# Laboratory Procedure Manual

*Analyte:* **Urine Pregnancy**

*Matrix:* **Urine**

*Method:* ***Beckman Coulter ICON 25 hCG***

*Revised Date:* February 7, 2022

As performed by: The National Health and Nutrition Examination Survey
Mobile Examination Center

Contact: Renee Storandt, Laboratory Director

**Important Information for Users**

The Nation Health and Nutrition Examination Survey periodically refines these laboratory methods. It is the responsibility of the user to contact the person listed on the title page of each write-up before using the analytical method to find out whether any changes have been made and what revisions, if any, have been incorporated.

## Public Release Data Set Information

This document details the Lab Protocol for testing the items listed in the following table:

| File Name | Variable Name | SAS Label |
|---|---|---|
| **UCPREG_L** | URXPREG | Urine Pregnancy Result |

# 1. Urine Pregnancy Test

## 1.1 Purpose and Principle of the Test

Perform a pregnancy test on females of all appointment types who are aged 12-59 years and girls aged 8-11 years who report, when asked during the interview, that they have experienced their first menstruation. A positive test result excludes pregnant women aged 8-59 years from participating in the dual-energy X-ray absorptiometry (DXA), balance, and liver ultrasound transient elastography (LUTE) components of the MEC exam if they fall into an eligible age category for those components. The test should be performed and the results reported immediately, since these components are not assigned until the results of the pregnancy test are documented in the laboratory information system.

Laboratory tests for pregnancy are based on detecting elevated levels of human chorionic gonadotropin (hCG), a hormone that the placenta begins to produce in increasing amounts shortly after fertilization. The ICON® 25 hCG (Urine/Serum) test kit is a rapid chromatographic immunoassay for the qualitative detection of hCG in urine or serum to aid in the early detection of pregnancy. Pregnancy tests will be performed solely on urine for NHANES.

In normal pregnancy, hCG can be detected in urine as early as 7-10 days after conception. The hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL (milli-international units per milliliter) by the first missed menstrual period and peaking in the 100,000-200,000 mIU/ml range about 10-12 weeks into pregnancy. The appearance of hCG in urine soon after conception, and its subsequent rapid raise in concentration during early gestational growth, make an excellent marker for the detection of pregnancy.

The ICON® 25 hCG test is a rapid test that qualitatively detects the presence of hCG in urine samples at the sensitivity of 25 mIU/mL. The test uses a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the ICON® 25 hCG test shows no cross-reactivity interference from the structurally related glycoprotein hormones human follicle stimulating hormone, human luteinizing hormone, and human thyroid stimulating hormone at high physiological levels.

The assay is conducted by adding urine to the sample well of the test device. The sample migrates via capillary action along the membrane to react with colored conjugate. Positive samples react with the specific antibody-hCG-colored conjugate to form a colored line at the test region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

## 1.2 Special Safety Precautions

### ICON® 25 hCG Test Kit

- This test is for professional *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- The test device should remain in the sealed pouch until use.
- Observe standard guidelines for handling biological hazards.
- Wear gloves while handling specimens. After use, dispose of gloves and other contaminated materials appropriately in a proper container and wash your hands.

### Sure-Vue™ hCG Urine Control Sets

- Sure-Vue™ hCG urine controls are intended to be used to monitor the performance and accuracy of pregnancy test kits. These controls are for professional use only.
- The use of known controls in the laboratory is invaluable. It is important to verify testing procedures to confirm the validity of the results reported. Testing Sure-Vue™ hCG Urine Controls will provide assurance that the pregnancy test kit is performing properly.
- Reagents in these kits contain 0.2 percent of sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide buildup. This reagent is harmful if swallowed. Contact with acids liberates very toxic gas. After contact with skin, wash skin immediately with plenty of water.
- Do not use the controls beyond the expiration date.

## 1.3 Computerization: Integrated Survey Information System (ISIS)

The MEC-automated ISIS system captures all data and stores it electronically at Westat's home office in Rockville, Maryland. Access the Pregnancy QC module to enter the quality control results. The session number, clinical laboratory scientist ID, and run number are automatically captured; enter the kit lot number and expiration date as well as the urine control lot and expiration dates. Record control results and save them to the database. All pregnancy quality control results are immediately available electronically at the home office. All data is backed up and stored at Westat's home office.

## 1.4 Specimen Collection and Preparation

Collect a urine sample as described in Chapter 4 and perform a urine pregnancy test on females aged 12-59 years and girls aged 8-11 years who report, when asked during the interview, that they have experienced their first menstruation.

If the urine pregnancy test is positive for SP's aged 8-17 years, repeat the pregnancy test a second time. Notify the clinician of the positive results and submit a UFO to notify that the positive pregnancy results were confirmed.

## 1.5 Reagents and Supplies

### 1.5.1 Reagents

**ICON® 25 hCG Urine/Serum Test Kit**

- Product Number 43025 (25)
- Beckman Coulter
  4300 N Harbor Blvd.
  Fullerton, CA 92834-3100

http://www.beckmancoulter.om/pcd

- Components
    - One test device (25) – Contains anti-hCG particles and anti-hCG coating on the membrane;
    - Disposable sample droppers – plastic pipettes for measuring and dispensing patient samples (packaged together with the test device in a white foil pouch);
    - Zip-closable bag with two extra sample droppers; and
    - Product instructions.
- Storage and stability
    - Store the ICON® 25 hCG test kit at 2-25°C (35-77°F). The test device is stable up to the expiration date printed on the sealed pouch. Keep the test device in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date. Date and initial the kit when putting it into use.

### Sure-Vue™ hCG Control Sets – Urine

- Product Number SA087413-F;
- Fisher Scientific Company; and
- Components.
    - Urine is a stable human urine-based material for use as a quality control material.
    - Use controls in the same manner as SP specimens in accordance with the protocol provided in the Sure-Vue™ hCG Control Sets directional insert.
    - Low Positive Control: Human urine containing approximately 25 mIU of hCG/mL and 0.2 percent sodium azide as a preservative (1 x 5 mL).
    - High Positive Control: Human urine containing approximately 250 mIU of hCG/mL and 0.2 percent sodium azide as a preservative (1 x 5 mL).
    - Negative Control: Contains 0.2 percent sodium azide as a preservative (1 x 5 mL).
- Storage and stability
    - Store the urine control set at 2-8°C (35-46°F) until the expiration date printed on the label.

### 1.5.2 Supplies

1.5.2.1 Timer

## 1.6 Assay Procedure

#### ICON® 25 hCG Test Kit

- Label each test device with the SP ID on a clear section of the test device using a felt tip pen. Label test devices used for quality control as "-" or "+."
- Use a new transfer dropper for each specimen (**use the ICON® 25 hCG plastic pipette that is in the package with the device** for each individual test).

#### Sure-Vue™ hCG Urine Control Sets

- The Sure-Vue™ urine controls have droppers built into the tip. The use of the control droppers to add control to the device has been validated; **do not** use the ICON® 25 hCG plastic pipette to add controls.
- Allow controls to reach room temperature before testing. The controls are ready to use. No dilution is required.
- The controls are used in place of the specimen and should be tested according to the ICON® 25 hCG test procedure.

#### Urine Testing Procedure

Perform the test procedure for the ICON® 25 hCG Urine test at room temperature (17-25°C, 63-77°F). Before proceeding, carefully read Section 5.11, titled "Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions."

- Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer three full drops of urine (approximately 100 µL) to the sample well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the sample well.
- Wait for the red line(s) to appear. Read the results at 3 minutes when testing a urine sample. It is important that the background is clear before the result is read.

**Note:** A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period; therefore, do not interpret the result after 3 minutes when testing a urine sample.

## 1.7 Reportable Range of Results

Report test results as Positive, Negative, or Invalid.

## 1.8 Quality Control (QC)

Run negative and low positive urine controls containing hCG at concentrations of 0 and 25 mIU/mL, respectively, just prior to or concurrently with the first examinee pregnancy test each exam day, and when putting a new lot into use. The pregnancy QC module contains the following information:

- The session ID number links to the stand number, stand location, and date, including day, month, and year. The technologist ID is automatically captured.
- Kit lot number and expiration date fill in automatically from the prior QC report. Update or manually enter this information if necessary.
- The control lot number and expiration date for the urine control fills in automatically from the prior QC report. Update or manually enter this information if necessary.
- The Control QC Type is urine.
- Negative Control result.
- Positive Control result.
- Upon a lot change during a stand, test the new lot with low positive and negative controls and update the lot numbers in the Quality Control module.

