

 <p>VA PUGET SOUND HEALTH CARE SYSTEM Pathology & Laboratory Medicine Service Seattle & American Lake Divisions</p>	Document ID: PC00015
	Effective Date: 02-12-2012
	Distribution: Seattle/AMLK
	SECTION: POC
TITLE: OTHER TEST ENTRY USING ACCU-CHEK INFORM II METER	

PRINCIPLE:

1. Purpose:

- a. The Other Test Entry (OTE) feature allows for entry of quality control and patient test results for the following manually performed tests via the of the ACCU-CHEK® Inform II meter.
 - Urine dipstick (UA) (Visual UA)
 - Urine Pregnancy (Pregnancy)
 - Rapid Drugs of Abuse (DAT) (Rapid DAT)
- b. OTE is a data-entry function only. The tests are not performed on the ACCU-CHEK® Inform II meter. Entry of patient results using OTE provides an accessioning system as well as remote download of these POC testing results for review by the Laboratory and upload to the Lab Information System (LIS) also called RALS Plus and Hospital Information System (HIS).

2. Policy:

- a. Results of quality control and patient tests are entered at the time of testing by the person that performed the test.
- b. Only staff that have current competency may perform testing and enter results using OTE.
- c. If an operator does not have a current competency in the RALS Plus database for a specific OTE test, they are locked out of entering OTE results.
- d. The ACCU-CHEK® Inform II meter will not flag the operator or lock out patient testing if quality control results exceed acceptable ranges. Therefore, the operator will reference the control assay sheet when quality control testing is performed and results are entered manually in the meter.
- e. If quality control results fall within expected ranges, patient testing may be performed.
- f. If quality control results fall outside the expected ranges, the operator will initiate corrective actions. No patient testing is performed until testing is repeated and results of all controls are within expected ranges.
- g. Quality control testing is performed and results entered into the ACCU-CHEK® Inform II meter:
 - As indicated with each kit or at the same time each day- to be determined by individual POC testing sites.
 - When new lots of reagent are opened.

SPECIMEN COLLECTION: N/A

REAGENTS: N/A

EQUIPMENT:

1. ACCU-CHEK® Inform II Glucose Meter

CALIBRATION: N/A

ID #	TITLE	Effective Date
PC00015	OTHER TEST ENTRY USING ACCU-CHEK INFORM II METER	02-12-12

QUALITY CONTROL:

1. Quality Control Data Entry Procedure:

- a. Remove Accu Chek meter from base unit and wait at least 5 seconds before pressing the On button.
- b. With Operator ID screen displayed, press Scan and scan Operator ID badge or manually enter employee ID and press ► (the large forward arrow button under the touch screen).
- c. With the Main Menu displayed, press Control Test
- d. Press Other Control Tests.
- e. Press the appropriate control test button (Pregnancy, Visual UA, Rapid Drugs of Abuse (DAT)).
- f. Press either the Positive/Abnormal or Negative/Normal Liquid Control button for the control tested.
- g. Confirm the kit (reagent) lot number or enter the kit lot number by pressing the number and/or letter keys on the touch screen.
- h. Pregnancy kit lot number is recorded on each individual pouch that contains the test device.
- i. Urine Dip (Visual UA) kit lot number is recorded on Chemstrip 5 OB bottle label.
- j. Rapid Drugs of Abuse (DAT) number is recorded off of each pouch that contains the test device.
- k. Enter the expiration date of the kit (reagent) lot if prompted to do so. Note: for single digit numbers, add a leading zero.
- l. Confirm the control lot number (found on control label) or enter the control lot number by pressing the number and/or letter keys on the touch screen.
- m. Enter the expiration date of the control lot number (found on control label) if prompted to do so.
- n. Select the result of the control bar test as Acceptable or Not Acceptable for Urine Pregnancy and Rapid Drugs of Abuse (DAT) only. Acceptable indicates that the control bar is present.
- o. Depending on the type of Quality Control Test performed,
- p. Select the result of the liquid control test as Acceptable or Not Acceptable for Urine Pregnancy and Drugs of Abuse.
- q. Select results for color, clarity, and each test result obtained for the Urine Dipstick (Visual UA).
- r. The Control Summary screen will show the kit (reagent) lot number, control lot number, control bar (if appropriate), and the control result.
- s. Note: Perform review of entered data to accept or change before exiting the meter.
- t. To change any information, press the appropriate button to display that choice. Select or enter the correct information. The change will now be displayed on the Control Summary screen.

PROCEDURE:

1. Patient Data Entry Procedure:

- a. Remove Accu Chek meter from base unit and wait at least 5 seconds before pressing the ON button.
- b. With Operator ID screen displayed, press Scan and scan Operator ID badge or manually enter employee ID (DUZ#) and press ► (the large forward arrow button under the touch screen).
- c. With the Main Menu displayed, press Patient Test button to display the Patient Test Menu.
- d. Press Other Patient Tests button.
- e. Press the appropriate test button (Pregnancy, UA, Rapid Drugs of Abuse (DAT))

