ACCU-CHEK® Inform II

<Insert facility name>

In-Service Plan for Blood Glucose Testing

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Roche

Table of Contents

Section 1: Introduction

Communication and planning are key to a successful in-service and implementation!

Introduction / How to use this guide

Roche Diagnostics is pleased to offer this guide to assist you in creating and executing comprehensive in-service training for the use of the ACCU-CHEK® Inform II system in your facility. This guide contains in-service training documentation and resources that provide initial step-by-step system instructions, hands-on practice exercises and tracking forms for operator proficiency and certification in blood glucose monitoring with the ACCU-CHEK Inform II system.

This is a working guide that generally conforms to CLSI document GP21-A3 (Training and Competence Assessment; Approved Guideline – Third Edition). Portions of this guide are editable to reflect information specific to your facility and preferences. You will find blank spaces ____ and <*italicized text*> within brackets throughout this guide. These are provided to alert you to areas that you will commonly want to customize and to provide examples of text for you to consider. You will need to change the font of the <*italicized text*> back to regular after you have customized your entries, or possibly delete it if it was not necessary. To un-italicize, simply highlight the text and press the “control” and “i” keys simultaneously.

The “Introduction” and “Pre In-Service Activities” sections are designed to help create and plan for an Operator In-Service training. The next section, “Operator In-Service,” is designed to help the instructor plan, train and execute an in-service training for the ACCU-CHEK Inform II system. This section can also be copied and used as a more detailed reference for the operator during in-service training.

Hospital's Commitment

Roche Diagnostics is committed to a successful implementation. The hospital, in return, must also make a commitment to:

- Proactively involve all necessary staff and administration.
- Stress the importance of participation to all Unit Managers.
- Follow-up with departments that are not complying.
- Support the "train the trainer" sessions for resource personnel who will be training as needed after formal in-servicing is completed.
- Limit the use of unit-to-unit in-servicing. These are known to decrease comprehension due to distractions but may be needed with some departments.

The Advantages of Centralized In-Servicing

- Maximize attention (less distractions).
- Increase comprehension (classroom setting with bullet points posted, support material).
- Maximize efficiency (staff is aware of timeframe and can work into their own schedule).
- Provide sufficient ACCU-CHEK Inform II systems available for hands-on training (1-2 units per department vs. many units set up in classroom style).
- Standardize training (everyone gets the same step-by-step, hands-on exercises and message(s)).
- Effectively charge, clean and disinfect systems as needed (infection control).

The Advantages of using Computer-Based Training as a Component of Operator Training:

- Self-paced
- Inclusive of knowledge test and skills reinforcement
- Can serve as reference after training
- Consistent content

Section 2: Pre-In-Service Activities

Operator In-Servicing Policies and Processes

<table>
<tr><th colspan="3">Process Table</th></tr>
<tr><th>What Happens</th><th>Who is Responsible</th><th>Related Procedures</th></tr>
<tr><td>An operator certification program is developed for the purpose of training operators in the proper use of the ACCU-CHEK Inform II system.</td><td><Enter the staff positions(s) responsible for developing the operator certification program; e.g., Point of Care Coordinator, Nursing educator, manufacturer's representative.></td><td rowspan="7"><Enter the title of any general facility policies and procedures regarding employee education.>

<Enter the title of any general facility policies and procedures regarding trainer qualification.>

ACCU-CHEK Inform II Operator's Manual

ACCU-CHEK Inform II Policies and Procedures for Blood Glucose Testing

ACCU-CHEK Inform II In-Service Plan for Blood Glucose Testing</td></tr>
<tr><td>Individuals are designated and as qualified Operator Certification/Recertification in-service instructors.

<Enter a description of your preferred method(s) of training; e.g., classroom, self-paced, on nursing units, on-line sessions, etc.)></td><td><Enter the title(s) of qualified instructors and your instructor qualifications here; e.g., a manufacturer's representative or designee, designated staff member(s) trained by a manufacturer's representative or designee.>

Keep a list of qualified trainers in your policies and procedures manual.</td></tr>
<tr><td>Potential operators are scheduled for training sessions.</td><td><Enter the staff position(s) responsible for scheduling certification training sessions.></td></tr>
<tr><td>Operators attend and successfully complete a scheduled certification training session.</td><td>All designated individual staff member(s) whose job functions include ACCU-CHEK Inform II bedside glucose testing.

Qualified staff trainers.</td></tr>
<tr><td>Operators who successfully complete the certification training are added to the list of valid operators in the <enter the name of your data management system.></td><td><Enter the staff positions(s) responsible for maintaining operator certification records.></td></tr>
<tr><td>Attendees complete a Training Evaluation Form.</td><td>All staff members attending certification training.</td></tr>
<tr><td>Training Evaluation Forms are assessed and productive feedback is incorporated into the training as appropriate.</td><td><Enter the staff position(s) responsible for maintaining the operator certification training program.></td></tr>
</table>

Hospital Key Personnel List

Name/Title	Department	Phone # / Fax #	**Role** (During in-service planning or execution)
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	
<First Name, Last Name and Title>	*<Department>*	*<XXX-XXX-XXXX>*	

Site Assessment for In-Servicing

Considerations	Site Specific Needs for In-Service Training
List the total number of users that need to be trained	*<insert the total number of operators or users>*
If Train the Trainer format is chosen, list how may trainers must be trained	*<insert the total number of train the trainers>*
List the minimum and maximum number of attendees per in-service class (8-15 staff per class recommendation)	*<insert the number of operators per class, e.g., 10, 15, 20, 25, etc.>*
What are the appropriate dates and times for in-servicing?	*<insert all dates and times for in-servicing MM/DD/YY, 00:00 – 00:00 times>*
Duration of in-service	*<insert how long an in-service training should last, e.g., 45, 60, 90, 180 minutes>*
What is the content of the in-service class?	*<Insert all that apply: In-servicing video, interactive learning tool, hands-on system exercises (calibration, specimen collection, running a patient test, running controls, meter setup, review results, meter cleaning and disinfecting and troubleshooting)>*
Where will in-servicing take place?	*<insert classroom, self-paced, on nursing units, online, etc.>*
Determine which room(s) / location(s) are to be utilized for training and reserve / book room(s) required	*<insert the room(s) / location(s) reserved / identified for in-service training>*
Confirm room layout needs: AV equipment and power strips available at all locations during in-service	*<insert if room(s) reserved / location(s) identified for in-service training meet training layout needs>*
List how staff will be assigned to class times	*<insert format - sign-up sheets, pre-assigned lists (by whom) or first come first serve>*
Will signage and posters be created and posted indicating in-service room location(s)?	*<Y or N and list locations to post signage and / or posters>*
List shift/report times for weekday/ weekend days, if different	*<insert days and times of shifts>*
Develop in-service schedule	*<insert days, times and number of classes for in-service training>*
List and copy in-service training materials and packets	*<insert training material(s) being assembled, e.g., in-service equipment (test strips, controls, gloves, alcohol prep pads, sharps containers, etc.), support materials operator's manual, quick reference guide and certification tests>*