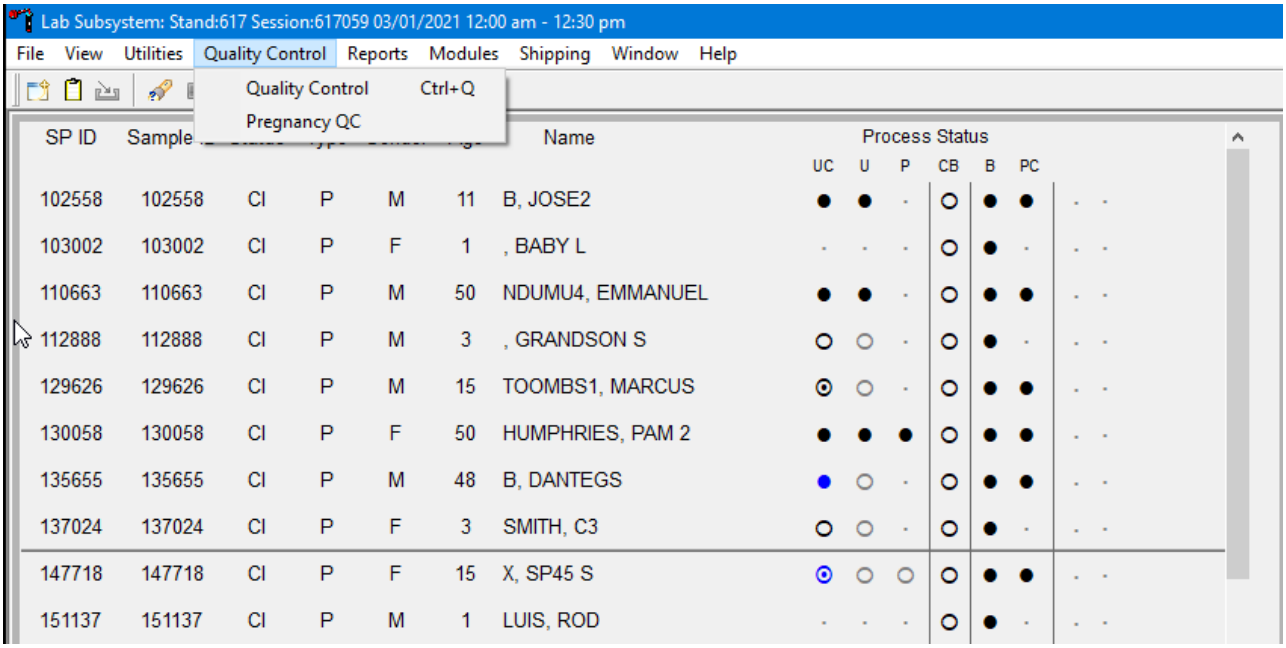
### CAP Proficiency Testing

For purposes of this document, proficiency testing is one method of external QC in which the analytical performance of a method is evaluated using specimens provided on a periodic basis (usually every 4 months).

Participation in the College of American Pathologists (CAP) proficiency-testing (PT) program is part of the comprehensive QC program. CAP compares the submitted results to established values and issues a report.

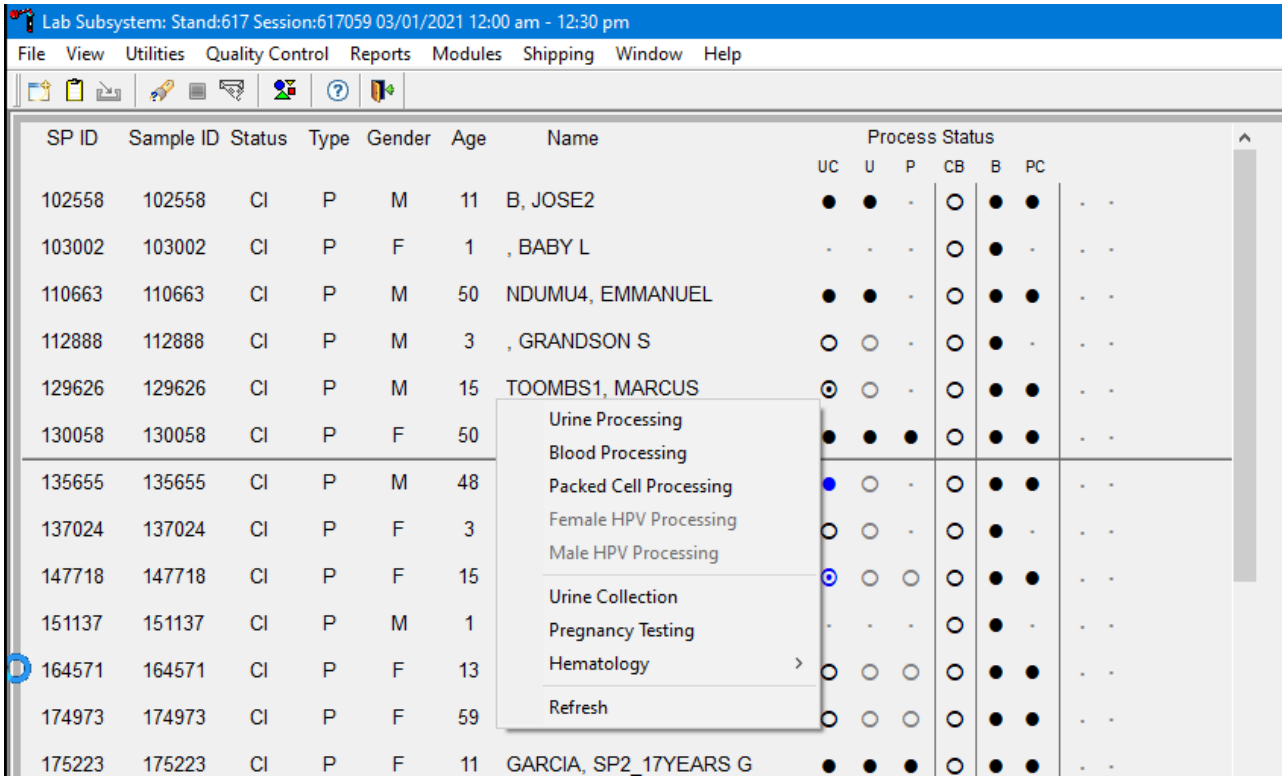
CAP sends samples three times a year for qualitative urine hCG. Each urine survey includes five liquid specimens. Handle and analyze these samples in a manner identical to SP samples. Record results on the correct CAP form, located on the CAP website, and submit results by the due date indicated on the survey. Send a copy of the CAP result form to the home office at the end of the stand. Do not share or compare CAP PT results with any other laboratory or MEC in operation.

Open the Pregnancy QC module.

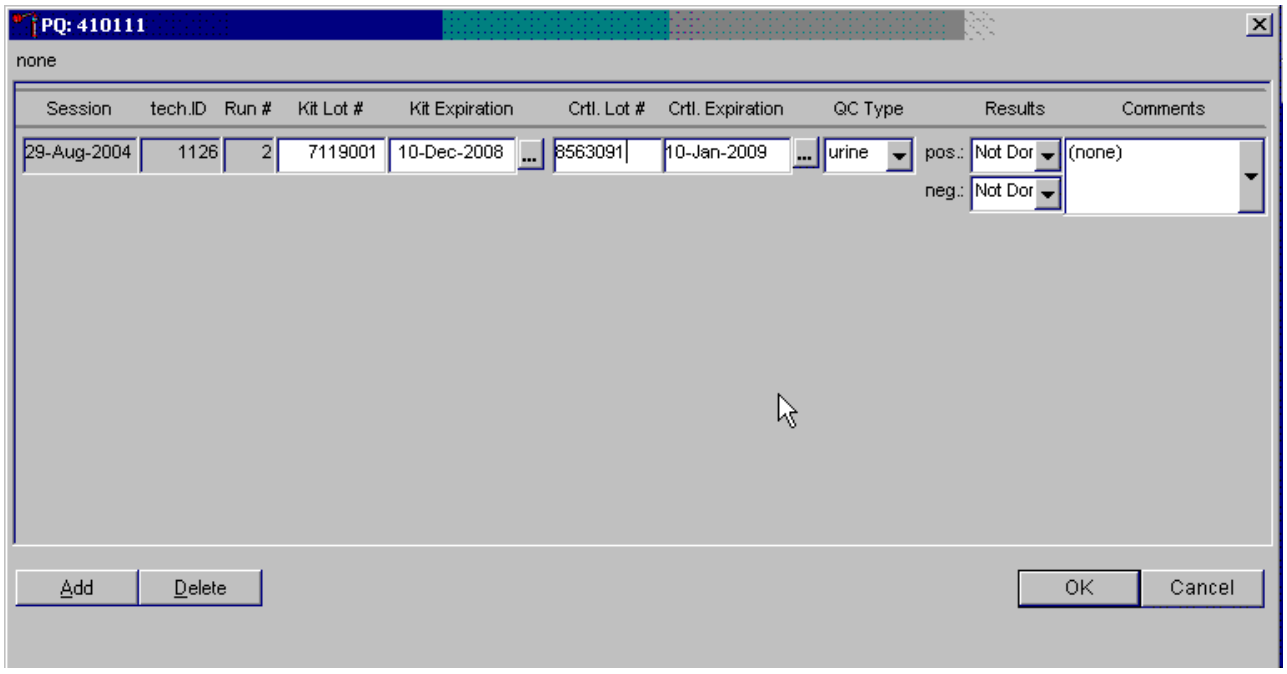



To open the pregnancy QC module, direct the mouse arrow to Quality Control in the top menu bar, drag the arrow to Pregnancy QC, and left-click.

