QUIDEL | QuickVue®

hCG Urine Test

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the QuickVue hCG Urine Test?
The suggested CPT codes is 81025.* The Medicare National Limit amount** is $8.61.

What is the CLIA complexity of this kit?
This test is CLIA waived.

Can any brand of external controls be used with this test?
No, we cannot guarantee results with another manufacturer's controls. We recommend using the QuickVue controls:

- Urine hCG control set – Cat. #00272

How often should external controls be run on the test?
Good Laboratory Practice suggest that external controls should be tested with each new lot or shipment of test materials, and as otherwise required by your laboratory's standard quality control procedures.

What is the shelf life of the QuickVue hCG Urine Test kit and hCG Control Set? How should they be stored?
From date of manufacture:

- QuickVue hCG Urine: 18 months, room temperature
- Urine Control (buffered): 12 months, room temperature

What is the detection limit of the test?
The QuickVue hCG Urine Test kit has a detection limit of 25 mIU/mL.

How soon after conception do your products detect pregnancy?
In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32-48 hours. For some patients, an hCG level of 25 mIU/mL (clinically significant pregnancy level) can be detected as early as 2-3 days before expected menses.

How long after delivery, spontaneous abortion (estimated to occur in up to 31% of pregnancies overall) or hCG injections, will hCG remain detectable in the patient sample?
hCG may remain detectable for a few days to two months after these events, depending upon the starting level of hCG.

Are there any diagnosis/conditions in which a patient may not have a normal pregnancy but produce a low-level positive test result?
Ectopic pregnancy, undiagnosed (sub-clinical) abortion, spontaneous abortion, blighted ovum, patients with trophoblastic and non-trophoblastic disease may have elevated hCG levels. The possibility of hCG secreting

neoplasms should be eliminated prior to the diagnosis of pregnancy. In addition, serum of postmenopausal women may also contain low-levels of hCG.[1]

Are there any known substances that interfere with the test?
The metabolites, analytes, chemicals, etc. we have studied at the levels indicated in our Package Insert have been shown not to interfere with the test. Birth control pills (BCP) do not affect our tests. There is no other data available regarding other chemicals that may cause interference.

Can serum or plasma be used on this test?
No. Serum and plasma are not FDA approved sample specimens for this test.

Can dilute urine (specific gravity of less than 1.007) produce a false negative result?
If the urine is very dilute and has a low specific gravity, the sample may not contain representative urinary hCG concentrations and may fall below the detection level of our test. If this is suspected, it is suggested that another sample be used, ideally first morning void. Significant variation of hCG in serum vs. urine may occur due to diurnal variation. If it is not medically advisable to postpone testing, it is advisable to perform a beta quantitative test.[2]

Can I read the results after the read time has passed?
Results are to be read at the 3-minute result read time. Results obtained when there are variations from the procedure cannot be guaranteed.

What volume of patient sample is dispensed by the droppers included in the QuickVue hCG Urine Test kit?
3 drops = 125 µL

*For state by state fee schedule go to www.cms.gov.

****Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service.*** Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.

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[1]Braunstein, G., M.D., hCG Testing: A Clinical Guide for the Testing of Human Chorionic Gonadotropin, Abbott Diagnostics Educational Services, Abbott Park, Ill., 1989: p. 23.
[2]Sanford, T., Clinical Diagnosis by Laboratory Methods. 14th Ed. P. 43.