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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QUICKVUE+ One-Step hCG Combo TEST

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 normally produced by the placenta. Since hCG is present in the serum and urine of pregnant women, it is an excellent marker for confirming pregnancy.

The QuickVue+ One-Step hCG Combo test is a lateral-flow test using a monoclonal antibody specific to the beta subunit of hCG to accurately detect hCG as early as 2 or 3 days before the expected menses.

PRINCIPLE OF THE TEST
To perform the test, a serum or urine sample is collected and added to the Reaction Unit. If the sample contains hCG, a pink vertical line forms in the Read Result Window. This pink vertical line, together with the pre-printed blue horizontal line, form a plus sign (+) to indicate a positive result. If hCG is not present in the sample, the Read Result Window shows only the pre-printed blue horizontal line, forming a minus sign (–) to indicate a negative result.

As the sample continues to move through the test, a bar in the Control Window becomes blue. Blue color in the Control Window indicates that the test is functionally active and is also evidence that the test has been performed correctly.

REAGENTS AND MATERIALS SUPPLIED
Each QuickVue+ One-Step hCG Combo test kit contains enough materials for 30 tests (Catalog No. 00178) or 90 tests (Catalog No. 00179).
- Reaction Unit (30 or 90)
  Contains a murine monoclonal antibody and a caprine polyclonal antibody to hCG.
- Disposable Dropper (30 or 90)
- Package Insert (1)

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- Procedure Card (1)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or watch that measures minutes and seconds.
- Specimen Collection Containers

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 appropriate precautions in the collection, storage, handling and disposal of patient samples and used kit contents.
- Use of Nitrile or Latex gloves is recommended when handling patient samples.[1]
- Dispose of containers and unused contents in accordance with Federal, State and Local requirements.
- The Reaction Unit must remain sealed in the foil pouch just prior to use.
- 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. Do not freeze.

SPECIMEN COLLECTION AND STORAGE

Urine

Collect urine specimens in a clean container. Urine collected anytime during the day can be used. For optimal results, it is best to test the first urine voided in the morning because it contains the greatest concentration of hCG. Samples can be stored for 8 hours at room temperature (59–86°F; 15–30°C) or up to 72 hours refrigerated (36–46°F; 2–8°C). DO NOT freeze the urine sample.

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 refrigerated (2–8°C) for up to 48 hours prior to assay. If testing will be delayed for more than 48 hours, the sample may be frozen once at

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-20°C or below. If frozen, mix after thawing. Do not re-freeze. Do not chemically modify the serum in any way.

QUALITY CONTROL

External Quality Control

Positive and negative controls can be run with each shipment of a new kit lot number and as otherwise required by your laboratory's quality assurance plan. The Serum hCG Control Set (Catalog No. 00281) or the hCG Control Set (Catalog No. 00272) can be used for this purpose. The use of other hCG controls may be incompatible with the assay.

1. External Positive Control:
Process the control as you would a patient sample. A positive signal is indicated by a pink and blue plus sign (+) in the Read Result Window along with a blue procedural Control Line in the Control Window.

2. External Negative Control:
Process the control as you would a patient specimen. A negative signal is indicated by a blue minus sign (–) in the Read Result Window along with a blue procedural Control Line in the Control Window.

Internal Control Features

The QuickVue+ One-Step hCG Combo test contains built-in control features. The manufacturer's recommendation for daily quality control is to document these controls for the first sample tested each day. Quality Control log sheets are available from Technical Support. No additional external quality control is required.

1. Internal Positive Procedural Control:
A blue line in the Control Window is considered an internal positive procedural control. If the test has been performed correctly and the Reaction Unit is working properly, this indicator will appear.

2. Internal Negative Procedural Control:
A clear background in the Read Result Window is considered an internal negative procedural control. If the test has been performed correctly and the Reaction Unit is working properly, the background will clear to give a discernable result.

If the controls do not perform as expected, do not use the test results. Repeat the test or contact Technical Support.

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PROCEDURAL NOTES

- DO NOT remove the Reaction Unit from the foil pouch until you are ready to perform the test.
- Use a new disposable dropper for each sample to avoid cross-contamination.

TEST PROCEDURE

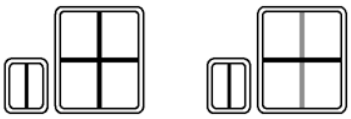
- Remove the Reaction Unit from the pouch.
- Draw serum or urine into the disposable dropper and dispense **4 drops** into the Add Sample well.
- Shortly after the sample is added, a pink-to-purple color will be seen moving across the Reaction Unit's windows. The Read Result Window contains a pre-printed horizontal blue line on the membrane.
- **Read result at 3 minutes for urine and 5 minutes for serum.**
  Note: *Some positive results may appear sooner.*

INTERPRETATION OF RESULTS

**Refer to the color procedure card included in the kit.*

Positive Result:

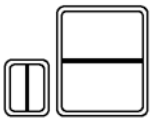
The sample contains a detectable amount of hCG when you see: A pink and blue plus sign (+) in the large square Read Result Window, along with a blue line in the small square Control Window.



NOTE: *any shade of a pink vertical line in the Read Result Window should be interpreted as a positive result.*

Negative Result:

The sample does not contain detectable amounts of hCG when you see: A blue minus sign (–) in the large square Read Result Window, along with a blue line in the small square Control Window.



Invalid Result:

The result is invalid if: No blue line appears in the small square Control Window; or background color in the large square Read Result Window interferes with test interpretation. In the case of an invalid result, a new patient specimen should be tested using a new QuickVue+ One-Step hCG Combo test or contact Technical Support.

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If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48–72 hours and tested.