Alternatively, open the Pregnancy QC module from the heads-up screen. To access the Pregnancy QC module from the heads-up screen, use the up and down arrow keys to move up and down the list until the correct SP is highlighted, or direct the mouse arrow to the correct SP, right-click, drag the mouse arrow to Pregnancy Testing, and left-click.



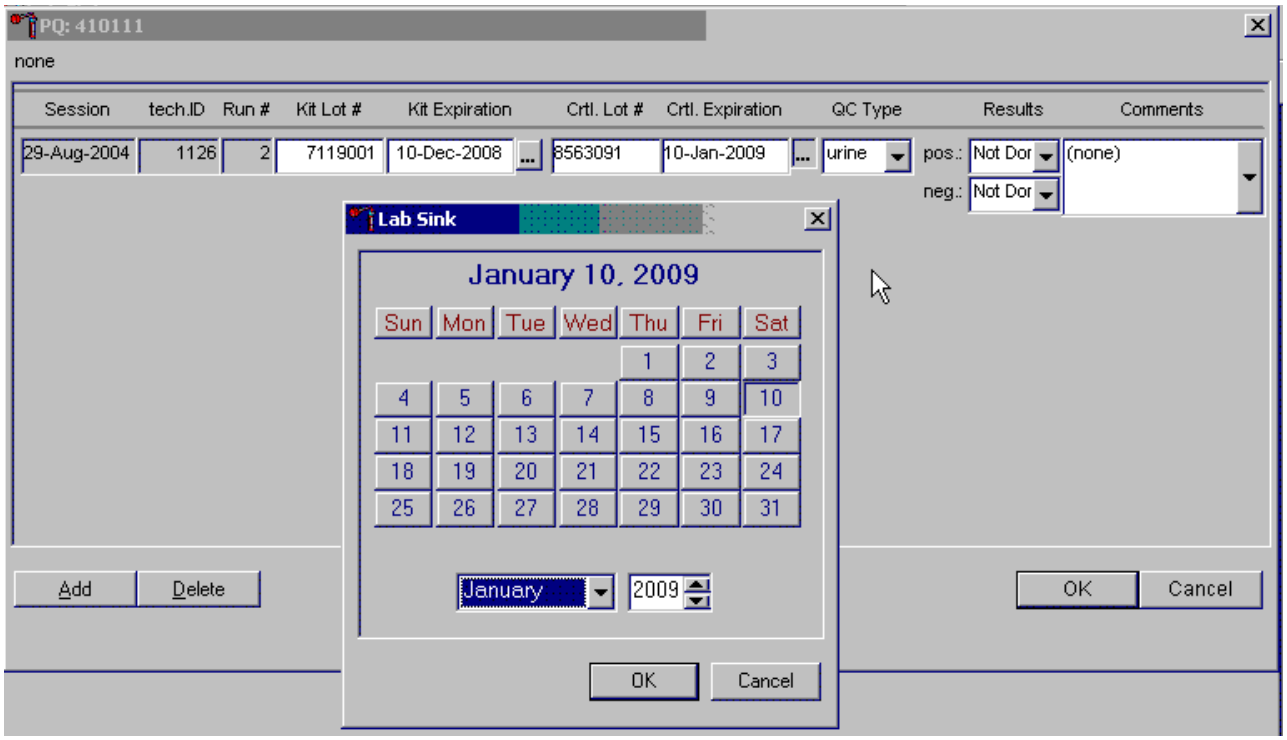

The Pregnancy QC window displays.



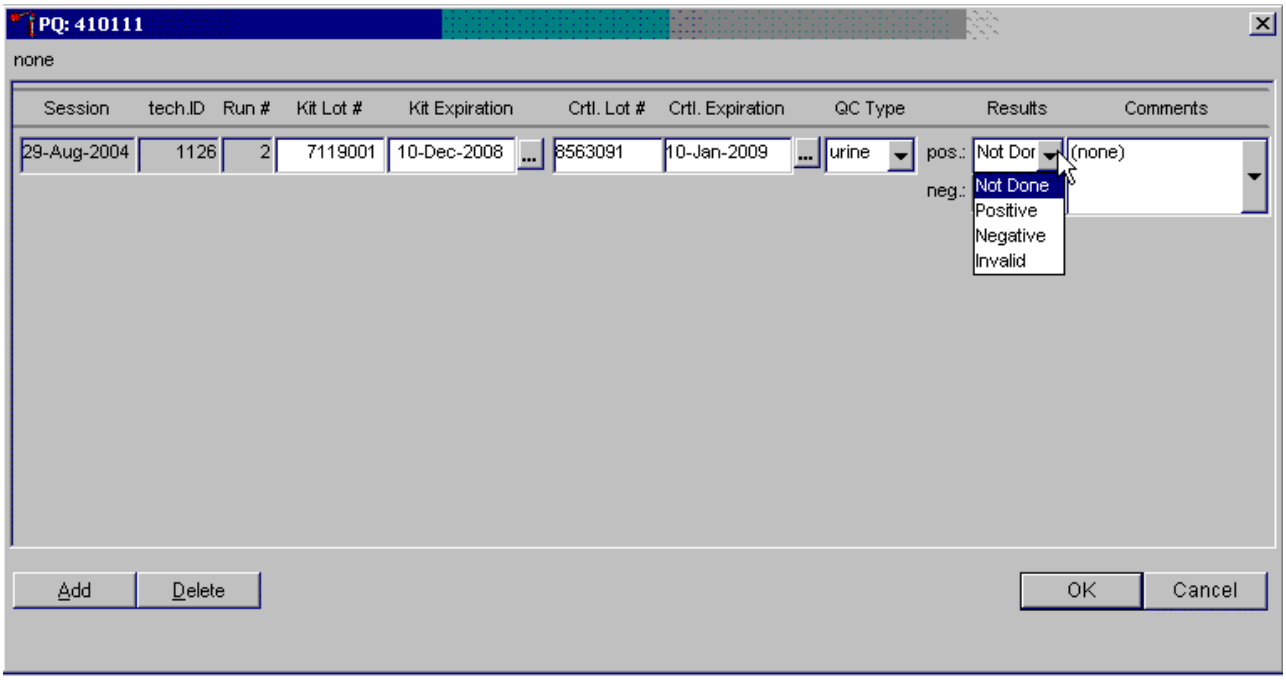

The Pregnancy QC module automatically captures the session date and clinical laboratory scientist ID and assigns the run number. The module defaults to the last kit lot number, kit expiration date, Ctrl (control) lot number, Ctrl expiration date, and the QC type – urine.

Verify the existing kit lot number and expiration date.

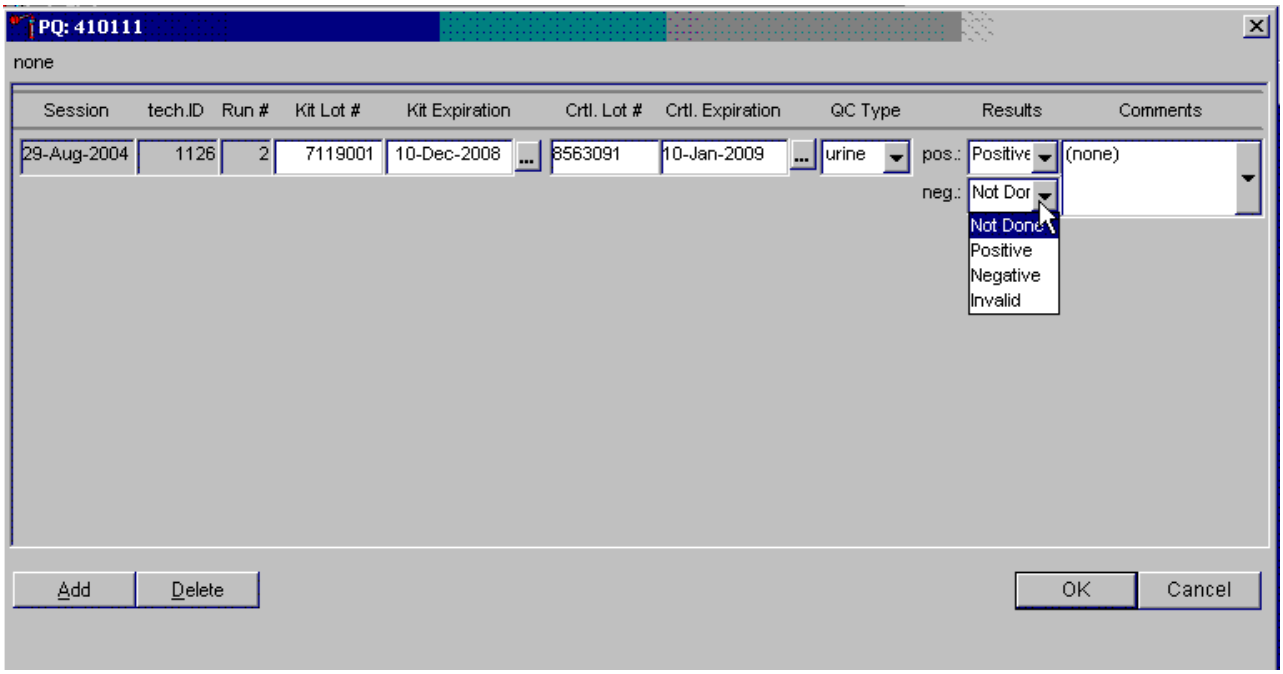
If the lot number is incorrect, type in the new kit lot number using the keyboard's numeric keys and press the Tab key to progress to the Kit Expiration blank. Use the calendar to correct the Kit Expiration date. If the screen defaults to the current Ctrl lot number, verify the existing lot number and expiration date. If the lot number is incorrect, type in the new control lot number using the keyboard numeric keys and press the Tab key to progress to the Ctrl Expiration blank. Use the calendar to correct either the Kit Expiration or Ctrl Expiration date.