ACCU-CHEK Inform II Blood Glucose System – Sample In-Service Schedule

Monday, Month, 2012

TIME	LOCATION
7:00 a.m. - 8:00 a.m.	Classroom C
8:00 a.m. - 9:00 a.m.	Classroom C
9:00 a.m. - 10:00 a.m.	Classroom C
11:00 a.m. - 12:00 p.m.	Classroom C
1:30 p.m. - 2:30 p.m.	Classroom C
2:30 p.m. - 3:30 p.m.	Classroom C
3:30 p.m. - 4:30 p.m.	Classroom C

Tuesday, Month, 2012

TIME	LOCATION
7:00 a.m. - 8:00 a.m.	Classroom D
8:00 a.m. - 9:00 a.m.	Classroom D
9:00 a.m. - 10:00 a.m.	Classroom D
11:00 a.m. - 12:00 p.m.	Classroom D
1:30 p.m. - 2:30 p.m.	Classroom D
2:30 p.m. - 3:30 p.m.	Classroom D
3:30 p.m. - 4:30 p.m.	Classroom D

Wednesday, Month, 2012

TIME	LOCATION
7:00 a.m. - 8:00 a.m.	Classroom C
8:00 a.m. - 9:00 a.m.	Classroom C
9:00 a.m. - 10:00 a.m.	Classroom C
4:00 p.m. - 5:00 p.m.	Classroom C
6:00 p.m. - 7:00 p.m.	Classroom C
7:00 p.m. - 8:00 p.m.	Classroom C
8:00 p.m. - 9:00 p.m.	Classroom C

Thursday, Month, 2012

TIME	LOCATION
3:00 a.m. - 4:00 a.m.	Classroom C
4:00 a.m. - 5:00 a.m.	Classroom C
6:00 a.m. - 7:00 a.m.	Classroom C
7:00 a.m. - 8:00 a.m.	Classroom C
2:00 p.m. - 3:00 p.m.	Classroom D
3:00 p.m. - 4:00 p.m.	Classroom D

Commonly Asked Questions During In-Service Training

Use form below to prepare for questions during in-service training

1. What are the appropriate ID numbers for operator and patient?	
2. What should I do if my operator ID is denied?	
3. When is QC due?	
4. Will QC due times ever rotate to different shifts?	
5. What should I do if QC tests continue to fail or fall outside of the acceptable ranges?	
6. What if someone asks to use my operator ID?	
7. What if I don't have a patient ID number (NICU, ED, etc.)?	
8. Are there specifications for dialysis and recovery?	
9. What are the patient critical ranges? • General Nursing Low- High- • NICU Low- High- • PEDS Low- High- • Other (specify)	
10. Do I have to wipe the first drop of blood from a patient's finger before dosing the strip?	
11. What is the policy and procedure for a critical result?	
12. What if I get a result that is out of normal range but not critical?	
13. What should I do if a repeated test is significantly different from the first test?	
14. What comments are required and when must I enter them?	
15. How and where should QC and patient results be recorded? How is this different from what I am doing currently?	
16. Where are the policies and procedure manuals kept?	
17. What should I do if the meter is malfunctioning?	
18. How and where do I procure supplies?	
19. Other than Clorox Germicidal Wipes (EPA* reg. no. 67619-12) solution or I, what else may be used for disinfecting the meter?	
20. What policy and procedure changes will take place when using this meter vs. the existing meter?	
21. How do I utilize this meter in an isolation room?	
22. When will we be switching to the new meter?	

* Environmental Protection Agency

Section 3: Operator In-Service

Planning

Introduction

Quality patient care demands that tests are performed correctly, testing equipment is maintained properly, and personnel are thoroughly trained. Training and in-servicing are most often used to provide initial instruction and practice when teaching small groups of personnel to perform blood glucose monitoring.

The following information will assist you in developing an ACCU-CHEK Inform II system in-service program for your institution. A Knowledge Test and ACCU-CHEK Inform II System Skills Checklist have also been added to document proficiency and certification in blood glucose monitoring with the ACCU-CHEK Inform II system. A recertification program and schedule in compliance with your regulatory agency guidelines are recommended.

Preparation

- The suggested time for each in-service is 30-75* minutes.
- Schedule the in-service in a room that is free from distractions.
- Schedule the in-service at shift change so both incoming and outgoing personnel have an opportunity to attend.
- Organize the presentation, gather needed supplies, and ensure equipment is operational.
- Ensure there are enough supplies for everyone.
- Whenever possible, make all in-services mandatory.
- Review your facility's policies and procedures for blood glucose monitoring.
- Ask all personnel to sign the Operator Certification Roster.

Instructors

<Insert facility policy for certifying in-service instructors (e.g., a certified ACCU-CHEK Inform II system instructor may be a Point of Care Coordinator or designee, Diabetes Clinical Specialist, QA Nurse, Roche Diagnostics Account Manager, or another designated individual who is trained in the use of the ACCU-CHEK Inform II system.)>

<Maintain and store a list of certified in-service trainers in the facility's policies and procedures manual.>

* Depending on hospital's prior experience with ACCU-CHEK blood glucose systems and IT connectivity solution; longer time is need if unfamiliar with ACCU-CHEK products and connectivity.

In-service Objectives

The operator will learn and understand:

- Essential facility policies for bedside glucose testing
- Infection control and safety principles and policies
- Proper specimen collection procedures
- Proper calibration (coding) of the ACCU-CHEK Inform II meter
- Proper patient testing
- Proper quality control testing
- Proper documentation of patient blood glucose results and follow-up of abnormal or unexpected test results
- Proper preventive maintenance
- Proper interpretation of common on-screen messages
- Proper troubleshooting procedures

At the conclusion of this training and in-servicing, the operator will successfully complete an ACCU-CHEK Inform II System Test and Skills Checklist to be certified for blood glucose testing with the ACCU-CHEK Inform II system.

Have the operator use the grid below to help track their learning and understanding of the ACCU-CHEK Inform II system.

Topic	Rating lowest (1) to highest (5) level of understanding 1 2 3 4 5	Comments
Essential facility policies for bedside glucose testing	☐ ☐ ☐ ☐ ☐	
Infection control and safety principles and policies	☐ ☐ ☐ ☐ ☐	
Proper specimen collection procedures	☐ ☐ ☐ ☐ ☐	
Proper calibration (coding) of the ACCU-CHEK Inform II meter	☐ ☐ ☐ ☐ ☐	
Proper patient testing	☐ ☐ ☐ ☐ ☐	
Proper quality control testing	☐ ☐ ☐ ☐ ☐	
Proper documentation of patient blood glucose results and follow-up of abnormal or unexpected test results	☐ ☐ ☐ ☐ ☐	
Proper preventive maintenance	☐ ☐ ☐ ☐ ☐	
Proper interpretation of common on-screen messages	☐ ☐ ☐ ☐ ☐	
Proper troubleshooting procedures	☐ ☐ ☐ ☐ ☐	

Blood Glucose Monitoring Supplies

- ACCU-CHEK Inform II System (meter, base unit, accessory box, code key reader)* (1 system for every 1-2 operators)
- ACCU-CHEK Inform II test strips and code key (1 vial for every 1-2 operators)
- ACCU-CHEK Inform II glucose control solutions 2-level (1 set for every 1-2 operators)
- Auto-disabling single-use lancing device
- Cotton balls, gauze or tissue for wiping fingers if fingersticks will be performed
- Personal protection equipment as required for universal blood collection precautions (e.g., gloves, hand washing area, etc.)
- Biohazard / sharps containers
- Alcohol wipes (if required)
- Cleaning and disinfecting wipes (if required)

Other Supplies

- TV/DVD player
- In-service programs
- ACCU-CHEK Inform II System Hospital In-service Video / DVD
- ACCU-CHEK Inform II System Interactive Learning Tool (for electronic training)
- Capillary Blood Sampling – interactive learning tool (for electronic training)
- Operator certification roster
- Copies of the in-service certificate (optional)
- Copies of your facility's QC, maintenance, and patient result logs
- Copies of the ACCU-CHEK Inform II system Test and Skills Checklist
- ACCU-CHEK Inform II Operator's Manual
- ACCU-CHEK Inform II Quick Reference Guide
- Posters (optional)

* Depending on your facility's policies, operators may not enter test strip codes into the system and therefore may not need the code key reader for in-service training.

Training and Exercises

ACCU-CHEK Inform II Operator Certification: In-Service Agenda

	Topic	Estimated Time to Present or Practice
I.	Operator Certification In-Service Overview	10 minutes
II.	View the ACCU-CHEK Inform II System Hospital In-Service Video/ DVD* *or* View the ACCU-CHEK Inform II System Interactive Learning Tool*	20 minutes 20–45 minutes
	Note: *The ACCU-CHEK Inform II System Interactive Learning Tool is a substitute for the system overview section (Steps III-XII) of the in-service.*	
III.	Overview of the ACCU-CHEK Inform II System Components	5 minutes
IV.	Calibrating (coding) the ACCU-CHEK Inform II System using Code Key Reader (as necessary)	5 minutes
V.	Specimen Collection	10 minutes
VI.	Performing Patient Testing	5 minutes
VII.	Interpreting and Recording Patient Results	5 minutes
VIII.	Performing Quality Control Testing	5 minutes
IX.	Interpreting Quality Control Results	5 minutes
X.	Interpretation of On-Screen Messages and Troubleshooting	5 minutes
XI.	Results Review - Recalling Test Information	5 minutes
XII.	ACCU-CHEK Inform II System Maintenance	10 minutes
XIII.	Review Other Quality Assurance Procedures	5 minutes

* May be viewed prior to the in-service as prerequisite, to minimize classroom time.

Operator Certification In-Service Overview

1. Review in-service agenda.
2. Explain the institution's policy for the ordering and performance of ancillary blood glucose testing.
3. Review the policy for operator certification. Explain that each operator will be asked to successfully complete the ACCU-CHEK Inform II System Test and Skills Checklist to be properly certified to perform blood glucose testing on the ACCU-CHEK Inform II system.
4. Review storage of testing supplies and locations and procedures for re-stocking supplies.

Review of Essential Testing Policies

Topic	Policy	Comments
Infection Control and Safety	Follow all established facility policies for infection control, safety, patient isolation and biohazard/sharps handling and disposal.	Attendees are expected to be proficient in their understanding of infection control and safety policies. Review location and content of policies as needed.
Entering reagents into the ACCU-CHEK Inform II System	*<Enter your policy regarding who is responsible for entering reagents into the system>*	Procedures for entering reagents into the system should be included in the in-service program only if operators will be expected to enter new reagents periodically.
Cleansing and disinfecting of the intended skin puncture site	*<Enter your policy for cleansing and disinfecting the intended puncture site>*	
Wiping away the first drop of blood when collecting samples	*<Enter your policy for wiping away the first drop of blood when collecting capillary samples>*	This is advantageous because it ensures that the cleansing agent is dry, it stimulates blood flow and clears interstitial fluid from the sample[1,2]
Entering Operator IDs	*<Enter your policy for entering operator IDs (e.g., barcode scanning, manual entry, etc.)>*	Do not perform testing under any operator ID other than your own. Do not allow anyone else to perform testing under your operator ID

1. CLSI Document H4-A5: Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture – Approved Standard; Fifth Edition; 2004; Page 11
2. Document C30-A2: Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Second Edition; 2002; Page 10

Topic	Policy	Comments
Entering Patient IDs	*<Enter your policy for entering patient IDs. Include all identifiers required and method of entry (e.g., barcode scanning, manual entry, etc.)*	
Verifying Test Strip Codes	*<Enter your policy for verifying test strip codes (e.g., barcode scanning, on-screen confirmation, etc.)>*	
Adding Comments to Results	*<Enter your policy for adding comments to results>*	
Documentation of patient results	*<Enter your policy for documenting results in patient charts (e.g., electronic transfer, manual entry, etc.>*	
Follow-up on patient results that are unexpected or that exceed critical limits	*<Enter your policy for follow-up on patient results that are unexpected or that exceed critical limits>*	
QC Testing Schedule	*<Enter your QC schedule policy. Include number of levels and time intervals>*	
QC Results Display	*<Enter your policy for displaying QC results as Pass/Fail or numeric values>*	
Follow up on out-of-range QC results	*<Enter your policy for follow-up on out-of-range QC results>*	
Allowing QC bypassing for stat tests	*<Insert your policy for allowing bypass of QC for STAT tests>*	

View the ACCU-CHEK Inform II System Interactive Learning Tool or In-Service Video

View the ACCU-CHEK Inform II System Hospital In-service Video/DVD or Interactive Learning Tool (optional). This will provide an overview of the testing procedure, quality control testing, and maintenance.

Overview of ACCU-CHEK Inform II System Parts

Front of the Meter	Back of the Meter	System Components
• Test strip port • Touchscreen • On/Off button • Checkmark button – enter confirmation	• Barcode scanner window • Rechargeable battery pack • Reset Button • Charging contacts • Infrared window • Cover for RF card (optional)	• Test Strip • Code key reader • Base Unit • Accessory Box • Control Solutions 2-Level • Linearity Kit

Calibrating (Coding) the ACCU-CHEK Inform II Meter

Demonstrate this procedure if operators will not be authorized to enter test strip codes into the system. Have operators perform this procedure if they will be expected to enter new test strip lots periodically.