ID #	TITLE	Effective Date
PC00015	OTHER TEST ENTRY USING ACCU-CHEK INFORM II METER	02-12-12

- f. Enter the patient ID (entire social security number). Verify that the number has been entered correctly. Use the to backspace and clear incorrectly. Press ► once you are sure the patient ID has been entered correctly.
- g. Confirm the reagent lot number or enter the reagent lot number by pressing the number and/or letter keys.
- h. Pregnancy kit lot number is recorded on the box and each individual pouch that contains the test device
- i. Urine Dip (Visual UA) kit lot number is recorded on Chemstrip 5 OB bottle label
- j. Rapid Drugs of Abuse (DAT) on each individual pouch containing testing device.
- k. Enter the kit (reagent) expiration date if prompted to do so. For single digit numbers, add a leading zero. Press ► to continue to the next screen.
- l. If performing Urine Dip (Visual UA) test, proceed to step 15.
- m. If performing Pregnancy or Rapid Drugs of Abuse , proceed to step 14.
- n. Select the result of the positive control (performance monitor) as Acceptable or Not Acceptable.
- o. Select the result of the negative control (performance monitor) as Acceptable or Not Acceptable and proceed to step 15.
- p. Select the result of the control bar test as Acceptable or Not Acceptable for Urine Pregnancy and Rapid Drugs of Abuse only. Acceptable indicates that the control bar is present.
- q. Select the patient result(s) obtained by pressing the appropriate result button.
- r. Note for Pregnancy and Rapid Drugs of Abuse tests: if unable to determine if a patient line is present:
- s. Do not enter a result in Other Test Enter (OTE) system.
- t. Make a note in the patient record- "unreadable"
- u. Notify provider that a blood sample must be sent to lab for quantitative Pregnancy (hCG) or repeat urine for Urine Drugs of Abuse (DAT) be sent to main laboratory.
- v. Once the result(s) are entered, the Patient Result screen is displayed.
- w. To change the result, press Result or the appropriate test button for the UA and select the correct result.
- x. To enter comments, press Comments.
- y. The text of Preprogrammed Comments is displayed in large buttons. Press the appropriate comment(s).
- z. One custom comment may be added by pressing the letter and number keys on the touch screen. You may clear a character if needed by pressing the key to backspace. Press ► button under the touch screen when finished entering custom comment. The Patient Result Summary screen will display.
- aa. To change any information, press the appropriate button to display the choice. Select the correct information. The change will now display on the Patient Result Summary screen.
- bb. Press ► button or the Menu button under the touch screen to record the test and return to the Main Menu screen.

METHOD RANGE(S): N/A

PROCEDURE NOTE(S):

1. Interpretation/Results/Alert Values
 - a. Warnings:
2. The ACCU-CHEK® Inform II Meter will display warning screens at various times when entering other patient and control tests. These warning screens display when the validity of the recorded result is in question and are therefore intended to flag the operator that test information may not be valid or accurate. OTE warnings and recommended actions are listed in the chart below.

ID #	TITLE	Effective Date
PC00015	OTHER TEST ENTRY USING ACCU-CHEK INFORM II METER	02-12-12

Warning	Alert	Recommended Action
The entered lot has expired. It is advisable to use unexpired lots when performing these tests.	The lot number entered has expired.	Press Ok , Do NOT report result, repeat test using new lot number of reagent or control that has not expired.
Warning: Patient result may be invalid due to control bar entered as Not Acceptable. Do you want to enter Not Acceptable? Yes/No	Because the control bar was not acceptable, the patient result may be invalid as well.	Press No . Initiate corrective actions and repeat test. Do not report or enter any patient results if the internal control bar does not yield acceptable results. Notify POC program if unable to resolve the problem.
Warning: Control result may be invalid due to control bar entered as Not Acceptable. Do you want to enter Not Acceptable? Yes/No	Because the control bar was not acceptable, the liquid control result may be invalid as well.	Press Yes if control bar result was entered correctly- document corrective actions by entering a text comment code. Patient testing should not be performed until the problem is resolved and acceptable results are obtained for all controls. Press No if control bar result was entered incorrectly and re-enter correct result. Notify POC program if unable to resolve the problem.
Warning: Control result is Not Acceptable. Are you sure you want to enter a QC result as Not Acceptable? Yes/No	Control result was entered as Not Acceptable.	Press Yes if control result was recorded correctly- document corrective actions by entering a text comment code. Patient testing should not be performed until the problem is resolved and acceptable results are obtained for all controls. Notify POC program if unable to resolve the problem. Press No if control result was

ID #	TITLE	Effective Date
PC00015	OTHER TEST ENTRY USING ACCU-CHEK INFORM II METER	02-12-12

Warning	Alert	Recommended Action
		entered incorrectly and re-enter correct result.
<p>This control result is invalid due to unacceptable control bar result.</p> <p>Please repeat test on new card.</p>	<p>Although the liquid control result was acceptable, the control test result may be invalid due to a not acceptable control bar result.</p>	<p>Press Ok, document corrective actions by entering a text comment code.</p> <p>Patient testing should not be performed until the problem is resolved and acceptable results are obtained for all controls.</p> <p>Notify POC program if unable to resolve the problem.</p>

REFERENCES:

1. Roche Diagnostics: ACCU-CHEK® Inform II Blood Glucose Monitoring System Operator's Manual, 2004.
2. RALS-Plus for ACCU-CHEK® Inform II "Other Test Entry" (OTE)1.2.1.SP1 MAS-5035 -0800(1.0) April 2004.

APPENDICES: N/A

