Sulaiman Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy, Fertil. Steril. 1982; 37(6): 773-778
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