The Johns Hopkins Hospital Point-of-Care Testing Program

Self-Study Packet

Urine Pregnancy
Quidel QuickVue+ One-Step hCG Combo Test

Operator Competency

Only operators who have completed a defined training program and can demonstrate competence will be able to perform Urine Pregnancy testing.

Operator competency will be assessed annually by two methods.
1. Successful performance of quality control (Quantimetrix Dropper Plus Levels 1 and 2)
2. One of the following:
   • Testing an unknown specimen
   • Having the supervisor or qualified delegate periodically observe routine work
   • Written test

Test Order

A physician’s order, standard protocol, or order by other health professionals authorized to request laboratory tests is required for Urine Pregnancy testing.

Reagents and Storage

The QuickVue+ One-Step hCG Combo test kits and Urine Controls are to be dated when initially opened.

The “Opened Date” and “New Expiration Date” are to be recorded on the Quantimetrix Dropper Plus Urine Control bottles when stored at room temperature.

Do not use Pregnancy Test Kits and Urine Controls after the expiration date.

1. The QuickVue+ One-Step hCG Combo test kit is stored at room temperature (15-30°C or 59-86°F). Keep out of direct sunlight and do not freeze.
2. The QuickVue+ One-Step hCG Combo test kit is stable until the manufacturer’s expiration date printed on the box.
3. The Quantimetrix Dropper Plus Urine Controls are stable for one month at room temperature (18-25°C or 64-77°F). Do not store above 30°C (86°F).
4. The Quantimetrix Dropper Plus Urine Controls can also be stored at 2-8°C (35-46°F) in a temperature monitored refrigerator. When stored refrigerated, the Urine Controls are stable until the expiration date stated on the label. Do not freeze.
5. Discard the Urine Controls if turbid or any evidence of microbial contamination is present.
Quality Control (QC) Label

A JHMI Quality Control label should be affixed to the QuickVue+ One-Step hCG Combo test kit box when it is first opened. Record the open date at the top of the QC label in the space below “Date Opened”.

Quality Control Frequency

Quality Control consists of:

1. External Liquid Controls- QC performed:
   a. Weekly on each opened box of QuickVue+ One-Step hCG Combo test kits.
   b. Initially when opening a new box of test kits.
2. Internal Procedural Controls- QC performed:
   a. With each test

QuickVue+ One-Step hCG Combo Test Components

1. The QuickVue+ One-Step hCG Combo test kit consists of:
   a. 30 Reaction Units
   b. Transfer pipettes
2. The QuickVue+ Reaction Unit consists of:
   a. Sample Well
   b. Control Window (small square)
   c. Read Result Window (large square)
Quality Control- External Liquid Controls

1. Record the date, time, lot numbers and expiration dates of the test kit and controls on the Urine hCG QC log sheet.
2. Remove two Reaction Units from their pouches and place on a flat, dry surface. Label one Reaction Unit as “L1” for the Level 1 control and the second as “L2” for the Level 2 control.
3. Ensure controls are at room temperature. Mix the controls gently by inversion.
4. Uncap the Level 1 control bottle, and while holding the bottle vertically, dispense 4 drops of control solution into the Sample Well of the correspondingly labeled Reaction Unit.
5. Repeat step 4 for the Level 2 control.
7. Read results immediately at 3 minutes.
8. Record results on the Urine hCG QC Log Sheet.
9. Document any QC failures and corrective actions in the Comment Section of the QC log sheet.
10. Date and initial the JHMI QC label affixed to the test kit box to indicate successful completion of Quality Control.

Quality Control- Internal Procedural Controls

1. Internal Positive Procedural Control:
   a. A vertical blue line appears in the small square Control Window.
   b. This line indicates the Reaction Unit is working properly and the test has been performed correctly.
   c. The Positive Procedural Control must appear for the test to be valid; absence may indicate deterioration of the reagents.
2. Internal Negative Procedural Control:
   a. The background in the large Read Result Window is clear, giving a discernable result.
   b. The result is invalid if the background color interferes with the test interpretation.
3. Document any QC failures and corrective actions in the Comment Section of the Urine hCG QC log sheet.

Quality Control – Results Documentation Summary

1. Record date, time, operator initials, and the lot numbers and expiration dates of the test kit and controls on the Urine hCG QC log sheet.
2. Record the External Control results as “Pos/Positive” or “Neg/Negative”. Do not use (+) or (-) symbols.
3. Record a check mark (√) or “OK” in the Internal QC column to indicate the presence of the blue vertical line in the Control Window and that the Read Result Window background was clear, i.e., the Reaction Unit worked properly and the test was performed correctly.
4. Place a check mark (√) in the QC Pass/Fail box to note whether QC passed or failed.
5. Document any QC failures and corrective actions in the Comment Section of the Urine hCG QC log sheet.
Quality Control Failures and Corrective Actions

If the Quality Control test fails to give the expected results:

1. Check to make sure that the test kit and control solutions have not expired.
2. Repeat the test.
3. If repeat test fails, suspect deteriorated controls. Repeat test using new control solutions.
4. If this test fails using the new control solutions, open a new test kit box and retest using Reaction Units from the new test kit and the new control solutions.
5. If the repeat test fails using the new test kit and controls, STOP PATIENT TESTING AND REPORTING OF PATIENT RESULTS until the quality control issues are resolved and the expected results are obtained and recorded.
6. Document all steps taken in the Comment Section of the Urine hCG QC Log Sheet.
7. Contact the POCT Program Office for assistance.