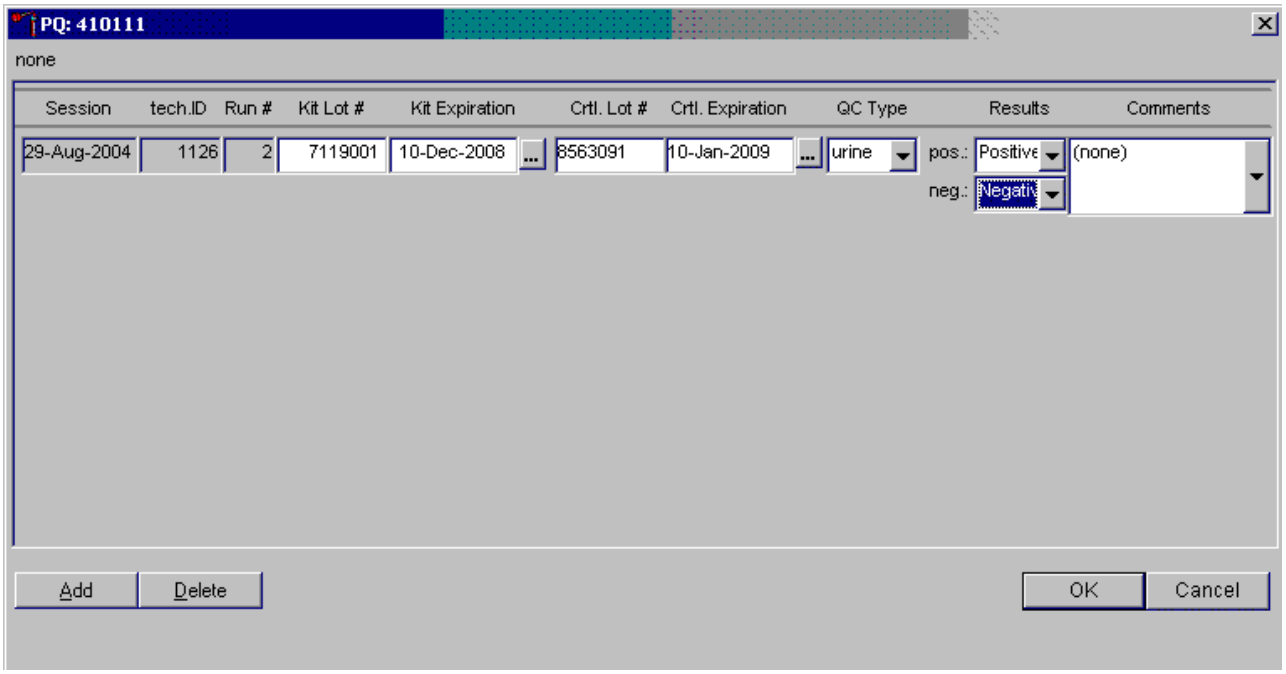

To update the Kit or Ctrl Expiration date using the calendar function, type in the date using the keyboard's numeric keys and the dd/mm/yyyy format and press the Tab key or use the calendar to enter the date. To access the calendar, direct the mouse arrow to the ellipsis (…) and left-click. To select the correct month, direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the scroll bar if necessary), and left-click. To select the correct day, direct the mouse arrow to the correct day on the displayed month and left-click. To correct the year, direct the mouse arrow to the up/down controls on the spin box and toggle the year up and down. To transfer this date into the text box, direct the mouse arrow to the OK button and left-click. To exit the calendar function, direct the mouse arrow to the Cancel button and left-click.




To enter a result in the positive result text box, type [P/p] for Positive, or use the up and down arrow keys to toggle among the three choices: Positive, Negative, and Invalid, and press the Tab key. Alternatively, direct the mouse arrow to the drop-down list; drag the mouse arrow to Positive, and left-click.

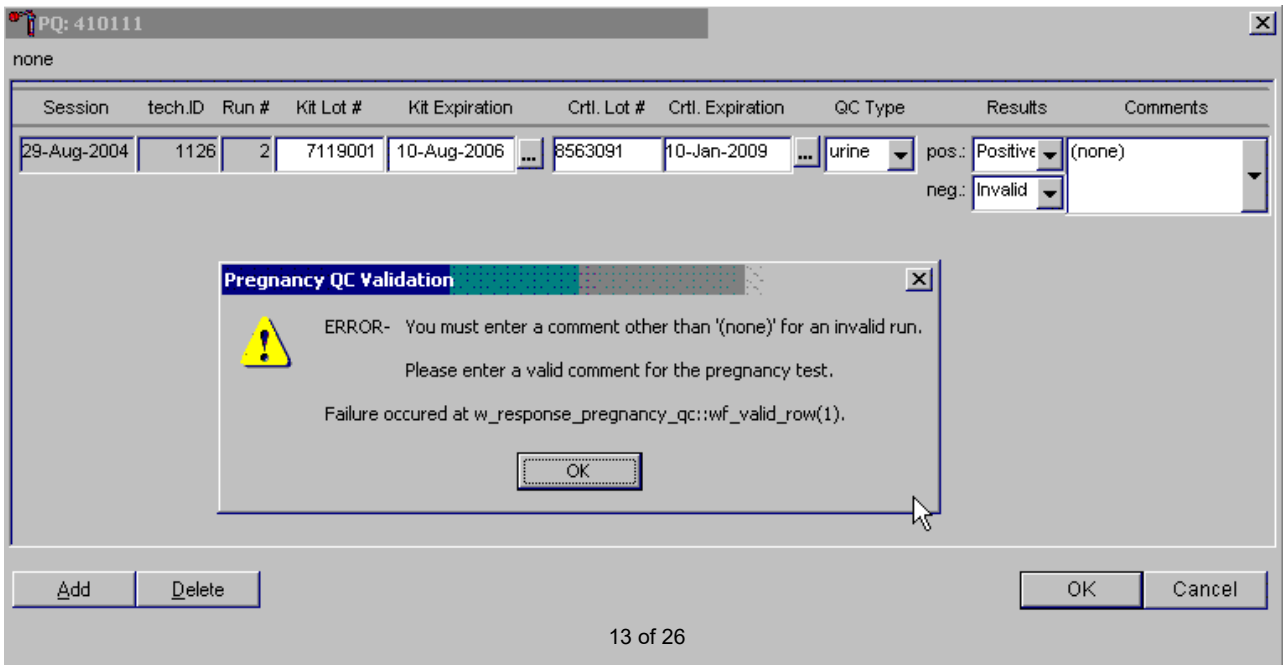



To enter a result in the negative result text box, type [N/n] for Negative or use the up and down arrow keys to toggle among the three choices: Positive, Negative, and Invalid and press the Tab key. Alternatively, direct the mouse arrow to the drop-down list; drag the mouse arrow to Negative, and left-click.