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.
- A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone.[2]
- Very low levels of hCG are present in serum and in urine shortly after implantation. Positive test results from very early pregnancy may later prove negative due to natural termination of pregnancy. This is estimated to occur in up to 50% of all conceptions.[3] If a very low, faint positive serum result is obtained, 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.
- 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.[4]
- If a urine sample is too dilute, it may not contain a representative urinary hCG concentration. If a negative result is obtained and pregnancy is still suspected, a first morning sample should be obtained and tested.

EXPECTED VALUES

The sensitivity of QuickVue+ One-Step hCG Combo test is 10 mIU/mL for serum or 20 mIU/mL for urine (WHO 3rd IS 75/537). In normal pregnancy, hCG levels in urine can reach 25 mIU/mL as early as 7 to 10 days post conception, and continue to increase exponentially to reach a maximum concentration in excess of 200,000 mIU/mL at the end of the first trimester.[5]

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PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity, and Accuracy

The clinical sensitivity, specificity and accuracy of the QuickVue+ One-Step hCG Combo test was determined by evaluating 497 urine samples and 1528 serum samples obtained from women presenting for pregnancy testing. Testing was performed by clinic personnel. Results were compared to results obtained with the Abbott TestPack® Plus hCG-Combo. A commercially available quantitative method was used to resolve any discrepant results.

The results are summarized below. Of the 497 urine samples tested, the QuickVue+ One-Step hCG Combo test yielded an accuracy of >99%.

Similarly, of the 1528 serum samples tested, the QuickVue+ One-Step hCG Combo test yielded an accuracy of >99%.

Serum Correlation
TestPack Plus hCG Combo

QuickVue+ One-Step hCG Combo test	+	-
+	510	6
-	0	1012

Sensitivity: 510/510= >99%
Specificity: 1012/1018= >99%
Accuracy: 1522/1528=>99%

Urine Correlation
TestPack Plus hCG Combo

QuickVue+ One-Step hCG Combo test	+	-
+	269	0
-	0	228

Sensitivity: 269/269= >99%
Specificity: 228/228= >99%
Accuracy: 497/497= >99%

Physician's Office Laboratory (POL) Studies

An evaluation of the QuickVue+ One-Step hCG Combo 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 different locations. The proficiency panel contained negative, low positive and moderate positive samples. Each level was tested in replicates of five at each site over a period of three days.

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

Cross-Reactivity

hTSH, hLH, and hFSH were tested in the QuickVue+ One-Step hCG Combo test at levels ranging from 1000 µIU/mL to 1000 mIU/mL and did not affect the expected results.

Interference Testing

The following chemical and biological compounds were tested in the QuickVue+ One Step hCG Combo test and did not affect the expected results.

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

Hormones	**Concentration**
LH	300 mIU/mL
FSH	1000 mIU/mL
TSH	1000 µIU/mL
Estriol 17-beta	1400 µg/dL
Pregnanediol	1500 µg/dL

Bacteria	**Concentration**
E. coli	10^8 CFU/mL
Group B *Streptococcus*	2.5×10^7 CFU/mL
Chlamydia Trachomatis	10^7 IFU/mL

Chemical Analytes	**Concentration**
Acetominophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL
Ascorbic Acid	20 mg/dL
β-Hydroxybutyrate	2000 mg/dL
Caffeine	20 mg/dL
Clomiphene	100 mg/dL
Gentisic Acid	20 mg/dL
Salicylic Acid	20 mg/dL
EDTA	80 mg/dL
Cannabinol	10 mg/dL
Cocaine	10 mg/dL
Codeine	10 mg/dL
Heroin	1 mg/dL
Methadone	10 mg/dL

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Methamphetamine	10 mg/dL
Methanol	10.0%
Ephedrine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Theophylline	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Benzoylecogonine (cocaine metabolite)	10 mg/dL
Ethanol	1.0%
DMSO	5.0%
Uric Acid	20 mg/dL
Heparin	2800 units/dL

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 am and 5:00 pm, Pacific Time, U.S.A. If outside the United States contact your local distributor or technicalsupport@quidel.com.

REFERENCES

1. Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, U.S. Department of Health and Human Services, CDC, NIH, Washington, DC (1999).

2. Rasor, J.L. and Braunstein, G.D., Obstet. Gynecol., 50, 553-558 (1977).

3. Edmonds, D.K., Lindsay, K.S., Miller, J.F., Williamson, E. and Wood, R.J., Fertility and Sterility, 38, 447-453 (1982).

4. Braunstein, G.D., Vaitukaitis, J.L., Carbone, P.P., and Ross, G.T., Ann. Intern. Med., 78, 39-45 (1973).

5. Lenton, E.A., Neal, L.M., and Sulaiman, R., Fertility and Sterility, 37, 773-778 (1982).

REF

00178 – QuickVue+ One-Step hCG Combo 30 Test Kit
00179 – QuickVue+ One-Step hCG Combo 90 Test Kit
00272 – hCG Control Set
00281 – hCG Serum Control Set

IVD

FOR URINE WAIVED CLIA '88

Lab Name:

CE

EC REP
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QUIDEL®
CORPORATION

0436406 (11/11)

EC REP Authorized Representative in the European Community	REF Catalogue number
CONTROL + Positive control	CONTROL − Negative control
Use by	Consult instructions for use
LOT Batch code	IVD For *In Vitro* diagnostic use
Manufacturer	Temperature limitation

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LOG SHEET

QUICKVUE+ One-Step hCG Combo TEST

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

	Date/Date Received	Patient Name	Positive Procedural Control (Blue Line)	Negative Procedural Control (White to light pink background)	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

QUICKVUE+ One-Step hCG Combo TEST

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

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

Lab Name:

LOG SHEET

QUICKVUE+ One-Step hCG Combo TEST

Need to run external Positive and Negative urine 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					

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