Specimen Collection

1. The preferred specimen for testing is the first morning sample; a freshly collected specimen may be taken at any time of the day.
2. Collect specimen in a clean, dry, plastic container without preservatives.
3. Use at least 2 unique patient identifiers (neither to be the patient’s room number) to verify the patient’s identity when collecting samples for testing.
4. Label the specimen container, not the lid, with the patient identifiers in the presence of the patient.
5. Samples must be fresh (not refrigerated) and tested promptly.
6. Gloves must be worn during sample collection and testing (Standard Precautions).

Patient Testing

1. Check the JHMI QC label affixed to the test kit box or the Urine hCG QC log sheet to make sure that quality control has been performed for the week. If not, stop and perform QC before doing any patient tests.
2. Remove a Reaction Unit from its pouch and place on a flat, dry surface.
3. Record patient identification on the Reaction Unit.
4. Using the transfer pipette provided in the test kit, dispense 4 drops of urine into the Sample Well of the Reaction Unit.
5. Use a separate transfer pipette and Reaction Unit for each patient specimen.
6. Set timer for 3 minutes.
7. Read the results immediately at 3 minutes. Do not leave the test during the development as overdevelopment can lead to false positive results.
8. Discard the Reaction Unit and transfer pipette in the appropriate biohazard waste container.
9. Record the patient’s results, along with the date, time and operator initials on the patient’s chart, flowsheet, or electronic patient record.
Patient Testing (continued)

8. When documenting the results in the patient’s chart, place a check mark (√) or “QC okay” next to the results to indicate that Quality Control has successfully been run within one week and the Internal Procedural Controls reacted correctly.

9. Results should be noted as Point-of-Care Testing results to distinguish them from central laboratory results.

Result Interpretation

The QuickVue+ One-Step hCG Combo result format consists of one pink vertical line (⅐) and one pre-printed blue horizontal line (–) that form a plus sign (+).

1. Positive result: A pink and blue plus sign (+) in the large square Read Result Window, along with a vertical blue line in the small square Control Window indicates the presence of detectable levels of hCG. Any shade of a pink vertical line in the Read Result Window should be interpreted as a positive result.

2. Negative result: A blue minus sign (–) in the large square Read Result Window, along with a vertical blue line in the small square Control Window indicates the absence of detectable hCG.

3. Invalid result: The result is invalid if no vertical blue line appears in the small square Control Window or the background color in the large square Read Result Window interferes with test interpretation.

This is considered failed Internal Procedural quality control. No patient/external QC results can be reported until the failed Internal Procedural quality control is corrected.

Gradual color increases may occur over time in both positive and negative specimens. Results should be read immediately at 3 minutes for urine. Do not leave the test during development.

Patient Result Reporting

1. Record the patient’s result as “Pos/Positive” for a positive result or “Neg/Negative” for a negative result, the date, time, operator initials and care actions in the patient chart.

2. Do not use (+) or (–) symbols for recording results.

3. Report result as “INDETERMINATE” when the patient’s result interpretation is not clearly positive or negative. Report result to the patient’s physician/provider to determine if additional follow-up is needed.

4. Place a check mark (√) or “QC okay” next to the patient result to indicate acceptable Internal Procedural Quality Control results were obtained and that external QC had been successfully run within one week.

5. Note the results as a Point-of-Care urine hCG to differentiate results from the central lab results.
Abnormal Result Follow-Up

Invalid results, questionable results, problems with the testing procedure, results that do not match the clinical condition or “Indeterminate” results should be reported to the physician/provider to determine if additional follow-up is needed.

A second urine sample may need to be collected after 48-72 hours and tested, or the test result should be confirmed with a quantitative hCG test.

Interferences

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
<th>Substance</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Acetaminophen</td>
<td>20 mg/dL</td>
<td>Ethanol</td>
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<tr>
<td>Acetoacetic Acid</td>
<td>2000 mg/dL</td>
<td>FSH</td>
<td>1000 mIU/mL</td>
</tr>
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<td>Acetylsalicylic Acid</td>
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<td>Gentiisic Acid</td>
<td>20 mg/dL</td>
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<td>Albumin</td>
<td>2000 mg/dL</td>
<td>Glucose</td>
<td>2000 mg/dL</td>
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<tr>
<td>Ascorbic Acid</td>
<td>20 mg/dL</td>
<td>Group B Streptococcus</td>
<td>2.5 x 10⁷ CFU/mL</td>
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<td>B-Hydroxybutyrate</td>
<td>2000 mg/dL</td>
<td>Hemoglobin</td>
<td>1000 µg/dL</td>
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<td>300 mIU/mL</td>
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<td>Methadone</td>
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<tr>
<td>Clamydia trachomatis</td>
<td>10⁷ IFU/mL</td>
<td>Methamphetamine</td>
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<tr>
<td>Clomiphene</td>
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<td>Methanol</td>
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<td>Phenylpropanolamine</td>
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<tr>
<td>Codeine</td>
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<td>Pregnanediol</td>
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<tr>
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<td>E. coli</td>
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<td>Theophylline</td>
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<tr>
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<td>Uric Acid</td>
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<td>Estriol 17-beta</td>
<td>1400 µg/dL</td>
<td>Urine pH</td>
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</table>
**Limitations**

1. The contents of this kit are for use in the **qualitative** detection of hCG in urine.

2. False positive or false negative results may be seen in the following situations:
   a. Conditions other than pregnancy, i.e. trophoblastic and non-trophoblastic diseases.
   b. Natural termination of the pregnancy.
   c. Dilute urine specimen (low specific gravity)
   d. Presence of heterophilic antibodies or nonspecific protein binding.

3. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone.