



Frequently Asked Questions

What is the CMS suggested CPT code and National Limit Amount for the QuickVue® H. pylori gII® kit?

The Medicare National Limit Amount* is \$18.34. The suggested*** CPT codes are:

- Whole Blood: 86318QW**
- Serum/Plasma: 86318

What is the CLIA status of this kit?

CLIA waived for whole blood; moderately complex for serum or plasma.

What is the kit shelf life and storage?

The kit shelf life is 14 months from the date of manufacture and should be stored at room temperature (59-86°F, 15-30°C).

What is the minimum sample requirement?

For venipuncture samples, use the droppers provided in the kit to place one drop of blood (plasma, serum or whole blood) onto the test cassette. For fingerstick samples add full volume of the capillary tube, filled to the black line, or 2 drops of hanging blood directly from fingertip. Approximate volume added is 50 µL.

What is the detection limit of the test?

The test is intended for the qualitative detection of the presence of *H. pylori* IgG antibodies. Correlation studies were performed with biopsy (culture and/or histology) serving as the reference method for the QuickVue H. pylori gII test. See Package Insert, Performance Characteristics. Quantitative EIA detection values are established by individual laboratories. EIA results may not reflect the actual presence of the *H. pylori* antibodies when below quantitative detection limits.

Will this kit differentiate between active and inactive infection? How long after diagnosis and treatment will the patient show positive?

No. This test detects the presence of *H. pylori*-specific IgG antibodies. Depending on the individual, it could take up to 9-12 months after treatment for the IgG antibodies to clear out of a person's bloodstream so that they are no longer detected by this test. This test cannot be utilized to monitor therapy nor confirm eradication of the bacteria in the weeks following treatment.¹

¹ Graham, K.S., MD and Graham, D.Y., MD. Contemporary Diagnosis and Management of H. pylori-Associated Gastrointestinal Diseases: 2nd ed. 2002; p.77.

What tests are available to confirm the results?

Confirmation tests include histology and rapid urease testing (RUT) from biopsy specimens, and tissue culture.²

The test result is negative at the 5 minute read time, but a pink test line develops after the 5 minute read time. What is the result?

Test results should be read at the specified read time. Verify the delivery of the specimen is according to the insert as this may affect the flow rate of the specimen across the strip. Conversion after the specified read time may occur on occasion. If the patient is symptomatic and results are negative, the patient may have a low antibody titer. Any result read after the read time is considered invalid.

Will hemolyzed blood affect the results?

Hemolysis is the breakdown of red blood cells. This will introduce a red color to a serum or plasma blood sample. The resulting samples may vary from pink tinged (slightly hemolyzed) to dark red (markedly hemolyzed). This color may affect the test background color making it difficult to read the test. If the background color interferes with the readability of the test, re-collect sample and run another test.

What affects the sample flow into the test well?

Viscous serum, excess or inadequate sample, or misplaced sample touching the sides of the well at delivery may retard or redirect the flow through the strip. Hematocrits up to 60 have not affected sample flow. Bubbles in the pipetted sample displace blood. If a significant volume is displaced, there may not be sufficient sample to test or flow may be disrupted.

Can this be used to test children?

Performance characteristics for persons under 18 years of age have not been established with this test.

How often should external Controls be run on this test?

Quidel recommends that Positive and Negative Controls be run with each new lot or shipment and as deemed necessary by your internal laboratory procedures.

*For state by state fee schedule go to 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.

² CDC *Helicobacter pylori*, Fact Sheet for HealthCare Providers (1998).