

Lab Name:

Procedure #:

Procedure: CLIA Complexity: Waived for urine samples; Moderate for serum samples

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2.

Quidel Corporation provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

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CLIA Complexity: Waived – Urine / Moderate – Serum

INTENDED USE

The QuickVue One-Step hCG Combo test is a one-step immunoassay intended for the qualitative detection of human Chorionic Gonadotropin (hCG) in serum or urine for the early detection of pregnancy. The test is intended for use by healthcare professionals.

SUMMARY AND EXPLANATION

Human Chorionic Gonadotropin is a hormone produced by the placenta shortly after implantation. Since hCG is present in the serum and urine of pregnant women, it is an excellent marker for confirming pregnancy.

PRINCIPLE OF THE TEST

The QuickVue test uses a monoclonal antibody specific to the beta subunit of hCG in a single-step technology to accurately detect hCG.

Serum or urine is added to the Sample Well on the Test Cassette. If hCG is present in the specimen at a level of 25 mIU/mL or greater, a pink-to-red Test (T) Line will appear along with a blue procedural Control (C) Line in the Result Window. If hCG is present at very low levels, or not present in the specimen, only a blue procedural Control Line will appear in the Result Window.

REAGENTS AND MATERIALS SUPPLIED

- 50 individually wrapped Test Cassettes
 - Test Strip contains murine monoclonal anti-hCG antibody
- 50 disposable pipettes
- 1 Package Insert
- 1 Procedure Card

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MATERIALS REQUIRED BUT NOT PROVIDED

- Watch or clock that measures minutes
- Specimen collection containers

MATERIALS RECOMMENDED BUT NOT PROVIDED

- External hCG controls traceable to WHO Standard (4th IS 75/589).

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use kit contents after the expiration date printed on the outside of the kit.
- Use of Nitrile or Latex gloves is recommended when handling patient samples.¹
- Use appropriate precautions in the collection, storage, handling and disposal of patient samples and used kit contents.
- Dispose of containers and unused contents in accordance with Federal, State, and Local requirements.
- To obtain accurate results, you must follow the Package Insert instructions.

KIT STORAGE AND STABILITY

Store kit at room temperature 59–86°F (15–30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box carton.

SPECIMEN COLLECTION AND STORAGE

Serum

No special patient preparation is necessary. A whole blood specimen should be obtained by standard medical procedures. After clotting has occurred, the separated serum should be used for testing.

Serum specimens may be stored at room temperature for up to 8 hours or refrigerated at 36–46°F (2–8°C) for up to 72 hours prior to assay. Samples may be frozen once at -20°C or below. If frozen, mix after thawing. Do not refreeze. Do not chemically modify the serum in any way.

Urine

Collect specimens in clean container. First morning specimens generally contain the highest concentrations of hCG and are recommended for early detection of pregnancy. However, any urine sample is suitable for testing.

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Urine specimens may be kept at room temperature for 8 hours or refrigerated at 36–46°F (2–8°C) for up to 72 hours. Samples may be frozen once at -20°C or below. If frozen, mix after thawing. Do not refreeze.

QUALITY CONTROL

Built-in Quality Control Features

The QuickVue test provides several levels of internal procedural controls with each test run. For daily quality control, Quidel recommends documenting these controls for the first sample tested each day.

The appearance of a blue procedural Control Line is an internal positive control. This indicates that sufficient sample fluid was added for capillary flow to occur and the correct procedural technique was used. If this line does not develop, the test result is considered invalid.

A clear background in the test result window is an internal background negative control. If the test has been performed correctly, the background should be white to light pink within 3 to 5 minutes and not interfere with the reading of the test result.

External Quality Control Testing

External controls may also be used to assure that the reagents are performing properly and that you are able to correctly perform the Test Procedure. For this purpose, we recommend using the hCG Control Set (Catalog Number 00272) or the hCG Serum Control Set (Catalog Number 00281). Some commercial controls may contain interfering additives and are not recommended for use in the QuickVue 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.