- A code key is packaged with each new box of test strips. Each code key belongs to a single lot number and provides important information about the lot specific parameters of the test strip.
- The properties of the test strips are uploaded (as a code file) from the code key using the code key reader and sent to the meter.
- The code file is stored in the meter / data management system and only needs to be uploaded once until a new lot is introduced.
- Coding is verified by matching the test strip lot number on the ACCU-CHEK Inform II meter touchscreen with the code number printed on the vial of test strips.

Note: This procedure will only occur once per new lot.

Gather the following items for calibration:

- ACCU-CHEK Inform II meter
- ACCU-CHEK Inform II code key reader
- ACCU-CHEK Inform II test strips with matching code key

ACCU-CHEK Inform II Calibration (Coding) Procedure:

1. Turn the meter on.
2. Enter your operator ID via the barcode scanner or manually according to facility policy.
3. Touch ✓ to confirm and display the *Main Menu*.
4. Touch ▶ to open the *Main Menu 2* screen.
5. Touch *Strip Lots* to open the related menu.
6. Touch *Add* to upload new test strip lot information from a new code key. The *Add Strip Lot* screen opens.
7. Insert the new code key in the opening of the code key reader. An LED flashes and signals that the reader is ready to upload data.
8. Place the code key reader on a level surface, such as a bench or table. Hold the meter 4-6 inches above the code key reader so that a connection can be made between the two infrared windows.
9. Touch ▶ on the meter to begin uploading data.
10. Information about the expiration date and parameters for control solutions is subsequently displayed.
11. Touch ✓ to store the data for this lot number in the meter without changes or touch X to modify the data for this lot number before storing it in the meter.
12. Once you have finished updating the test strip information, touch ✓ to confirm that you want this lot number to be the lot number currently in use.

    or

13. Continue entering additional lot numbers.

    or

14. Touch ☰ to return to the *Main Menu.*

Specimen Collection

NOTE: Follow all facility safety and infection control policies when collecting blood samples.

NOTE: Consider using the Capillary Blood Sampling – interactive learning tool in this section.

Fingerstick Sample Collection

NOTE: Before performing a fingerstick blood glucose test, carefully assess the patient for any indication that fingerstick blood glucose testing may not be appropriate. Consider the following potential interferences and compromising conditions:

- Hematocrit should be between 10–65%.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised, as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV and or peripheral arterial occlusive disease.
- This system has been tested at altitudes up to 10,000 feet.
- This system should not be used for patients who are critically ill.

1. Assemble the materials you will need to collect a blood sample (gloves, skin preparation pad, single use lancet device, gauze or cotton ball).
2. Wash hands and don gloves and any other personal protective equipment as required by infection control and isolation policies and procedures.
3. Follow all facility infection control protocols when testing isolation patients.
4. Assess the patient for compromised peripheral blood flow. Fingertips should be warm and pinkish when the hand is gently massaged from the palm outward to the fingertips. Fingertips should not appear pale, bluish or mottled. Patients with compromised peripheral blood flow are not good candidates for fingerstick blood glucose testing.
5. Select the finger site for puncture. It is preferred to select the side of a middle or ring finger that has not been punctured recently.
6. Enhance blood flow to the selected puncture site by means of:
    a. Warming the intended puncture site
    b. Instructing the patient to flex and move the arm, wrist, hand and fingers while you are assembling your supplies and preparing the system for testing
    c. Positioning the intended puncture site below heart level
    d. Gently massaging in an outward (distal) direction from the palm and the base of the finger to the fingertip

7. Cleanse the puncture site by means of

   <Enter your policy for cleansing and disinfecting the intended puncture site>

   Allow the site to air dry completely before puncturing.
8. Advise the patient of imminent puncture.
9. *<Insert device specific instructions for puncturing the site with the lancing device in use in your facility>*

   Example text using Safe-T-Pro® Plus lancet:

   a. Twist off the protective cap of the Safe-T-Pro Plus lancet and discard.

   b. Choose the desired depth setting

   c. Hold the Safe-T-Pro Plus lancet tip against the puncture site

   d. Press the purple trigger button

   e. Withdraw the Safe-T-Pro Plus lancet from the site
10. Hold the puncture site downward and gently apply intermittent proximal-to-distal pressure along the finger toward the puncture site to express a blood drop. Do not apply strong repetitive pressure at the fingertip as it may cause hemolysis or contamination of the sample with tissue fluid and may lead to questionable results.
11. *<Insert facility policy regarding wiping the first drop away.>*

    This is advantageous because it ensures that the cleansing agent is dry, it stimulates blood flow and clears interstitial fluid from the sample.[3,4]
12. Apply a well-formed drop to the ACCU-CHEK Inform II test strip as described in the patient testing procedure that follows.
13. Apply gentle direct pressure to the puncture site for several minutes and elevate the hand to reduce blood flow to the fingertip. Check the site to ensure that it is no longer bleeding before leaving the patient bedside.
14. Discard all sample collection and testing materials by means of

    <Insert facility policy for safely discarding sharps and testing materials.>
15. Wash hands before leaving the patient room.
16. Explain that specialized samples such as neonate heelstick, venous, arterial or line draw whole blood may be used, but collecting such samples requires advanced training.

3. CLSI Document H4-A5: Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture – Approved Standard; Fifth Edition; 2004; Page 11
4. Document C30-A2: Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Second Edition; 2002; Page 10

Performing Patient Testing

NOTE: Observe all facility infection control and safety policies when performing or practicing patient testing.

1. Wash hands and don gloves.
2. Turn the ACCU-CHEK Inform II meter on by pressing the **ON/OFF** button.
3. Barcode scan or manually enter your operator ID according to facility policy and touch ✓ to confirm and display the *Main Menu*.

   NOTE: If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to perform tests under another operator's ID.
4. From the *Main Menu*, touch *Patient Test.*
5. Barcode scan or manually enter the patient ID according to facility policy and touch ✓ to confirm.
6. Verify the test strip code by one of the following means according to facility policy:
   - Only view (and visually confirm) the required test strip lot number
   - Scan the barcode label on the test strip vial
   - Verify the current test strip lot number by touching ✓
7. Remove a test strip from the vial; immediately re-cap the vial.
8. An image of the test strip flashing on the touchscreen will prompt the user to insert a test strip and begin testing.
9. Gently insert the test strip into the test strip port with "ACCU-CHEK" facing up. (Insert the end with the gold bars.)

   NOTE: Insert test strip BEFORE dosing.
10. When the flashing drop icon appears on the touchscreen, obtain a blood sample according to established phlebotomy procedures (or obtain a drop of control solution if fingersticks are not included in training).
11. Touch and hold drop of blood (or control solution) to the front edge of the yellow target area on the test strip.

