



ARKRAY PROCEDURE IN BRIEF

Assure[®] Titanium System Procedures

The system provides Point-of-Care operators with safe, fast and convenient blood glucose *in vitro* for multiple-patient use in Professional Healthcare Settings. Accurate results can be obtained in seven seconds with a small (0.5µL) blood sample.

1. Performing a Blood Glucose Test

Safety Precautions


- Failure to follow instructions may cause inaccurate results.
- Treat all components that contact blood as biohazardous.
- Wear new gloves for each patient.
- Wash hands thoroughly before testing.
- Use only auto-disabling, single-use lancing devices.
- Clean and disinfect the meter after each use.

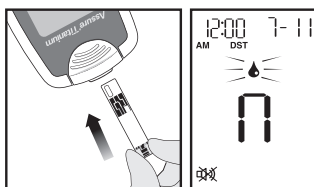
Step-by-Step Procedure

Step 1: Prepare the Sample site

- Use only auto-disabling, single-use safety lancets.
- Wash and dry hands and sample site thoroughly.
- If alcohol wipes are used, make sure the area is dry before taking a blood sample. Residual alcohol may lead to inaccurate readings.

Step 2: Prepare the Meter and Test Strip

- Remove a test strip and close the vial.
- Insert the strip (contact bars facing up) into the meter until it turns on and displays the blood drop symbol . The meter is ready to use.



Step 3: Obtain the Blood Sample

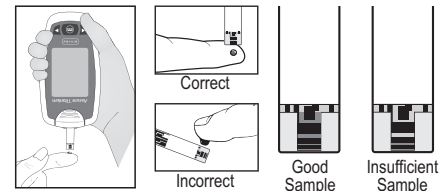
- Lance the fingertip (preferably middle or ring finger).
- Wait for a blood drop to form (minimum 0.5 µL).

Notes

- Meter turns off if blood is not applied within 5 minutes.
- Stored results are not linked to specific patients.

Step 4: Apply the Blood Sample

- Hold the meter vertically and place application tip to the sample site.
- Apply the blood to the edge of the test strip until the meter beeps.
- If the sample is insufficient, an E3 error may appear.



Step 5: View the Result

- The meter counts down from 7 to 1 and displays the result in mg/dL.
- Result is automatically stored in memory.

Step 6: Dispose of the Test Strip

- Use the ejector to discard the strip safely.
- Meter turns off automatically.



2. QC Lockout Feature

PCS (QC lockout) feature will lock out users once every 24 hours from performing a blood glucose test until a control solution test is performed.

- Prevents blood glucose testing until completed.
- If a blood glucose test is attempted, E0 will appear until a control solution test is completed.

To release QC Lockout: When PCS appears on the screen, control solution tests must be performed first with both Level 2 and Level 3 control solutions. After inserting the test strip, use the buttons to select the appropriate control solution level.

3. Performing a Control Solution Test

When to Perform

- First-time meter use.
- Practicing the procedure.
- New vial or a new lot of test strips.
- Every 24 hours to release QC Lockout.
- Suspected malfunction or damage.
- Inconsistent or abnormal results.

Safety and Handling

- Avoid contact with skin and eyes.
- Do not ingest.
- Use only Assure Control-Control Solutions.
- Record bottle open date; discard after 90 days.
- Use control solutions within the expiration date printed on the bottle. Discard after expiration date.
- Bring meter and control solution to room temperature (46–86°F) for 30 minutes before testing.

Ensure all components are used and stored following these guidelines:

	Storage Temperature	Operating Temperature	Relative Humidity
Meter	32-122°F (0-50°C)	46-104°F (8-40°C)	10-90% without condensation
Test Strips	34-86°F (1-30°C)	46-104°F (8-40°C)	10-90%
Control Solutions	36-86°F (2-30°C)	46-86°F (8-30°C)	10-90%

Step-by-Step Procedure

Step 1: Insert Test Strip

- