

ACCU-CHEK INFORM II Whole Blood Glucose Testing

Waived under CLIA

Universal Precautions are required



GETTING ACCURATE RESULTS

1. Remove one test strip from the vial and immediately re-cap.
 - All glucose test strips are sensitive to light, humidity, temperature, etc.
 - Re-Capping is one of the most important elements in this information sheet!
 - The Test Strips contains no interference from maltose
2. Getting a proper sample and dosing the test strip correctly is another key to getting accurate results.
 - Lance on the side of one of the middle fingertips (less nerve endings, better circulation)
 - The end of the test strip can be placed up against the sample.
 - Capillary action pulls blood into the strip.
 - Blood must completely cover the yellow target area and must be covered 100%. *No exceptions.*
 - **☆ An audible beep does not ensure target area is completely covered, must be visionally confirmed**
 - The Inform II gives the glucose result in 5 seconds after initial sample is applied to the strip.
 - Capillary, venous, arterial samples are all FDA cleared for use with this strip.
 - Plasma and serum cannot be used.
3. Do not use sharp or metal objects on the touch screen.
 - An unused capped Safe-T-Pro lancet makes a perfect "stylus" for touching the screen.
 - With the use of the lancet tip, the screen will stay clean from hand lotion, powder from gloves, etc.
4. Always store the Accu-Chek Inform in its base when not in use.
 - Communicates with the data management system.
 - Recharges the battery pack in the Inform II.
 - Note: If your site is using the wireless feature there will be a slight delay for transmitting data between patients.
5. When opening a new box of test strips
 - Note the expiration date, found on the box and the vial, is valid.
 - Code keys maybe thrown away, all strip lots will be uploaded by the POC department with a code key reader.

RUNNING GLUCOSE CONTROLS

To meet regulatory requirements, glucose controls must be run each shift. The Accu-Chek Inform II is programmed to automatically alert the operator when this procedure is required. Operators must run a set of controls once in a 90 day period to stay certified. Each time controls are run successfully your 90 day certification period re-starts. [POC strongly suggest picking your birth day and every month on that day, run a set of controls. Thus preventing being locked out due to control issues]

1. Turn on the Inform II with the **purple** button located below the screen.
 - If controls are required the message: QC Lockout will be displayed.
 - Either wait for the screen to advance to Operator ID or press Forward Arrow button after the beep is heard.
2. Press the Scan button and scan your operator ID barcode on the back of your name badge.
Using another operator's ID is grounds for disciplinary action for both operators. (Policy X.1046.3.9500.049)
 - A beep will be heard when the bar code is accepted.
 - The screen will display the Main Menu.
 - Touch the **Control** Test button.
 - Next screen shows buttons: Level 1 (Lo) Required, Level 2 (Hi) Required, Scan, Menu, backward arrow.
 - Touch the **Scan** button and scan the barcode on the Level 1 control (white bottle cap).
 - When the control is scanned successfully, the screen will display Strip Code and the Scan button.
 - Scan the barcode on the vial of Accu-Chek Inform II test strips.
 - The screen will displays Control L1 (Lo) lot XXXX and Accu-Chek Inform II test strip lot XXXX just scanned.
 - An icon representing a test strip with advancing arrow indicates the Inform is ready for a fresh test strip.
 - Insert the test strip (**grey** side facing up and gold bars going into the meter strip port (at the top of meter).
 - When inserted completely a beep will sound
 - An icon representing a drop of control solution will flash next to the strip icon.
 - Invert the Level 1 bottle (White bottle cap) once or twice to mix the solution but never shake the bottle.
 - Remove the cap, squeeze to form a small drop on the end of the nozzle.
 - Touch this drop to the front **edge (not top)** of the yellow test area on the strip.
 - capillary action will pull the sample in the target

- If strip is dosed correctly, no yellow is showing in the target area.
- An hour glass icon will appear showing the progress of the test, a beep will be heard when test is complete
 - **PASS** should display on the screen.
 - If PASS is displayed, press the Forward Arrow button to finish logging the test result.
 - If the display shows **FAIL**
 - It is required to press the flashing Comment button
 - Select at least one comment, e.g. 'Repeat Test'.
 - When comment is selected, it will highlight.
 - When finished selecting comments (3 maximum, plus 1 custom), press the Forward Arrow button.
 - Screen will return to FAIL screen.
 - To finish, press the Forward Arrow button and return to the Main Menu; then repeat the test as stated.
- 3. When Level 1 displays **PASS**, the same procedure is followed to complete Level 2 (Hi) control (**grey** bottle cap).
- 4. PASS must be obtained from both levels of control before processing to patient testing.

Possible reasons for glucose control test to FAIL.

1. Expired control solutions.
 - Note: always write the **Open Date and new expiration date** on freshly opened vials of Controls. Controls expire 3 months after opening.
2. Vial cap was left off the test strips for an extended period of time.
 - Discard vial of strips and replace with a new one.

PATIENT TESTING

1. Turn on the Inform with the **purple** button located below the screen.
2. Scan your **Operator ID**, (*Using another operator's ID is grounds for disciplinary action for both operators.*)
3. Select **Patient Test** from Main Menu.
 - Scan the patient's unique barcode (Patient CSN or EPIC number based on your location) or emergency barcode (340300000A)
 - If barcoding capability is not available, enter the patient ID number (EPIC number – clinic sites only) with the numerical keypad, if available on the screen. Then press the Forward Arrow button.
 - When prompted, scan the strip code. Meter displays: Patient XXXXXX, strip lot XXXXXX and the insert strip icon.
 - Insert a fresh test strip into the Accu-Chek Inform II and re-cap the vial.
4. Clean the patient's finger with alcohol but ensure the finger is dry from alcohol before lancing.
5. Twist the protective tip on the Safe-T-Pro lancet device until it "breaks loose", pull off tip and discard. Ensure the plastic tip is making good contact with the patient's skin before pushing the plunger to lance the finger. A little pressure applied below the lance site will cause a drop of blood to form on the patient's finger. Wipe this drop from the finger and gently squeeze the finger again and form another drop for testing.
6. Touch this drop of blood to the front **edge (not top)** of the yellow test area on the strip.
 - capillary action will pull the sample in the target
 - If strip is dosed correctly, no yellow is showing in the target area.
7. The glucose "critical" range for Scott & White is **<50 and >400 mg/dl**. The range of the Accu-Chek is 10 to 600 mg/dl; 'LO' is less than 10mg/dl and 'HI' is greater than 600 mg/dl
 - Result outside critical range should be repeated to confirm
 - Results outside critical range require at least 1 corrective action comment to be entered.
 - Touch the flashing Comment button.
 - Select at least one comment, e.g. 'Repeat Test', 'MD Notified'
 - When comment is selected, it will highlight.
 - When finished selecting comments (3 maximum, plus 1 custom), press the Forward Arrow button.
 - Screen will return the Main Menu.

REVIEWING RESULTS FROM MEMORY

1. Turn on the Inform with the **purple** button located below the screen and scan your Operator ID
2. Touch the **Review Result** button and all results will be displayed.
3. Touch the Patient button, scan or enter the patient's ID number
 - all the glucose results from that one patient will be displayed that were done on that particular Inform meter.