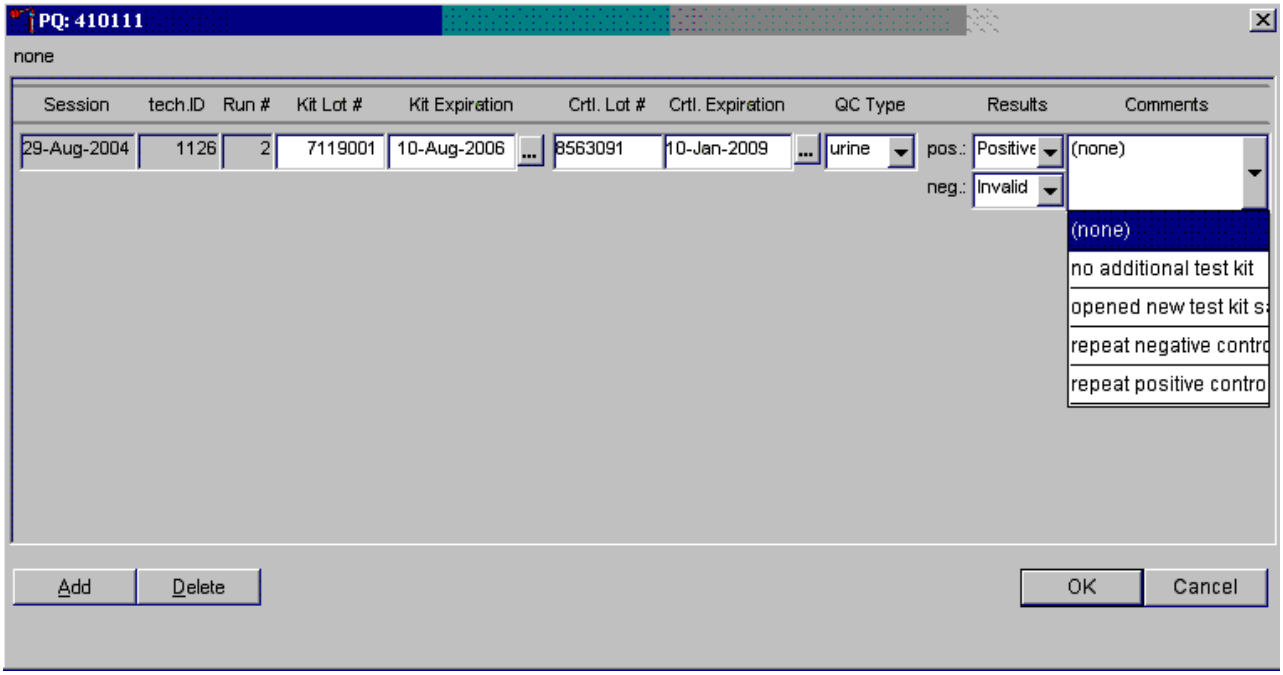



If the positive and negative controls demonstrate the expected result, direct the mouse arrow to the OK button and left-click to save the results and proceed with pregnancy testing. To cancel and exit the module without recording or saving any QC results to the database, direct the mouse arrow to the Cancel button and left-click. To delete the information in the window and exit the module without recording or saving any QC results to the database, direct the mouse arrow to the Delete button and left-click.

Enter a comment for any result that is inconsistent with expected results. If the OK button is selected before a comment is entered, the ERROR informational message box displays. Review the text in this box.

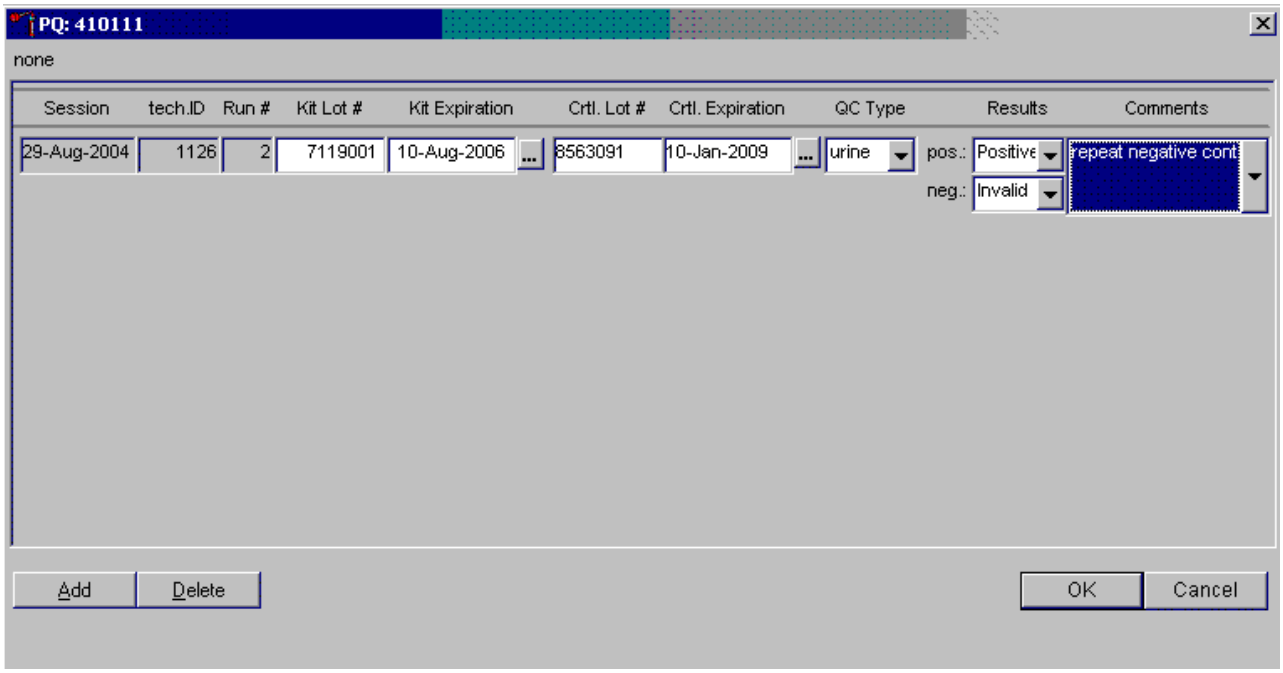


To close the box, direct the mouse arrow to the OK button and left-click or press Enter.

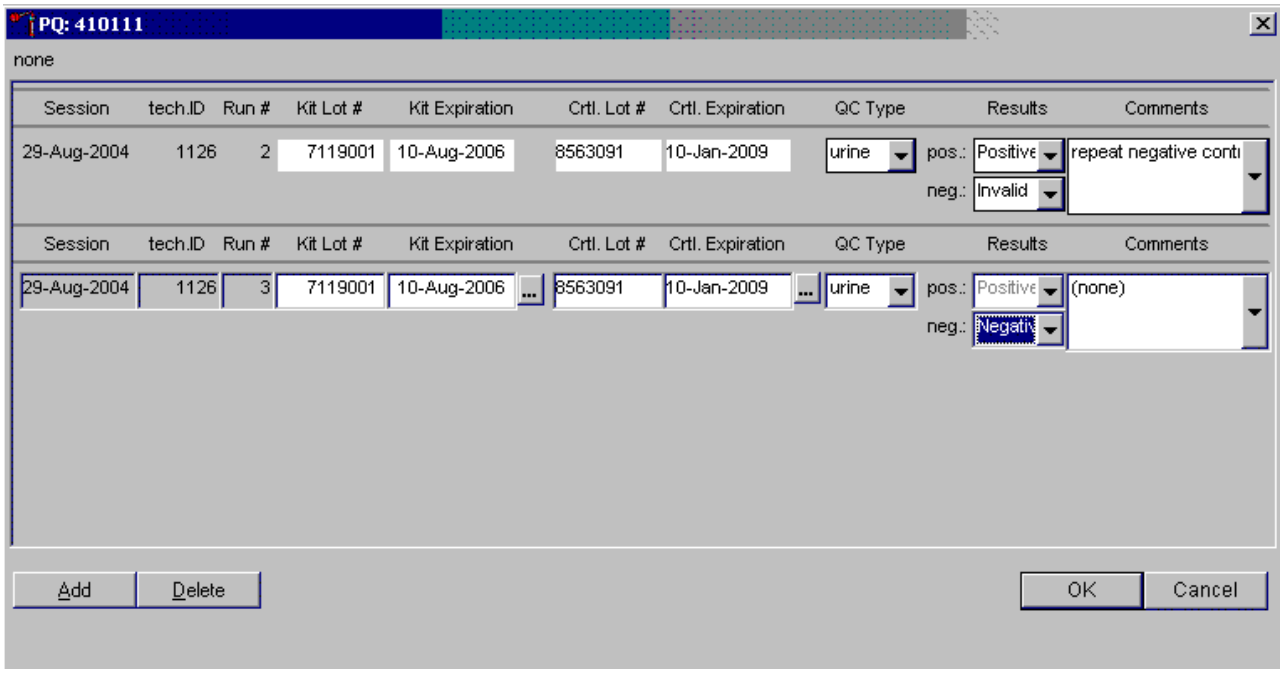



To enter a comment for any result that is inconsistent with expected results, enter the appropriate comment in the Comments column by directing the mouse arrow to the drop-down list, left-clicking to display the choices, dragging the mouse arrow to the most appropriate choice, and left-clicking when the correct choice is highlighted. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

Review the comment.