    NOTE: Operators may practice proper testing procedure by obtaining a blood sample from another operator or by testing with one of the glucose control solutions
12. The sample is drawn into the test strip by a capillary action.
13. When enough sample is applied, the meter beeps and a hourglass will appear while the test is running. When the test is completed and the result is ready the meter will beep again.
14. Touch 💬 to enter a comment as required by facility policy. Enter up to three preprogrammed comments and one custom comment, if necessary.
15. Touch ✓ to record the test and return to the *Main Menu* screen in order to run the next test.
16. Remove the used test strip and disposable gloves and discard them according to your facility's infection control policy.

17. Document the blood glucose result according to facility policy.
18. Perform any cleaning and disinfecting required by hospital policy after each patient test.
19. Place the meter into its base unit to upload the result into the data management system and re-charge the meter. If using a wireless meter, the results will transfer after being recorded. Then place the meter into the base unit for charging.

Interpreting and Recording Patient Test Results

1. The date, time, operator initials or ID, patient name/patient ID number, meter serial number, any noteworthy circumstances (e.g., fasting state, comments), and glucose value should be recorded per facility policy if results are handwritten or manually entered into another data management system.
2. Explain the follow-up procedure for any patient glucose level that is less than or greater than the reportable limits of the meter.
3. Explain the follow-up procedure for any patient glucose level that is less than or greater than the established critical values.
4. Review signs and symptoms of hypoglycemia and hyperglycemia.
5. Review facility policy for follow up of meter results that are not consistent with patient symptoms or presentation.
6. Interpretation of error messages and non-numeric results are covered in Section IX of this manual, “Interpretation of On-Screen Messages and Troubleshooting.”

Performing Quality Control Testing

NOTE: Observe all facility infection control and safety policies when performing or practicing quality control testing.

1. Review facility policies for quality control testing. Control testing should be performed:
   - As routinely scheduled (discuss facility policy for number of levels and frequency of routine QC testing)
   - When a new test strip lot is opened and placed into service
   - When a test strip vial is left open
   - Review other occasions when quality control testing should be performed – e.g., whenever you observe unexpected results of any kind, when the test strip lot is changed, when a meter is dropped, etc.)
2. Review policy for allowing STAT test bypassing of scheduled quality control testing.
3. Review facility policy for entering new control lots into the ACCU-CHEK Inform II system. (Review process of entering new control lots if operators are authorized to enter new control lots.)
4. Turn the ACCU-CHEK Inform II meter on by pressing the **ON/OFF** button.
5. Barcode scan or manually enter your operator ID according to facility policy and touch ✓ to confirm to display the *Main Menu*.

   NOTE: If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to perform tests under another operator’s ID.

6. From the *Main Menu*, touch *Control Testing*.
7. Barcode scan or manually select the level of control that you wish to test according to facility policy.
8. Verify the test strip code by one of the following means according to facility policy:
    - Only view (and visually confirm) the required test strip lot number
    - Scan the barcode label on the test strip vial
    - Verify the current test strip lot number by touching ✓
9. An image of the test strip flashing on the touchscreen will prompt the user to insert a test strip and begin testing.
10. Gently insert the test strip into the test strip port with “ACCU-CHEK” facing up. (Insert the end with the gold bars.)

    NOTE: Insert test strip BEFORE dosing.
11. Touch and hold control solution to the front edge of the yellow target area on the test strip.
12. The sample is drawn into the test strip by a capillary action.
13. When enough sample is applied, the meter beeps and a hourglass will appear while the test is running. When the test is completed and the result is ready the meter will beep again.
14. Touch 💬 to enter a comment as required by facility policy. Up to three comments may be entered.
15. Touch ✓ to record the test and return to the *Main Menu* screen in order to run the next test.
16. Remove the used test strip and disposable gloves and discard them according to your facility’s infection control policy.
17. Document the quality control result according to facility policy.
18. Place the meter into its base unit to upload the result into the data management system and re-charge the meter. If using a wireless meter, the results will transfer after being recorded. Then place the meter into the base unit for charging.

IX. Interpreting Quality Control Results

1. Results are displayed on the screen as a numerical value or “Pass/Fail” according to facility policy. Any result that shows an “out of range” message or “Fail” is an indication that the system may not be performing correctly for patient testing.
2. Review facility policy for follow-up to unacceptable quality control test results.
3. Patient testing may not be performed if quality control testing results are not within acceptable limits and the meter will not display the patient testing option if scheduled quality control results exceed acceptable limits.

Review Results – Recalling Test Information

1. Turn the ACCU-CHEK Inform II meter on by pressing the **ON/OFF** button.
2. Barcode scan or manually enter your operator ID according to facility policy and touch ✓ to confirm and display the *Main Menu*.

   NOTE: If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to review results under another operator's ID.
3. From the *Main Menu*, touch *Review Results.*
4. The *Review Results* screen displays the most recent stored result(s), the time and date of the result, and the patient ID, QC level or sample ID.
5. Touch ▼ to display results from previous dates. Touch ▲ to display results from tests before the one you are currently reviewing.
6. Touch any result to view result details. The following information will be displayed: Patient ID, QC level or sample ID, the lot number of the reagent(s) used to perform the test, the test result, the date and time the test was performed, and comments that were entered at the time the test was performed.
7. Touch ◀ to return to the previous screen.
8. Touch *Patient* to specify a patient whose result you want to see.
9. Barcode scan or manually enter the patient ID for the patient whose results you want to display. Use the arrow buttons to scroll through the patient results.
10. Touch any result to view result details. Touch ◀ to return to the previous screen.
11. Touch *QC* to review all QC results. Use the arrow buttons to scroll through the QC results.
12. Touch any *QC* result to view result details. Touch ◀ to return to the previous screen.
13. The system's memory can store up to 2,000 results.
14. Touch ☰ to return to the *Main Menu.*

Interpreting On-Screen Messages and Troubleshooting

Describe the basic error codes and troubleshooting steps that may occur when testing with the ACCU-CHEK Inform II system. The complete list is in the ACCU-CHEK Inform II Operator's Manual.

Examples of common on-screen messages:

- "QC Due Immediately" may appear. This could mean that controls were not run since the start of the previous shift (if the hospital requires them to be run each shift – this is called "QC lockout"); or the last controls may have been out of range or not run at the proper interval. It can also indicate that an incorrect time was entered during the setup of the ACCU-CHEK Inform II system or that the date and/or time in the ACCU-CHEK Inform II system have been changed.

- Non-numeric blood glucose results could include the following:
    - **HI** – the result may be above the reading range of the system
    - **LO** – the result may be below the reading range of the system
    - **RR HI** – the result may be above the reportable range set by the system administrator
    - **RR LO** – the result may be below the reportable range set by the system administrator
    - **CR HI** – the glucose result may be above the critical range set by the system administrator
    - **CR LO** – the glucose result may be below the critical range set by the system administrator
- Follow-up on any patient result that exceeds critical or reportable limits or is not consistent with the patient's condition, according to facility policy.
- If the error message "**Strip Defect Error**" appears on the display, the test strip may be defective or the blood glucose result may be extremely low and below the meter's measurement range. Refer to the test strip package insert, perform a quality control test using a new test strip, review proper testing procedure, and repeat the blood glucose test; or follow your facility's testing policy. If the message persists, contact ACCU-CHEK Customer Care at 1-800-440-3638.
- If the meter displays "**Type Bad Dose**," there may be insufficient amount of blood on the test strip. Repeat the test using a new test strip, ensuring proper sample application, or refer to the test strip package insert. If the message persists, contact ACCU-CHEK Customer Care at 1-800-440-3638.

All error messages displayed by the system have a letter identifying the message type, a number and a description of the error to help the operator take action to resolve the problem. The different message types are in the table below.	
E	• Identifies the notification as an Error. The information notifies the operator of an error that occurred.
W	• Identifies the notification as a Warning. The information does not block the operator from continuing, but rather gives the operator information that may suggest an alternate workflow is required.
I	• Identifies the notification as Informational only. • Informational notifications present the operator with contextual information, and allow the operator to proceed after confirming the notification.
D	• Identifies a Decision point. • Decision notifications provide the operator with a choice based on contextual information.

ACCU-CHEK Inform II System Maintenance

Cleaning and Disinfecting the ACCU-CHEK Inform II system

Important Cleaning and Disinfecting Guidelines:

- **Frequency of Cleaning and Disinfecting:**
  - At minimum, ACCU-CHEK Inform II meters are cleaned and disinfected following each patient use. FDA Public Health Notification: Use of Fingerstick Devices on more than One Patient Poses Risk for Transmitting Bloodborne Pathongens: Initial Communication, (2010)
  - Base Units and Accessory boxes are cleaned and disinfected according to facility policy.
- Cleaning and disinfecting are companion procedures that are generally performed together at the same time.
  - Cleaning removes visible soil and organic material prior to disinfecting.
  - Disinfecting destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms.
- The product used for cleaning and disinfecting the ACCU-CHEK Inform II meters and system components is Clorox® Germicidal Wipes (EPA* reg. no. 67619-12) Pre-moistened disinfecting cloths (active ingredient 1% (or less) solution of sodium hypochlorite in water) **NOTE:** Use of cleaners/disinfectants containing active ingredients other than those listed as acceptable by the manufacturer could result in damage to the system components.

Do's

- **Follow all facility safety and infection control policies when handling, cleaning and disinfecting ACCU-CHEK Inform II meters.**
- If you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system component and please contact ACCU-CHEK Customer Care at 1-800-440-3638 for assistance: Clouding of the touchscreen display, on/off-button button malfunction, clouding of the infrared data port and/or barcode scanner, or quality control results outside of the specified ranges.
- Obtain and dispose of acceptable cleaning and disinfection materials/products per facility guidelines.

Don'ts

- **Do Not** clean or disinfect the meter while performing any type of test.
- **Do Not** allow pooling of liquid on the touchscreen.
- **Do Not** spray anything onto the meter or base unit.
- **Do Not** immerse the meter or base unit in liquid.
- **Do Not** get liquid into the test strip port! If liquid does get into the test strip port, immediately dry the components with a dry cloth or gauze pad. If solution is allowed to collect in any meter opening, severe damage to the system can occur. If you suspect that moisture may have entered the strip, perform glucose control testing.
- **Do Not** wipe the electrical connectors on the back of the base unit.
- **Do Not** use any cleaning and disinfecting product other than that which is recommended by the manufacturer, identified in this procedure and provided through normal procurement policies and procedures.

http://www.fda.gov/ MedicalDevices/Safety/AlertsandNotices/ucm224025.htm, CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010).

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

* Environmental Protection Agency

Other Quality Assurance Procedures

Linearity Testing

Linearity Testing (if required) – Nurses may be asked to test 3-6 solutions to determine the linear range (or reporting range) of the meter.

> **NOTE:** Use personal protection equipment as required for universal blood collection precautions.

1. Turn on the ACCU-CHEK Inform II meter by pressing the **ON/OFF** button
2. Barcode scan or manually enter your operator ID according to facility policy and touch ✓ to confirm.
3. Then the *Main Menu* screen is displayed.
4. Touch ▶ to open the *Main Menu 2* screen.
5. Touch *Linearity* to start the linearity test.
6. Confirm the linearity lot number displayed on the ACCU-CHEK Inform II meter. Touch ✓ if the linearity lot number in the display is the same as the linearity lot you wish to use. Select ✗ to enter the linearity lot number and expiration date for the solution you wish to use.
7. Verify the test strip lot in one of the following ways:
   - Only view (and visually confirm) the required test strip lot number
   - Scan the barcode label on the test strip vial
   - Verify the current test strip lot number by touching ✓
8. In the Linearity Test menu, the levels available for the linearity tests are displayed
9. Select the first level required for linearity testing.
10. Perform linearity test.
11. Touch 💬 to enter up to three preprogrammed comments and one custom comment, if necessary. Then touch ✓ to record the result and return to the *Linearity Test* screen to run the next test.
12. Remove the used test strip and disposable gloves and discard them according to your facility's infection control policy.

Proficiency Testing

Proficiency Testing (if required) – Explain that nurses may be asked to perform a test on an unknown blood sample 3-4 times per year. This test is to be performed as if it were a patient test and is a way of ensuring consistent performance and accurate glucose results.

> **NOTE:** Use personal protection equipment as required for universal blood collection precautions.

1. Turn on the ACCU-CHEK Inform II meter by pressing the **ON/OFF** button.
2. Barcode scan or manually enter your operator ID according to facility policy and touch ✓ to confirm.

   > **NOTE:** If the operator ID you enter is not accepted, attempt to re-enter it. If it is still rejected, contact your supervisor or Point of Care Coordinator. **DO NOT** attempt to review results under another operator's ID.

3. Then the *Main Menu* screen is displayed.
4. Touch ▶ to open the *Main Menu 2* screen.
5. Touch *Proficiency* to start proficiency testing.
6. Barcode scan or manually enter the sample ID and touch ✓ to confirm.
7. Verify the strip lot in one of the following ways:
   - Only view (and visually confirm) the required strip lot number
   - Scan the barcode label on the test strip vial
   - Verify the current strip lot number by touching ✓
8. Perform the proficiency test.
9. Enter comment(s), if necessary.
10. Touch ✓ to confirm and return to the *Main Menu 2* screen to run the next sample, or press the **ON/OFF** button to turn off the ACCU-CHEK Inform II meter.
11. Remove the strip and discard it according to your facility's infection control policy.