TEST PROCEDURE

When performing more than one test, ensure Test Cassettes are labeled correctly. Use a new pipette for each sample/test.

- Remove the QuickVue Test Cassette from the foil pouch just before use and place it on a clean, dry, level surface.
- Using one of the disposable pipettes supplied, collect sample and add **3 DROPS** (125 µL) of serum or urine to the **Round Sample Well** on the Test Cassette. The Test Cassette should not be handled or moved until the test is complete and ready for reading.
- FOR URINE: Read result at **3 minutes**.

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- FOR SERUM: Read result at **5 minutes**.

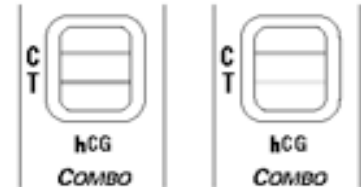
Note: Some positive results may be seen earlier.

INTERPRETATION OF RESULTS

See Procedure Card for color result interpretation.

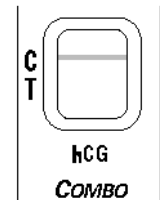
Positive:

Any pink-to-red Test Line (T) along with a blue Control Line (C) is a positive result for the detection of hCG.



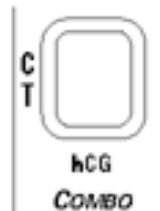
Negative:

A blue Control Line (C) and no pink Test Line (T) is a negative result.



Invalid Result:

The test result is invalid if a blue Control Line (C) is not visible at 3 to 5 minutes. If this happens, retest using a new sample and a new Test Cassette or contact Quidel Technical Support.



LIMITATIONS

- The contents of this kit are for use in the **qualitative** detection of hCG in serum or urine.
- Test results must always be evaluated with other data available to the physician.
- While pregnancy is the most likely reason for the presence of hCG in serum and urine, elevated hCG concentrations unrelated to pregnancy have been reported in some patients.^{2,3} Conditions other than normal pregnancy may be associated with detectable hCG, including, for example, ectopic pregnancy or molar pregnancy.⁴ Patients with trophoblastic and nontrophoblastic disease may have elevated hCG levels, therefore, the possibility of hCG secreting neoplasms should be eliminated prior to the diagnosis of pregnancy.
- hCG may remain detectable for a few days to several weeks after delivery, abortion, natural termination or hCG injections.^{5,6}

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- Abnormal pregnancies cannot be diagnosed by qualitative hCG results. The above conditions should be ruled out when diagnosing pregnancy.
- Early pregnancy associated with a low level of hCG may show color development after the 3 or 5 minute procedure time. If a negative result is obtained but pregnancy is suspected, hCG levels may be too low or urine may be too dilute for detection. Another specimen should be collected after 48–72 hours and tested. If waiting 48 hours is not medically advisable, the test result should be confirmed with a quantitative hCG test.

EXPECTED VALUES

Specimens containing as low as 25 mIU/mL (calibrated against the WHO 4th IS 75/589) hCG will yield positive results when tested with the QuickVue test. In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32 to 48 hours, peaking in excess of 100,000 mIU/mL in approximately ten to twelve weeks.⁷ For some patients, an hCG level of 25 mIU/mL can be detected as early as two to three days before expected menses.⁸ Serum hCG is rapidly cleared into the urine and the concentration of hCG in serum is approximately equal to the concentration in urine.

PERFORMANCE CHARACTERISTICS

A multi-center clinical study was conducted to establish the performance of the QuickVue One-Step hCG Combo test compared to results obtained from another commercially available hCG test. A quantitative method was used to resolve any discrepant results between the two test methods. In this multi-center field trial, 499 urine specimens and 750 serum specimens, collected from patients presenting for pregnancy testing, were evaluated. A concordance of >99% was determined with both urine and serum specimens.