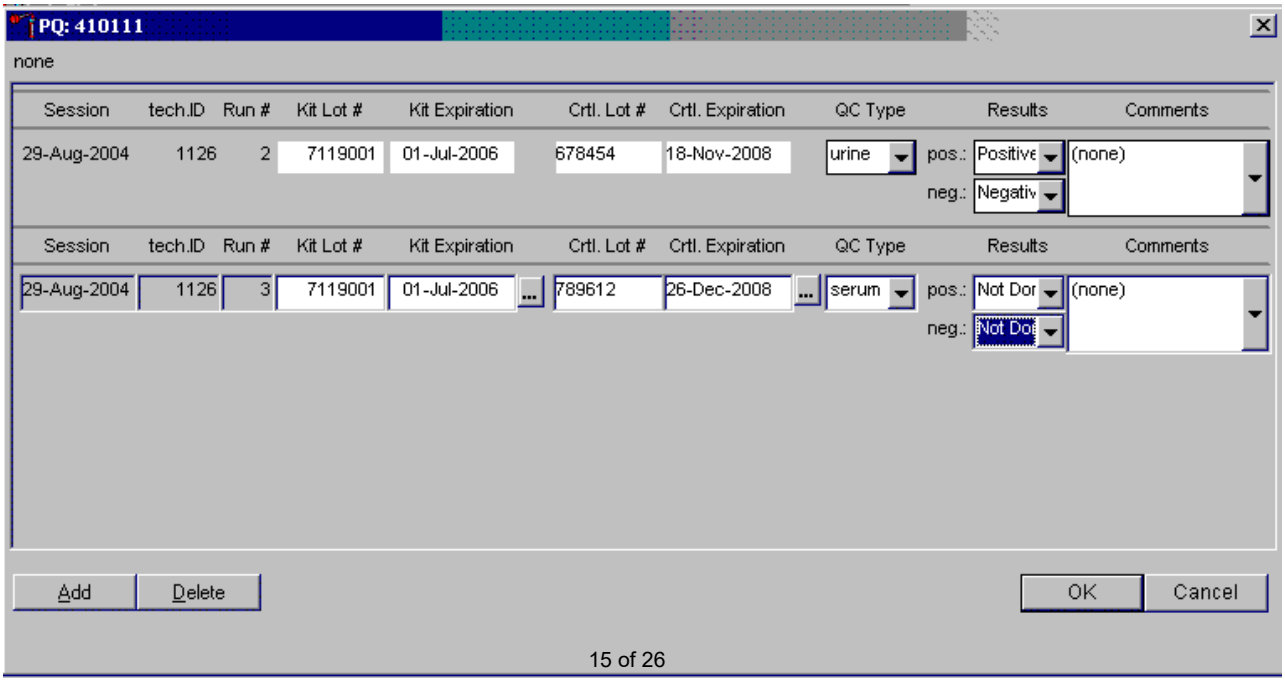


Review all the information in the QC window to verify its accuracy.




To add a new QC record and repeat the control for invalid or unexpected results, rerun or repeat the control that demonstrated the unexpected result. Add a new test line to record the new control results. To add a new QC test line, direct the mouse arrow to the Add button and left-click. Record the new results. If this resolves the inconsistency, direct the mouse arrow to the OK button and left-click to save these results and proceed with pregnancy testing.

If this does not resolve the situation, repeat the procedure with a different lot of controls. If this fails to resolve the problem, discard the entire lot of pregnancy test kits and test a new lot.



Add a new test line each time a control is run during a session. To add a new QC test line, direct the mouse arrow to the Add button and left-click. The QC type defaults to "Urine." Correct the control lot number and expiration date.

## 1.9 Interpretation of Results and Remedial Action

### ICON® 25 hCG Test

Exhibits 5-1 through 5-4 depict, respectively, the ICON® 25 test device, a positive result, a negative result, and an invalid result.

**Exhibit 5-1. ICON® 25 test device**

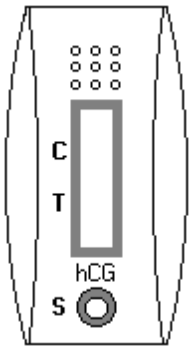
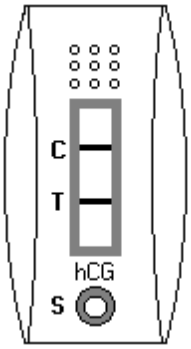
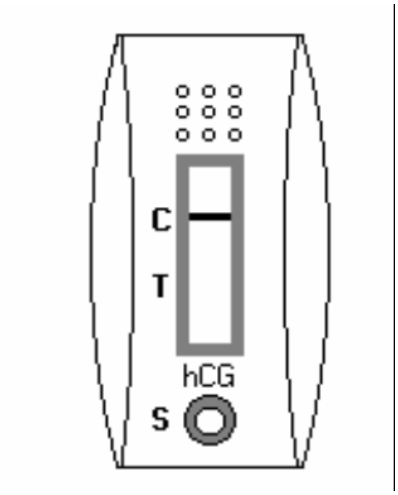



**Exhibit 5-2. Positive result**



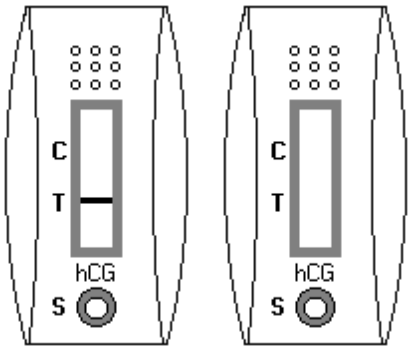

| |
|---|
| **Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).** |

**Exhibit 5-3. Negative result**




| |
|---|
| **One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).** |

**Exhibit 5-4. Invalid result**




| |
|---|
| **Control line fails to appear.** |

**Positive Result.** A specimen that produces two distinct red lines is positive for the presence of hCG. One line should be in the control region (C) and another line should be in the test region (T).

**Negative Result.** A specimen that produces a red line in the control region (C) and no apparent red or pink line in the test region (T) is negative for the presence of hCG.

**Invalid Result (any of the following).** For the test to be valid, a red line must appear in the control region (C). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit and immediately contact the Lab Component Lead.

If an invalid test result occurs repeatedly, or if you need technical assistance, contact the Technical Support Department at Beckman Coulter.