Certification and Proficiency

This page is intended to be used by a designated trainer to ensure all system components and procedures have been reviewed and discussed prior to competency testing of an end user.

ACCU-CHEK Inform II System In-Service Checklist

- ☐ Explain the facility's policy for the ordering and performance of blood glucose testing.
- ☐ Review the facility's policy for operator certification and periodic competency checks.
- ☐ Review the components of the ACCU-CHEK Inform II system.
- ☐ Review the calibration procedure of the ACCU-CHEK Inform II meter.
- ☐ Review the steps to enter test strip codes (if user competency is required).
- ☐ Explain any special instructions or restrictions for specimen collection, such as interferences, and the fact that capillary, venous, or arterial whole blood specimens may be used.
- ☐ Review the steps of proper patient preparation.
- ☐ Explain the proper use of the lancet device and review the steps for obtaining a blood sample.
- ☐ Indicate the location of any extra testing supplies and the proper storage of the test strips and glucose control solutions.
- ☐ Review the proper testing procedure with the ACCU-CHEK Inform II meter and the documentation of a patient glucose result.
- ☐ Explain the follow-up procedure for any patient glucose level that exceeds critical or reportable limits established by the facility.
- ☐ Review signs and symptoms of hypoglycemia and hyperglycemia.
- ☐ Review your facility's policy for quality control testing, documentation, how to handle any control results that are not in the acceptable range, and how to record corrective action.
- ☐ Review the procedure for reviewing test information.
- ☐ Discuss your facility's infection control policy.
- ☐ Review your facility's policy for the performance of preventive maintenance.
- ☐ Review the preventive maintenance procedures including:
  - ☐ Cleaning and disinfecting the ACCU-CHEK Inform II system.
  - ☐ Describe the basic error codes and troubleshooting steps that may occur when using the ACCU-CHEK Inform II system.
- ☐ Review proficiency and linearity testing, if appropriate.

ACCU-CHEK Inform II System Test

Name: _____ ID#: _____

Date: _____ Unit: _____

Mark “T” if the statement is True and “F” if the statement is False.

T	F	
☐	☐	1. Before running a patient test, you must be sure the test strip lot number on the test strip vial corresponds to the test strip lot number displayed in the ACCU-CHEK Inform II meter.
☐	☐	2. If “Quality Control is Due” or “QC Due Immediately” appears in the display, you should run controls and make sure that the results are in range before proceeding to do a patient test.
☐	☐	3. The ACCU-CHEK Inform II system cannot record operator or patient ID information.
☐	☐	4. Personal protection equipment must be worn when performing blood glucose or glucose control testing and when cleaning and disinfecting the ACCU-CHEK Inform II system.
☐	☐	5. The six-digit number on the meter screen needs to match the number on the test strip vial you are using.
☐	☐	6. The test strip is placed in the test strip slot with the yellow target area or test window facing up and the end with the gold bars inserted into the meter.
☐	☐	7. The proper site for the finger puncture is on the side of the fingertip.
☐	☐	8. The test will start when the appropriate amount of sample is applied to the ACCU-CHEK Inform II test strip, about 0.6 µL.
☐	☐	9. Glucose control solutions do not have to be dated when first opened.
☐	☐	10. Only capillary whole blood samples should be used when testing with the ACCU-CHEK Inform II meter and ACCU-CHEK Inform II test strips.
☐	☐	11. The ACCU-CHEK Inform II meter should be docked in the base unit when not in use.
☐	☐	12. The ACCU-CHEK Inform II meter uses a rechargeable battery.
☐	☐	13. You should touch and hold the drop of blood to the front edge of the ACCU-CHEK Inform II test strip.
☐	☐	14. Does the meter system detect if there is enough blood sample prior to running the blood glucose test?

Fill in the blanks.

15. Where are the expiration dates for test strips and control solutions found?

_____

16. Where can a troubleshooting guide for the ACCU-CHEK Inform II system be found?

_____

17. “HI” on the ACCU-CHEK Inform II system display indicates that the blood glucose value is over _____ mg/dL, and the result may be _____ the reading range of the meter.

18. “LO” on the ACCU-CHEK Inform II system display means the blood glucose is below _____ mg/dL, and the result may be _____ the reading range of the meter.

19. What type(s) of blood can be used with the ACCU-CHEK Inform II meter and ACCU-CHEK Inform II test strips?

_____

20. ACCU-CHEK Inform II control solutions are stable for _____ months after opening.

21. If patient results are higher than _____ mg/dL or lower than _____ mg/dL, a lab backup should be ordered.

22. ACCU-CHEK Inform II test strips are stable until the expiration date listed on the

_____

23. The proper fingerstick procedure is

_____

_____

_____

ACCU-CHEK Inform II System Test Answer Key

1. T
2. T
3. F
4. T
5. T
6. T
7. T
8. T
9. F
10. F
11. T
12. T
13. T
14. T
15. on the vial or bottle labels or in the meter
16. The ACCU-CHEK Inform II System Operator's Manual
17. 600, above
18. 10, below
19. Capillary, venous, arterial and neonatal heelstick. Cord blood samples cannot be used.
20. 3
21. (insert facility policy)
22. test strip vial label
23. (insert facility policy)

ACCU-CHEK Inform II System Skills Checklist

Trainer should check activity as it is demonstrated or described.

User Assembles Equipment

- ☐ ACCU-CHEK Inform II system
- ☐ ACCU-CHEK Inform II test strips
- ☐ ACCU-CHEK Inform II glucose control solution
- ☐ Blood sample collection materials – (lancing device, gauze pad or cotton balls, alcohol wipes (if used))

User Performs Procedures

Coding (Calibrating ACCU-CHEK Inform II system)

- ☐ States when coding is necessary (when new lot introduced).
- ☐ Properly demonstrates the procedure for adding a test strip lot into the ACCU-CHEK Inform II meter (if user is required to do so).

Routine Testing Procedure

☐ Properly demonstrates the patient testing procedure including:

- Proper infection control and safety practices (handwashing, donning personal protective equipment)
- Assesses patient condition to ensure POC testing is appropriate.
- Enters Operator ID according to policy
- Enters Patient ID according to policy
- Verifies test strip lot according to policy
- Inserts test strip properly and recaps vial immediately
- Performs fingerstick properly (stimulates blood flow, cleanses intended site, wipes first drop away, performs appropriate aftercare)
- Applies blood to strip properly (fills window completely)
- Reads and interprets result correctly
- Enters comment(s) as needed according to policy
- Understands proper follow-up to critically abnormal or unexpected results
- Turns meter off
- Discards testing materials according to policy
- Documents result according to policy
- Docks meter in base unit properly
- Performs cleaning and disinfecting procedures as required by hospital infection control policy

☐ Properly demonstrates QC testing procedure including:

- Understands when QC testing must be performed according to policy
- Understands that controls expire 3 months from opening and ensures that the open expiration date is written on the control solution
- Proper infection control and safety practices (handwashing, donning personal protective equipment)
- Enters Operator ID according to policy
- Enters control lot and level according to policy
- Verifies test strip lot according to policy
- Inserts test strip properly and recaps vial immediately
- Applies control drop to strip properly (fills window completely)
- Enters comment(s) as needed according to policy
- Understands proper follow up to out-of-range QC results
- Turns meter off
- Discards testing materials according to policy
- Documents result according to policy
- Docks meter in base unit properly

☐ Reviews Results

- Properly reviews results including:
- Enters operator ID according to policy
- Selects Review Results on the Main Menu screen to view list of most recent results
- Uses down arrow to view previous tests
- Uses up arrow to view most recent tests
- Selects Patient to view only patient results
- Enters patient ID according to policy to view specific patient results
- Selects All to return to viewing all results
- Selects QC to review only QC results
- Understands that the meter memory stores up to 2,000 results

Tips for Best Results and Troubleshooting

☐ Trainer reviews information from respective Operator's Manuals with the user:

- Getting a good drop of blood
- General hints
- Proper test strip and test strip vial handling
- Troubleshooting/Error codes
- If problem persists, calls the ACCU-CHEK Customer Care Service Center at 1-800-440-3638

Cleaning and Disinfecting

- ☐ Demonstrates cleaning and disinfecting procedure of ACCU-CHEK Inform II system as stated in the Operator's Manual.
- ☐ Correctly states minimum cleaning and disinfecting frequency.

User Signature _____ Date _____

Trainer Signature _____ Date _____

Section 4: Appendix

ACCU-CHEK Inform II System Trainer Skills Checklist

Trainer's Name: _____ User ID: _____ Date: _____

Examiner should check each activity as it is demonstrated or described by trainer

Demonstrates Proficiency Assembling Equipment for In-Service Sessions

- ☐ ACCU-CHEK Inform II test strips and code key
- ☐ ACCU-CHEK Inform II glucose control solutions 2-level
- ☐ Materials for sample collection and personal protection (as needed)
- ☐ Auto-disabling single-use lancing device
- ☐ Audio-Visual equipment

Demonstrates Proficiency Presenting Audio-Visual Training Components as Required

- ☐ Power Point presentation(s) <include titles of presentations>
- ☐ Interactive learning tool(s) <include titles of interactive learning tools>

Demonstrates Proficiency Understanding Policies and Performing Procedures

Calibrating (Coding) the ACCU-CHEK Inform II meter

- ☐ Understands when coding is necessary
- ☐ Properly demonstrates calibrating (coding) ACCU-CHEK Inform II meter using the Code Key Reader

Patient Testing

- ☐ Properly demonstrates the patient testing procedure including:
  - Proper infection control and safety practices (handwashing, donning personal protective equipment)
  - Assesses patient condition to ensure POC testing is appropriate
  - Enters Operator ID according to policy
  - Enters Patient ID according to policy
  - Verifies test strip lot according to policy
  - Inserts test strip properly and recaps vial immediately
  - Performs fingerstick properly (stimulates blood flow, cleanses intended site, wipes first drop away, performs appropriate aftercare)
  - Applies blood to strip properly (fills window completely)
  - Reads and interprets result correctly
  - Enters comment(s) as needed according to policy
  - Understands proper follow-up to critically abnormal or unexpected results
  - Turns meter off
  - Discards testing materials according to policy
  - Documents result according to policy
  - Docks meter in base unit properly
  - Performs cleaning and disinfecting procedures according to hospital policy

Quality Control Testing

- ☐ Understands facility policy regarding purpose and frequency of control testing
- ☐ Properly demonstrates QC testing procedure including:
  - Understands when QC testing must be performed according to policy
  - Understands that controls expire 3 months from opening and ensures that the open expiration date is written on the control vial label
  - Proper infection control and safety practices (handwashing, donning personal protective equipment)
  - Enters Operator ID according to policy
  - Enters control lot and level according to policy
  - Verifies test strip lot according to policy
  - Inserts test strip properly and recaps vial immediately
  - Applies control drop to strip properly (fills window completely)
  - Enters comment(s) as needed according to policy
  - Understands proper follow up to out-of-range QC
- ☐ Understands what to do when "QC Due Immediately" appears on the ACCU-CHEK Inform II meter display
- ☐ States when to discard control solutions (at the expiration date, or three months after opening, whichever comes first)
- ☐ Knows to writes the "Open Date" and "Discard Date" on control vial label

Reviewing Results

- ☐ Properly reviews results including:
  - Enters operator ID according to policy
  - Selects Review Results on the Main Menu screen to view list of most recent results
  - Uses down arrow to view previous tests
  - Uses up arrow to view most recent tests
  - Selects Patient to view only patient results
  - Enters patient ID according to policy to view specific patient results
  - Selects All to return to viewing all results
  - Selects QC to review only QC results
  - Understands that the meter memory stores up to 2,000 results

System Troubleshooting

- ☐ Understands when and how to reset the meter
- ☐ Understands effective methods for optimizing fingerstick sample quality
- ☐ Understands the correct sequence of ACCU-CHEK Inform II meter displays when it is placed in a base unit and transmits results
- ☐ Understands common on-screen messages including:
  - QC due immediately
  - Out of range QC results
  - Out of critical/reportable limits patient results
- ☐ Understands that ACCU-CHEK Customer Care is available to help resolve issues at all hours at 1-800-440-3638

System Cleaning and Maintenance

☐ Demonstrates the cleaning and disinfecting procedures of ACCU-CHEK Inform II System as stated in the Operator's Manual and hospital policy

Use of In-Service Plan, System Test and Skills Checklist

☐ Demonstrates total understanding and system knowledge while utilizing the ACCU-CHEK Inform II In-Service Plan

☐ Demonstrates proficiency explaining and taking the operator's system test (scoring 100%)

Instructor's Signature _____

Examiner's Name/Position _____

Examiner's Signature _____

Notes:

General Information

Roche Diagnostics has made all reasonable efforts to ensure that all the information contained in this plan is correct at the time of printing. However, Roche Diagnostics reserves the right to make any changes necessary without notice as part of ongoing product development.

Questions or comments regarding the contents of this guide can be directed to:

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Revision History

Revised pages for this manual are provided by Roche Diagnostics when necessary.

Publication Reference Number	Date	Pages Affected
4830-00-1112	November 2012	New document

<Insert facility name>

Certificate of Attendance

This certifies that

<Insert name of operator or user>

has successfully completed the

ACCU-CHEK® Inform II System For Blood Glucose Testing

Training Program

Facilitator: <insert name of the instructor> *Date: <insert date>*

Roche