LIMITATIONS OF TEST

.The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of HCG in urine from individual subjects. Failure to follow the procedure may lead to inaccurate results.

.If a urine specimen is too diluted, it may not contain representative levels of HCG. If pregnancy is still suspected, a first morning urine should be obtained from the person and the test repeated. The HCG concentration less than 25 mIU/mL may be detected as negative.

.A number of disease conditions other than pregnancy such as trophoblastic disease, proteinuria, hematuria, choriocarcinoma, ovarian and testicular teratomas can cause elevated levels of HCG. The diagnosis should be considered if appropriate to the clinical evidence.

.Immunologically interfering substances such as those used in antibody therapy treatments may invalidate this assay.

.Samples containing very high levels of HCG ≥ 500,000 mIU/mL may yield a test line with

.Color intensity lighter than that, which is expected.

.Ectopic pregnancy cannot be distinguished from normal pregnancy from HCG measurements alone.

.Samples from patients on chemotherapy for cancer should be ruled out before running the assay.

.Positive HCG levels may be detectable for several weeks following delivery or abortion.

.Specimens testing positive during the initial days after conception may be negative later due to natural termination of the pregnancy.

.Low HCG levels may be found in the specimens from highly suspected pregnant women. Some abnormal conditions should be ruled out, such as miscalculation of pregnancy dating, possible miscarriage or blighted ovum, ectopic pregnancy, or cryptic pregnancy.

. A single HCG measurement may not provide enough information for most diagnoses as the change in HCG concentration is more important than the concentration detected. When obtaining negative test results during a suspected pregnancy, it is recommended to retest a few day later, or test with a specific alternative test method, such as ultrasonography.

.Results obtained with the HCG Rapid Test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

EXPECTED VALUES

. Healthy men and healthy non-pregnant women do not have detectable HCG by the HCG Rapid Test.

The HCG levels of 100 mIU/mL can be reached on the day of the first missed menstrual period.

The HCG levels peak about 7-12 weeks after the last menstrual period and then decline to lower values for the remainder of the pregnancy.

Following delivery, HCG levels rapidly decrease and usually return to negative shortly after parturition.

REFERENCES

.Montagnana M, Trenti T, Aloe R, Cervellin G, Lippi G. Human chorionic gonadotropin in pregnancy diagnostics. Clin Chim Acta. 2011 Aug 17; 412(17-18):1515-20.

.Cart KJ, Dufau ML, Vaitukaitis JL. Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyst. J Clin Endocrinol Metab. 1975 40:537-40.

.Braunstein GD, Rasor J, Danzer H, et al. Serum human chorionic gonadotropin levels throughout normal pregnancy. Am J Obstet Gynecol. 1976, 126:678-81.

INDEX OF SYMBOLS

Symbol	Meaning	Symbol	Meaning
	Caution/Warning (Read instruction before use)		Date of Expiry
	Manufacturer	LOT	Batch/Lot Number
	Date of Manufacturing		Don't re-use
REF	Catalogue number	IVD	Invitro Diagnostic device
	Temperature Limitation		Consult IFU
	Keep away from sunlight		Do not use if package damaged
	NON-STERILE	CE	CE Syymbol
EC REP	Name and address of European union representative		

IFU No.: R/IFU/PG/01
Issue Date: 01/12/2022
Rev.00

REVITAL HEALTHCARE (EPZ) LIMITED,
LR NO. 5025/1239 TAKAUNGU,
P.O BOX 80713-80100 MOMBASA, KENYA ,
Email: info@rhcare-epz.com,
Website: www.revitalhcare.com .
Consumer Complaint cell/Coordinator: +254722412900

Revital®

CADY® PREGNANCY RAPID TEST

INTENDED USE

CADY pregnancy rapid test is a lateral flow chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in human urine. It is intended to be used by professionals or consumer self-test and provides a preliminary test result of early pregnancy. It is mainly used for the auxiliary diagnosis of early pregnancy, and cannot be used for the detection of trophoblastic tumor.
Any use or interpretation of this preliminary test result must also rely on other clinical findings and the professional judgement of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY

Human chorionic gonadotropin (HCG) is a chemical created by trophoblast tissue, tissue typically found in early embryos and which will eventually be a part of the placenta. Measuring HCG levels can be helpful in identifying a normal pregnancy, pathologic pregnancy and can also be useful following an aborted pregnancy.
The hormone itself is a glycoprotein composed of two subunits, the alpha and the beta subunits. There are multiple forms found in the serum and urine during pregnancy including the intact hormone and each of the free subunits. HCG is primarily catabolized by the liver, although about 20% is excreted in the urine. The beta subunit is degraded in the kidney to make a core fragment which is measured by urine. In a 28 days cycle with ovulation occurring at a day 14, HCG can be detected in urine or serum in minute quantities around day 23, or 5 days before the expected menstruation. Its function includes facilitation of implantation as well as maintenance and development of the corpus lutem. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mena concentration of 500,000 mIU/ml. Concentrations as high as 100,000 mIU/ml have been reported in normal pregnancies during the first trimester. In normal condition, HCG in urine provides an early indication of pregnancy. Since elevated HCG levels are also associated with trophoblastic disease and certain non-trophoblastic neoplasms, the possibility of having these diseases must be eliminated before a diagnosis of pregnancy can be made.
Urine test for HCG is immunometric assays, is more convenient, affordable, comfortable for patients has a fast turnaround (3 to 5 minutes) and does not require a medical prescription.

TEST PRINCIPLE

CADY pregnancy rapid test is a lateral flow chromatographic immunoassay.
The test strip in cassette device consists of:
1.A burgundy conjugate pad containing antibodies to anti-HCG conjugated with colloidal gold.
2.A nitrocellulose membrane strip containing atleast line (T line) and control line (C line). The T line is pre-coated with antibodies to beta-HCG and the line C line is pre-coated with a control line antibody. The antibodies recognize the beta-HCG antigens from urine sample. When an adequate volume of specimen is dispensed into the sample well of the tests cassette, the specimen migrates by capillary action across the cassette. The HCG if present at the level equal or higher than 25 mIU/mL in urine specimen will bind to the anti-HCG conjugated with colloidal gold.

The immunocomplex is then captured on the membrane by the pre-coated antibodies to HCG antigens forming a burgundy T line, indicating HCG positive test result and suggesting ana early pregnancy.
Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a burgundy line of the immunocomplex of the control bodies, regardless of colour development on the test line (T line). If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED.

Individually sealed foil pouch containing:
1.One test strip/device (according to product specification and model).
2.One desiccant.
3.Plastic droppers (optional)
4.Plastic container (optional)
5.One package insert (instruction for use)
·The quantity of plastic container, sealed foil pouches and plastic droppers is confirmed according to the packaging specification.

MATERIAL REQUIRED BUT NOT PROVIDED

Clock or timer.

WARNINGS AND PRECAUTIONS

For In Vitro diagnostic use.
1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2.Do not open the sealed pouch unless ready to conduct the assay.
3.Do not use expired devices.
4.Bring all reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7.Users of this test should follow the US CDC universal precautions for prevention of transmission of HIV, HBV or other pathogens.
8.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9.Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10.The test result should be read 3-5 minutes after a specimen is applied to the sample well or sample pad of the device. Any results interpreted outside of the 10 minutes window should be considered invalid and must be repeated.
11.Do not perform the test in a room with strong air flow, i.e electric fan or string air conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

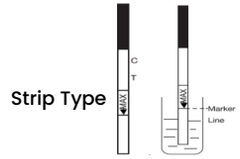
All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-35°C. if stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 35°C.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

Consider any materials of human origin as infectious and handle them using standard bio- safety procedures. First morning urine usually contains the highest concentration of HCG and is therefore the best sample when performing the urine test. However, randomly collected urine specimens may be used. Collect a urine specimen in a Plastic, clean glass, or wax coated container.
Test specimens as soon as possible after collecting. If not tested immediately, store specimens at 2-8°C for up to 48 hours. If refrigerating or freezing specimens, please allow the specimen to equilibrate to room temperature before testing.

ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once the specimen is thawed, mix well prior to performing the assay.
Step 2: When ready to test, open the pouch at the notch and remove test strip/devices.
Step 3: Be sure to label the device with the specimen's ID number.
Strip Type:
Please immerse the end of the test strip with the arrow mark vertically into the container containing urine and take at least 15 seconds. Place the test strip on a flat and clean surface.
* the urine interface should not exceed the "Max" line on the test strip



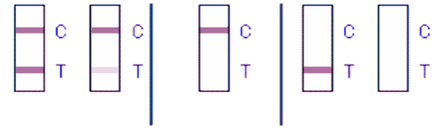
Devices Type:
Place the test device on a flat and clean surface. Fill the plastic dropper with the specimen. Fill the plastic dropper with the specimen. Holding the dropper vertically, dispense 2-3 drops (60-105 µL) of specimen into the sample well making sure that there

QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C line. The C line develops after adding specimen. Otherwise, review the whole procedure and repeat test with a new device.

INTERPRETATION OF ASSAY RESULT

1.POSITIVE RESULT: If both C and T lines develop, the test indicates for the presence of HCG in the specimen. The result is HCG positive or reactive.
* Specimens with reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.
2.NEGATIVE RESULT: If only the C line develops, the test indicates that no detectable HCG is present in the specimen. The result is HCG negative or non-reactive.
3.INVALID: If no C line develops, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.



ASSAY PROCEDURE

Clinical Performance
A total of 319 fresh urine specimens were randomly collected from two groups of patients (pregnant and non-pregnant) at two geographically dispersed centers, and tested by HCG Rapid Test and by HCG chemiluminecence or ELISA. Comparison for all subjects is shown in the following table 1:

No. 00

Table 1 HCG Rapid Test Kit

Reference	*Positive*	*Negative*	*Total*
Positive	*187*	*0*	*187*
Negative	*0*	*132*	*132*
Total	*187*	*132*	*319*

Relative Sensitivity: 100% (95% CI: 98.1% - 100%)
Relative Specificity: 100% (95% CI: 97.2% - 100%)
Overall Agreement: 100% (95% CI: 98.9% - 100%)
ØAnalytical Sensitivity
The detection limit of HCG for the HCG Rapid Test is 25 mIU/mL in urine specimen. The following experiments were done to validate the sensitivity of the HCG Rapid Test: Five groups of urine from 20 normal non-pregnant healthy individuals. (confirmed HCG negative using CE/FDA cleared HCG test) were spiked with HCG to the standard (5th IS) concentrations of 0, 6.25, 12.5, 25, 50 mIU/mL.The specimens were run on the HCG Rapid Test. Results were observed at 5 minutes and tabulated in tables 2.

Table 2

hCG mIU/mL in urine specimens	*0*	*6.25*	*12.5*	*25*	*50*
Number of Positive	*0*	*0*	*11*	*20*	*20*
Number of Negativ	*20*	*20*	*9*	*0*	*0*
Detection Rate %	*0%*	*0%*	*45%*	*100%*	*100%*

n=20; Positive Detection Rate at 25 mIU/mL is 100%

Analytical Specificity

Specificity of the HCG Rapid Test was determined from studies on specimens with the following standard obtained from SIGMA. Specimens containing these structurally related hormones at tested concentrations were found not to significantly cross-react with the HCG Rapid Test.
human luteinizing hormone (hLH) 1,000 mIU/mL
human follicle stimulating hormone (hFSH) 1,000 mIU/mL human thyroid stimulating Hormone (hTSH) 1,000 mIU/mL

Dose Hook Effect

No false negative results due to the dose hook effect were observed for urine specimens containing HCG at concentrations up to 500,000 mIU/mL.

Interference

Biologicals and chemicals analytes commonly found in OTC, prescriptions, or abuse drugs were tested in two HCG standard spiked confirmed negative urine at 50 mIU/mL and 25 mIU/mL. Spiked samples were tested against following substances or pHs at the indicated concentrations resulted in no interference with or without the existence of the chemical and biological analytes using HCG Rapid Test.
Biological Analytics