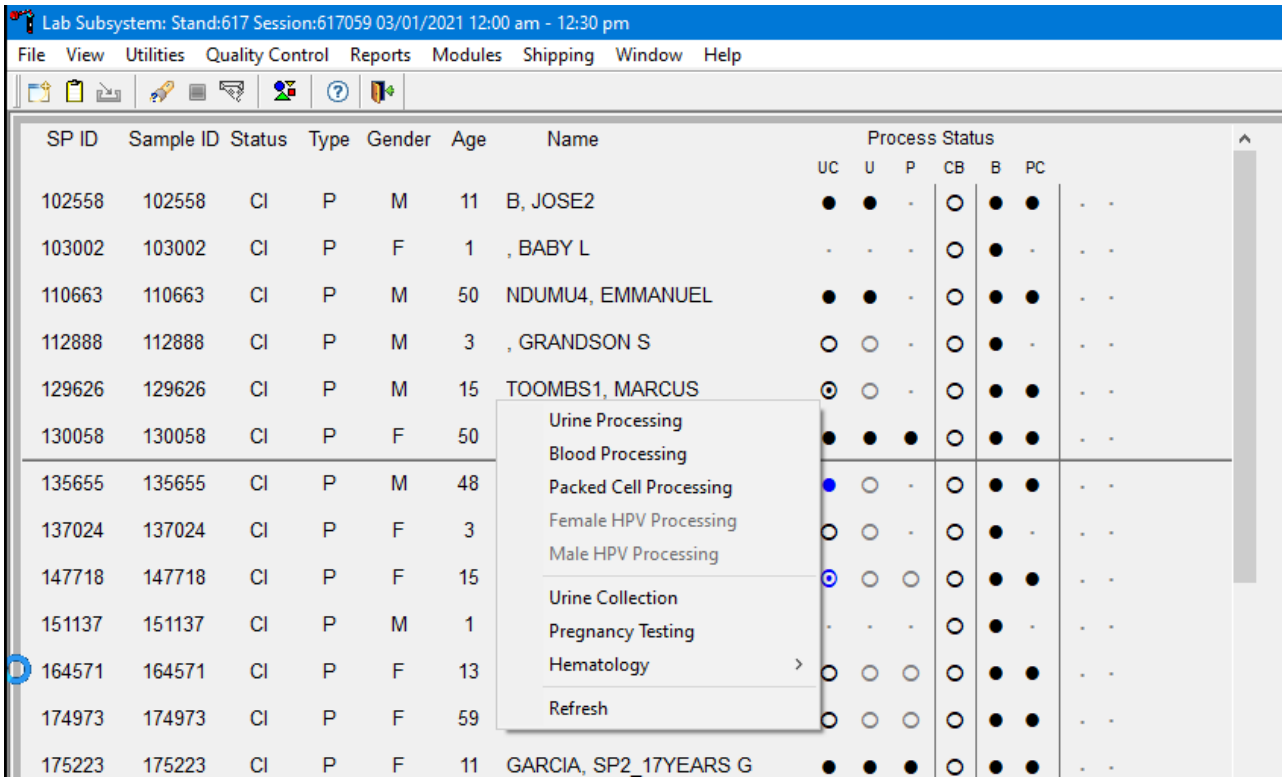
### Sure-Vue™ hCG Urine Control Sets

**Positive Result.** The 25 mIU/mL hCG positive urine controls should produce positive results.

**Negative Result.** The negative urine control should produce a negative result.

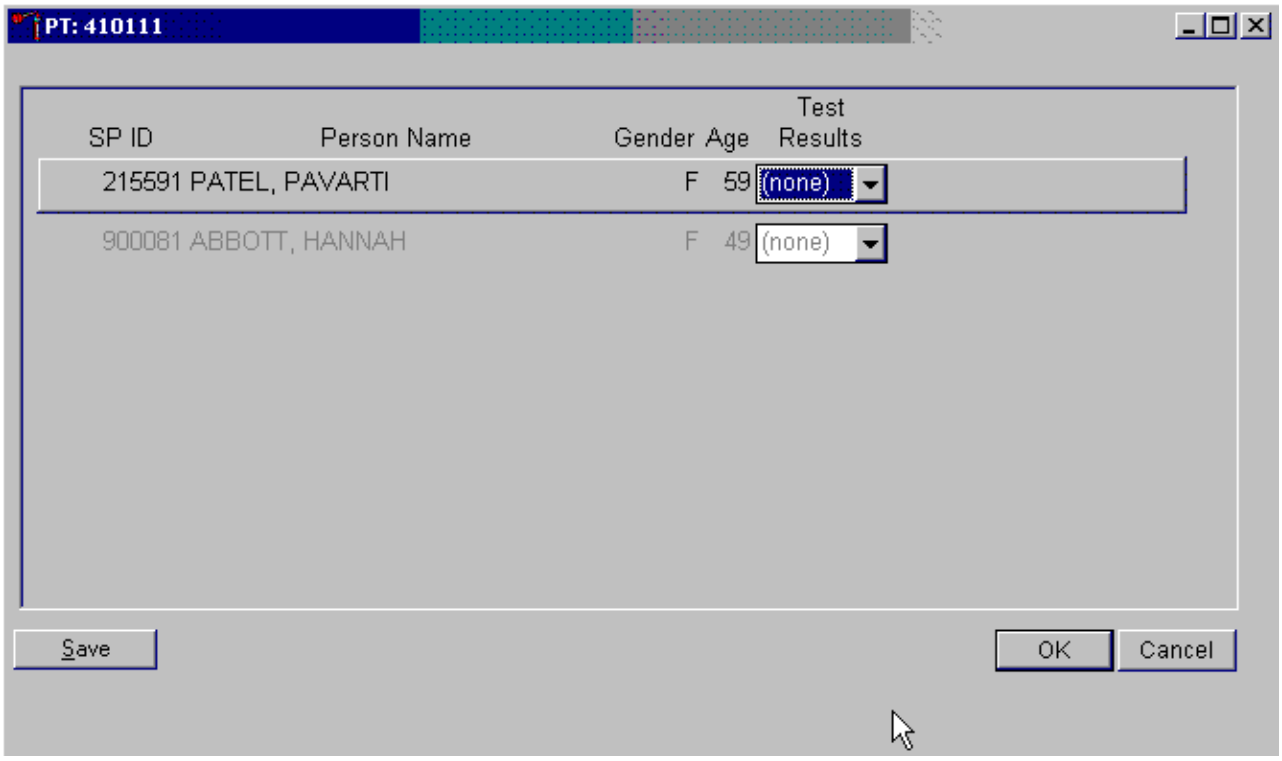
## 1.10 Record Results

Use the heads-up display and the Pregnancy Testing module to enter the results of the ICON® 25 hCG test kit pregnancy test for each SP. Note that the first urine collection must be marked as verified for the Pregnancy Testing module to enable on the heads-up display and on the right-click menu.

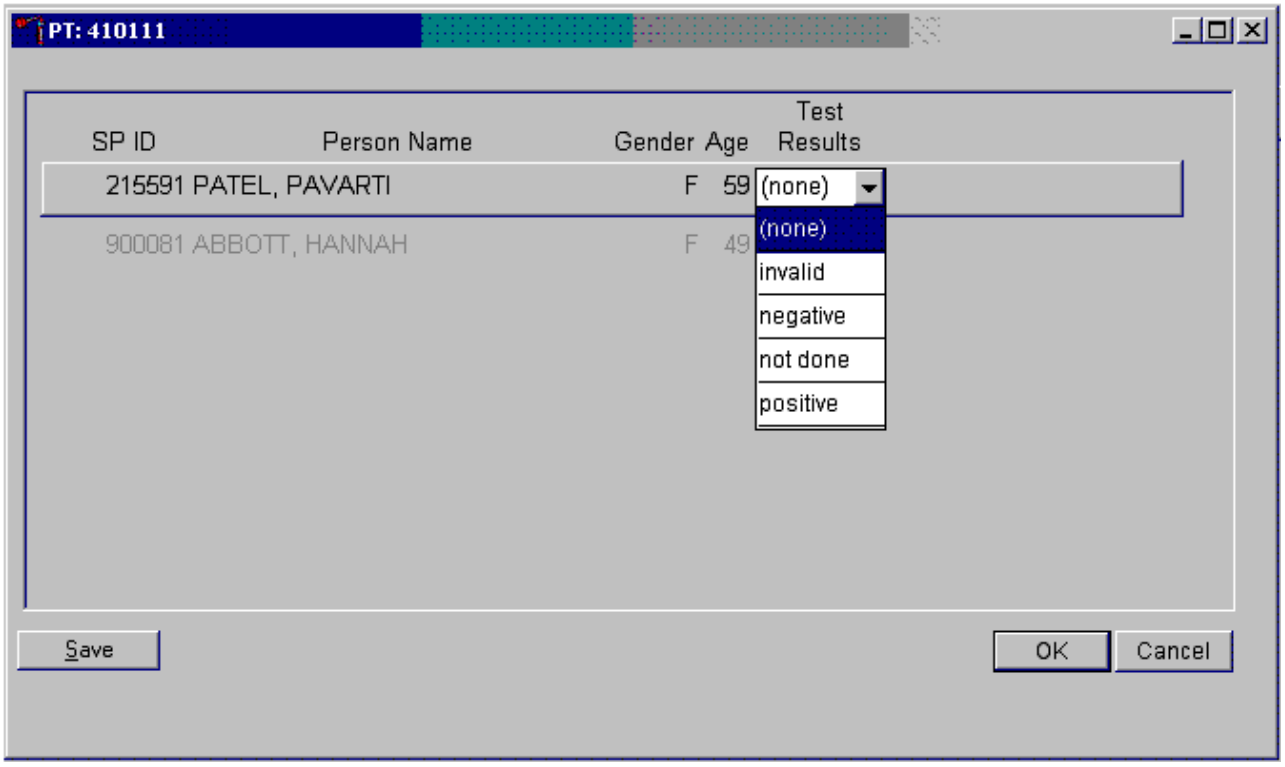



To access the Pregnancy Testing module, direct the mouse arrow to the correct SP, right-click, drag the mouse arrow to Pregnancy Testing, and left-click. Alternatively, use the up and down keys to move up and down the list until the correct SP is highlighted, right-click, drag the mouse arrow to Pregnancy Testing, and left-click.

The Pregnancy Testing window displays.




The text is black for SPs who have urine collection results recorded as "Yes" or "Yes/QNS." The text is gray for SPs who do not have urine collection results recorded. The window lists the SP ID, Person Name, Gender, and Age and includes a Test Results column (text box).

