

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

hCG, Urine by Acceava®

Principle

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta. The placenta begins to produce detectable amounts of this hormone as soon as the first week following implantation (about the time as the first missed menstrual period). The concentration of hCG in the urine increases rapidly in a normal pregnancy, reaching a maximum concentration in excess of 100,000 mIU/mL during the latter part of the 1st trimester of pregnancy.

Urine hCG levels are used to confirm pregnancy. However, hCG can also be produced pathologically by some tumors, particularly those arising from trophoblastic cell lines. Increased levels of urine hCG may also be found in women with hydatidiform moles and in ectopic pregnancies. Some testicular tumors in men secrete hCG and/or alpha fetoprotein.

The hCG molecule is composed of two noncovalently bound subunits. The alpha subunit has a molecular weight of approximately 2,000 daltons, and is structurally similar to the alpha subunits of follicle stimulating hormone (FSH), luteinizing hormone (LH), and thyroid stimulating hormone (TSH). This structural homology accounts for crossreactivity problems with some antisera. The beta subunit has a molecular weight of approximately 30,000 daltons, and it is the structure of this subunit that accounts for the biological activity of the hCG molecule.

The Acceava® hCG Combo II test is a solid phase, sandwich-format chromatographic immunoassay for the qualitative detection of hCG in urine. The test uses mouse monoclonal anti-hCG and goat polyclonal anti-hCG antibodies to detect hCG present in the sample, which will react with the anti-hCG gold conjugate to produce a colored line in the test region of the membrane.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Specimen Requirement

1. Sample requirement is 2-5 mL of fresh urine. (1 hour at room temp)
2. Urine specimens are stable at 2-8°C for 48 hours.
3. The first morning urine is optimal because it generally contains the highest concentration of hCG.

4. Very turbid urine or off colored urine should be sent to Core Lab to be processed.

Limitations

1. The test cassette should remain in the sealed pouch until use.
2. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. False negative results may occur when the levels of hCG are below the sensitivity level of the test.
4. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

The following potentially interfering substances were added to hCG negative and positive specimens. All substances listed in mg/dL unless otherwise noted.

Acetaminophen	20	Acetone	1,000
Acetylsalicylic Acid	20	Acetonacetic Acid	2,000
Ampicillin	20	Ascorbic Acid	20
Atropine	20	Albumin	2,000
β -Hydroxybutyrate	2,000	Benzoyllecgonine	10
Bilirubin	20	Brompheniramine	20
Caffeine	20	Cannabinol	10
Chlomiphene	100	Cocaine	10
Codeine	10	Cholesterol	500
Creatine	20	Dextromethorphan	20
DMSO	5%	EDTA	80
Ephedrine	20	Ethanol	1%
Estriol	2	Estrone 3-Sulfate	10
Gentisic Acid	20	Glucose	2,000
Hemoglobin	1,000	Heroin	1
Ibuprofen	20	Methadone	10
Methamphetamine	10	Methanol	10%
Morphine	0.6	Oxalic Acid	40
Phenothiazine	20	Phenylpropanolamine	20
Pregnanediol	2	Salicylic Acid	20
Tetracycline	20	Triglycerides	1,200
Theophylline	20	Urea	2,000
Uric Acid	20		

None of the substances at the concentration tested interfered in the assay.

Linearity

1. Detects the presence of ≥ 20 mIU/mL hCG.

Reference Range

1. Healthy pregnant females should have an hCG of 20 mIU/mL or greater as early as 1 day after the first missed period.
2. Healthy males and non-pregnant females should be negative for urine hCG.

Alert Values

None.

Quality Control

1. Quantimetrix the dropper urine control levels 1 and 2 is run each time that a new kit is opened, before patient testing is performed. Controls must be brought to room temperature before testing, no preparation required.
2. Run controls as described in the Procedure section below, using 3 drops of QC material instead of patient's sample.
3. Each test cartridge has a control (C) position that must appear as a distinct reddish band to indicate proper function of the test cartridge. If the control band is not present, or is incomplete, the result is invalid and must be repeated with a fresh cartridge.
4. For patient tests, record the Internal Quality Control in the patient's electronic medical record in EPIC as 'passed'.
5. Record kit lot number, control lot number, expiration dates, and results of QC in the POC urine hCG log book.
6. Write 'QC'd' date on the kit box.

Procedure

1. If patient sample has been refrigerated, allow it to warm to room temperature before testing.
2. Remove test cartridge and pipette from the foil pouch.
3. Label the test cartridge for each patient sample and control level to be tested.

4. While holding the provided pipet vertically, dispense three (3) drops of the patient's sample into the sample well on the right side of the test cartridge. If running controls, dispense three (3) drops from the control vial into the sample well on the right side of the test cartridge.
5. Incubate the test cartridge at room temperature and read results between three (3) and five (5) minutes only.

Reporting Results

1. For each sample report the hCG result from the Accева cartridge. Interpret as follows:

COLOR DEVELOPMENT	RESULT	INTERPRETATION
Two reddish bands, one at T (Test), and one at C (Control)	Positive	Positive
One reddish band at only the C (Control) position	Negative	Negative
No band development at the C (Control) position, or incomplete bands at either T or C positions	Invalid, repeat with new cartridge	Invalid, do not report.

2. Record the patient results in the patient's medical record. Include the results of the internal QC.
3. Do not report patient results if the Control line fails to appear next to the letter C. The test result is invalid. The test MUST be repeated using a new test cartridge.
4. At the read time, the background should appear white to light grey and not interfere with the reading of the test. The test is invalid if the background fails to clear and obscures the formation of a distinct control band. The test MUST be repeated using a new test cartridge.
5. If the repeat Control line fails to appear, do not repeat again. Send the urine sample to the Core Laboratory.

Notes

1. The C (Control) zone of the results window must show a distinct reddish band. Absent, incomplete or beaded bands in the control zone indicate an invalid result. Repeat the assay using a new test cartridge.
2. If the repeat run does not resolve the problem, do not report results. Send the urine sample to Core Lab for the urine hCG test.

Reagents

1. The Acceava hCG Combo II Test kit (logistics #145604) is stable at room temperature (15-30°C) until the expiration date printed on box.
2. The Quantimetrix Dropper Plus Urine Control, Level 1 and 2 (logistics #154396). Store controls at 2-8°C until label expiration.

References

1. Burtis, C A, Ashwood, E R; Tietz Fundamentals of Clinical Chemistry, 5th Edition, 2001; 908.
2. Wilcox, A J, et. al. Time of Implantation of the Conceptus and Loss of Pregnancy. New England Journal of Medicine. 1999; vol 340 no 23: 1796-1799.
3. Lenton, E A, Neal, L M, Sulaiman, R; Plasma Concentrations of Human Chorionic Gonadotropin From the Time of Implantation Until the Second Week of Pregnancy. Fertility and Sterility, 1982. Vol. 37, No. 6: 773-778.
4. Acceava hCG Combo Test package insert, 12/2008.

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