



## Frequently Asked Questions

### **What are the CMS suggested CPT codes and National Limit Amounts for the QuickVue® One-Step hCG Urine, Combo, and QuickVue+® One-Step hCG Combo test kits?**

The suggested\*\*\* CPT codes are:

- Urine: 81025QW\*\*
- Serum: 84703

The Medicare National Limit Amount\* is \$9.06 when billing for Urine and \$10.76 when billing for Serum.

### **What is the CLIA status of our kits?**

CLIA waived for urine and moderately complex for serum.

### **What is the ICD-9 code for these kits?**

This is NOT to be suggested by Quidel or representatives on behalf of Quidel. This is determined by the clinician's diagnosis.

### **What is the shelf life of your products? How should they be stored?**

From date of manufacture:

- QuickVue® One-Step hCG Urine: 18 months, room temperature
- QuickVue One-Step hCG Combo: 18 months, room temperature
- QuickVue+® One-Step hCG Combo: 21 months, room temperature
- Urine Control (buffered): 12 months, room temperature
- Serum Control (lyophilized): 24 months, refrigerated
  - Reconstituted aliquots: 6 months frozen. After thawing, 2 weeks, refrigerated

### **What is the detection limit of the test?**

- QuickVue One-Step hCG Urine: 25 mIU/mL (urine only)
- QuickVue One-Step hCG Combo: 25 mIU/mL (urine or serum)
- QuickVue+ One-Step hCG Combo: 10 mIU/mL for serum, 20 mIU/mL for urine

### **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 to 48 hours. Levels at 25 mIU/mL of hCG (clinically significant pregnancy level) are reportedly present in serum and urine 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.

**What should be done if a very low, faint positive result is obtained from a serum sample?**

Another sample should be obtained in 48 hours and retested. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test.

**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.<sup>1</sup>

**Do heterophilic antibodies interfere with the test?**

The presence of heterophilic antibody (HA) against mouse, goat, rabbit, horse or sheep antigens may be present in serum, however, it is not found in urine. This may cause discordant results. Use of a competitor's product may not block this interference. Phantom hCG may be due to HA binding to immunoglobulins of animal origin in the test. The reported frequency of HA in serum of healthy patient populations is 3-15%. Quidel has incorporated heterophilic antibody blocking agents to neutralize this interference. Heterophile antibodies do not interfere with our hCG test kits.<sup>2</sup>

**Are there any known substances that interfere with your tests?**

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

**Can plasma be used on your tests?**

No. Plasma is not an FDA approved sample specimen for these tests.

**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.

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<sup>1</sup>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.

<sup>2</sup>Reference design history file (on file at Quidel Corporation).

**Can I read the results after the read time has passed?**

Results are to be read at the time specified in the Package Insert. Results obtained when there are variations from the procedure cannot be guaranteed.

**Can any brand of external controls be used with our tests?**

No, we cannot guarantee results with another manufacturer's controls. We recommend using the QuickVue controls:

- Urine hCG control set #00272
- Serum hCG control set #00281

**What volume of patient sample is dispensed by the droppers included in your kits?**

- QuickVue One-Step hCG Urine: 3 drops = 125 µL
- QuickVue One-Step hCG Combo: 3 drops = 125 µL
- QuickVue+ One-Step hCG Combo: 4 drops = 160 µL

\*For state by state fee schedule go to [www.cms.gov](http://www.cms.gov).

\*\*\*"QW" modifier is added to report use of CLIA-Waived test system(s) for Medicare/Medicaid claims.

\*\*\****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.