		Urine Correlation		
		hCG Comparative Test		
QuickVue hCG-Combo		+	-	Sensitivity: >99% Specificity: >99% Agreement: >99%
		+	252	
-	0	247		

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		Serum Correlation		
		hCG Comparative Test		
QuickVue hCG-Combo	+	+	-	
	-	375	0	

Physician’s Office Laboratory (POL) Studies

An evaluation of the QuickVue test was conducted at three Physicians’ Offices using a panel of coded specimens. Testing was performed by physician’s office personnel with diverse educational backgrounds and work experience at three geographically distinct locations. The proficiency panel contained negative, low positive and moderate positive samples. Each sample level was tested in multiple replicates at each site over a period of three days.

The results obtained at each site had 100% agreement with the expected results. No significant differences were observed within run, between runs, or between sites.

Cross-Reactivity

hTSH, hLH, and hFSH were tested and showed no cross-reactivity in the test.

Anticoagulant Testing

Matched blood samples were drawn into tubes containing sodium heparin (green-top tube), lithium heparin (green-top tube), potassium EDTA (lavender-top tube) and sodium citrate (pale blue-top tube) and showed no interference in the test.

Interference Testing

The following compounds were tested and did not interfere with the performance of the test.

Chemical Analytes	Concentration
Acetaminophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
β-Hydroxybutyrate	2000 mg/dL
Benzoylcegonine (cocaine metabolite)	10 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Chlomiphene	100 mg/dL
Cocaine	10 mg/mL

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Codeine	10 mg/mL
DMSO	3%
Ephedrine	20 mg/dL
Ethanol	1%
Heroin	1 mg/dL
Gentisic Acid	20 mg/dL
Methadone	10 mg/dL
Methamphetamine	10 mg/dL
Methanol	10%
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic Acid	20 mg/dL
Theophylline	20 mg/mL
Uric Acid	20 mg/dL

Urine Analytes	Concentration
Albumin (serum)	2000 mg/dL
Bilirubin	1000 µg/dL
Hemoglobin	1000 µg/dL
Glucose	2000 mg/dL
Urine pH	5-9

Serum Analyte	Concentration
Triglyceride	800 mg/dL

Hormones	Concentration
hLH	500 mIU/mL
hFSH	1000 mIU/mL
hTSH	1000 µIU/mL
Estriol 17-beta	1400 µg/dL
Pregnanediol	1500 µg/dL

Bacteria	Concentration
<i>E. coli</i>	10 ⁸ CFU/mL
Group B <i>Streptococcus</i>	2.5 x 10 ⁷ CFU/mL
<i>Chlamydia trachomatis</i>	10 ⁷ IFU/mL

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support number, (800) 874-1517 (toll-free in the U.S.A.) or (858) 552-1100, Monday through Friday, between 7:00 a.m. and 5:00 p.m. Pacific Time, U.S.A. If outside the United States contact your local distributor or technicalsupport@quidel.com.

REFERENCES

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8. McCready J., Braunstein G.D., Helm D., Wade M.E. Clin Chem 24: 1958–1961, (1978).

REF

20110 – QuickVue One-Step hCG Combo 50 Test Kit
00272 – hCG Control Set
00281 – hCG Serum Control Set

IVD

CE

EC REP

MDSS GmbH
Schiffgraben 41
30163 Hanover,
Germany







Quidel Corporation
Worldwide Headquarters
10165 Mckellar Court
San Diego, CA 92121 USA



Lab Name:

QUIDEL[®]

1040702 (02/11)

EC REP Authorized Representative in the European Community	REF Catalogue number
 Use by	IVD For <i>In Vitro</i> diagnostic use
LOT Batch code	 Consult instructions for use
 Manufacturer	 Temperature limitation

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LOG SHEET



Record Built-in Procedural Controls on the first patient tested each day.

	Date	Patient Name	Negative Procedural Control (Clear Bkgd)	Positive Procedural Control (Blue Line)	Test Results At 3 minutes for urine and 5 minutes for serum	Lot Number and Exp. Date	Technician
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

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LOG SHEET



Need to run external Positive and Negative Controls once per lot or shipment of material per CLIA package insert requirements.

	Date/Date Received	External Positive Control	External Negative Control	Lot Number and Exp. Date	Technician
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					