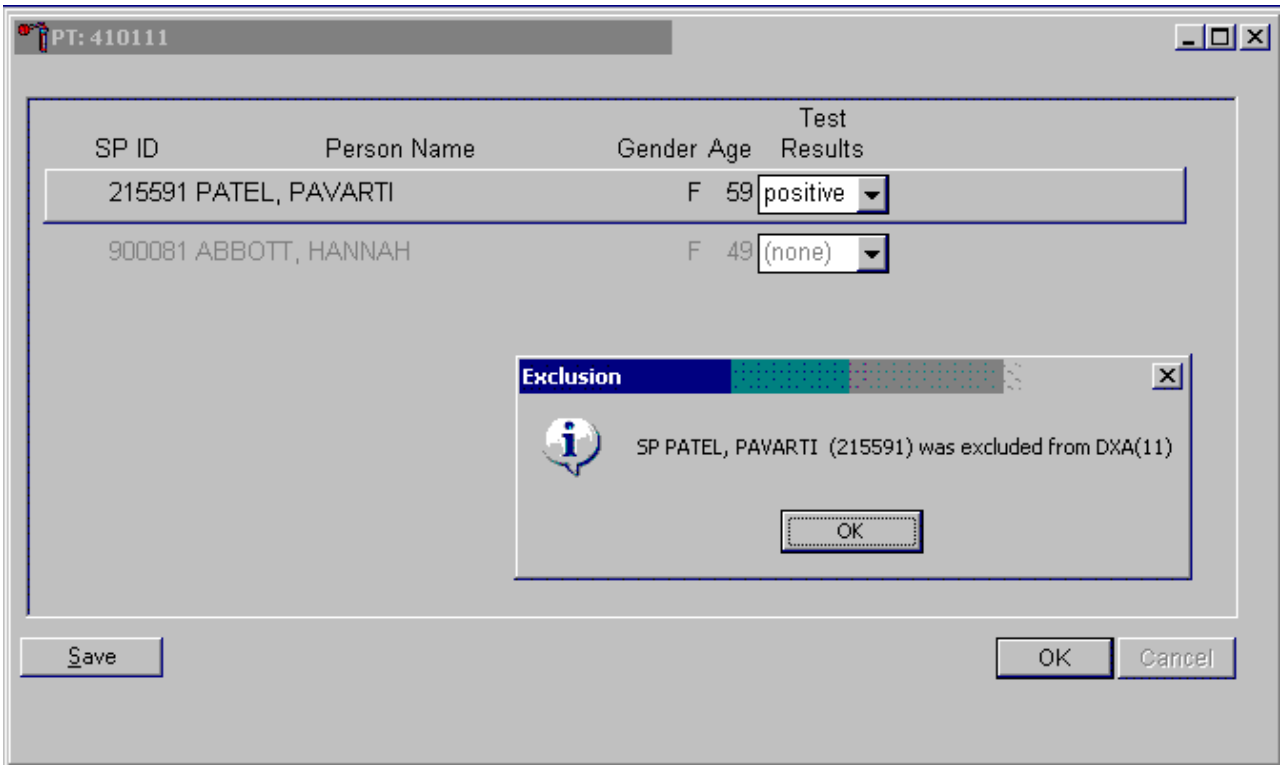


If the Test Result field is black or highlighted, record the result by typing [P/p] for positive, [N/n] for negative, or [I/i] for an invalid result. Enter [N/n] for "not done" when the test was not performed. Alternatively, to record a result, direct the mouse arrow to the drop-down list, drag the arrow to the correct choice, and left-click. To update the results without exiting the window, direct the mouse arrow to the Save button and left-click. To update the results and exit the window, direct the mouse arrow to the OK button and left-click or select Enter. To exit the module without saving any result, direct the mouse arrow to the Cancel button and left-click.

Continue performing pregnancy tests and recording the results. Save the test results after entering each positive, negative, or invalid result. To update the results without exiting the window, direct the mouse arrow to the Save button and left-click. To update the results and exit the window, direct the mouse arrow to the OK button and left-click or select Enter. To exit the module without saving any result, direct the mouse arrow to the Cancel button and left-click.

A series of message boxes displays to inform you that an SP has been excluded (blocked).

As each positive result is saved to the database, a blocking message displays.




To close the informational message box, direct the mouse arrow to the OK button and left-click, or select Enter.

### 1.10.1 Partial Exams Requiring Repeat Pregnancy Testing

When SPs return a second day for completion of an exam (e.g., the DXA machine was down for a session), they must submit another urine sample to confirm a negative pregnancy test on the day of the partial exam. In these cases a second urine pregnancy test will appear on the heads up for the repeat visit. Laboratory staff will perform the urine pregnancy test, then send a message to the coordinator to appropriately assign the SP to pertinent component exams. Should the result of the second visit pregnancy test be positive, a UFO will be submitted in addition to notifying the clinician and the coordinator. The SP will not be assigned to any component where this is an exclusion.

## 1.11 Limitations of Method: Specimen Rejection, Interfering Substances, and Conditions

Read the following procedural notes to ensure the best results with the ICON® 25 hCG test kit.

#### ICON® 25 hCG Test

- **Dispensing Specimen.** Do not reuse a test device or use a test device for multiple patient samples or controls, as this will produce inaccurate results.
- **Color Intensity.** The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the sample. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.
- **Batch Processing.** If several specimens are to be tested during one run, perform each test step for all specimens and controls at timed intervals before proceeding to the next test step. It is recommended that no more than 10 test devices be run in one batch.
- **Specimens Containing Particulate Matter.** Urine samples exhibiting visible precipitates should be allowed to settle to obtain a clear sample for testing.
- **Very dilute urine samples,** as indicated by a low specific gravity, may not contain representative levels of hCG.
- **False negative results** may occur when the levels of hCG are below the sensitivity level of the test.
- **Very low levels of hCG** (less than 50 mIU/mL) are present in urine samples shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed.

- **A number of conditions** other than pregnancy—including trophoblastic disease and certain nontrophoblastic neoplasms, including testicular tumors, prostate cancer, breast cancer, and lung cancer—cause elevated levels of hCG. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.

- **This Test Provides A Presumptive Diagnosis for Pregnancy.** A clinician should make a confirmed pregnancy diagnosis only after all clinical and laboratory findings have been evaluated.

- **Negative Results are Expected in Healthy Nonpregnant Women and Healthy Men.** Healthy pregnant women have hCG in their urine samples. The amount of hCG will vary greatly with gestational age and between individuals. Concentrations of hCG in pregnant women are generally between 10 and 30 mIU hCG/mL in the 7-10 days following implantation or 3 weeks after the last menstrual period. During the latter part of the first trimester of pregnancy, the hCG concentration reaches a maximum level of greater than 100,000 mIU/mL.

- **The ICON® 25 hCG test** has a stated sensitivity of 25 mIU/mL and is capable of detecting pregnancy as early as 1 day after the first missed menses.

### Sure-Vue™ hCG Urine Control Sets

These controls are formulated for use as QC specimens in the reagent verification of pregnancy test kits.

### Accuracy, Sensitivity, and Specificity: ICON® 25 hCG Test

**Accuracy.** A multicenter clinical evaluation was conducted comparing the results obtained using the ICON® 25 hCG test and another commercially available urine/serum membrane hCG test. The urine study included 159 samples, and both tests identified 88 negative and 71 positive results. The results demonstrated a 100 percent overall agreement (for an accuracy of >99%) of the ICON® 25 hCG test with the other urine/serum membrane hCG test, as shown in Exhibit 5-5.

### Exhibit 1-5. Comparison of hCG tests

| Kit | Possible result | Commercially available test | |
|---|---|---|---|
| | | Positive | Negative |
| ICON® 25 hCG Urine | Positive | 71 | 0 |
| | Negative | 0 | 88 |

**Sensitivity.** The ICON® 25 hCG test detects hCG at concentrations of 25 mIU hCG/mL or greater. The test has been standardized to the World Health Organization Third International Standard. The addition of 300 mIU/mL of luteinizing hormone, 1,000 mIU/mL of follicle stimulating hormone, and 1,000 mIU/mL of thyroid stimulating hormone to negative (0 mIU/mL hCG) urine/serum specimens and to positive (25 mIU/mL hCG) urine/serum specimens did not exhibit cross-reactivity in the assay.

**Specificity.** The following potentially interfering substances were added to hCG negative and positive samples, as shown in Exhibit 5-6. None of the substances at the concentrations tested interfered in the test.

### Exhibit 1-6. Interfering substances

| Substance added | Concentration (mg/dl unless noted) |
|---|---|
| Acetaminophen | 20 |
| Acetone | 1,000 |
| Acetylsalicylic Acid | 20 |
| Acetoacetic Acid | 2,000 |
| Ampicillin | 20 |
| Ascorbic Acid | 20 |
| Atropine | 20 |
| Albumin | 2,000 |
| B-Hydroxybutyrate salt | 2,000 |
| Benzoylecgonine | 10 |
| Bilirubin | 20 |
| Brompheniramine | 20 |
| Caffeine | 20 |
| Cannabinol | 10 |
| Clomiphene | 100 |
| Cocaine | 10 |
| Codeine | 10 |
| Cholesterol | 500 |
| Creatine | 20 |
| Dextromethorphan | 20 |
| DMSO | 5 percent |
| EDTA | 80 |
| Ephedrine | 20 |
| Ethanol | 1 percent |
| Estriol | 2 |
| Estrone 3-sulfate | 10 |
| Gentisic acid | 20 |
| Glucose | 2000 |
| Hemoglobin | 1,000 |
| Heroin | 1 |
| Ibuprofen | 20 |
| Methadone | 10 |
| Methamphetamine | 10 |
| Methanol | 10 percent |
| Morphine | 0.6 |
| Oxalic acid | 40 |
| Phenothiazine | 20 |
| Phenylpropanolamine | 20 |
| Pregnanediol | 2 |
| Salicylic acid | 20 |
| Tetracycline | 20 |
| Triglycerides | 1,200 |
| Theophylline | 20 |
| Urea | 2,000 |

### Sure-Vue™ hCG Urine Controls

These controls have been designed to produce correct results in pregnancy test kits. These controls have been tested with the ICON® 25 hCG test and were found to produce satisfactory results.

## 1.12 Reference Ranges

Not applicable.

## 1.13 Action Limits

Not applicable.

## 1.14 Specimen Storage and Handling During Testing

A urine sample must be collected in a clean and dry container. Urine samples exhibiting visible precipitates should be allowed to settle to obtain a clear sample for testing.

## 1.15 Alternative Method for Performing the Test or Storing Specimens if the Test System Fails

There is no alternative method for testing.

## 1.16 Test Results Reporting System Protocol for Reporting Action Limits

Not applicable.

## 1.17 Specimen Accountability and Tracking

All records, including quality assurance/QC data, are maintained for 6 years. Use only numerical identifiers for SP results.

## 1.18 Quality Control Summary Statistics and Graphs

Quality control reports are monitored by stand and maintained for 6 years.

## 1.19 References

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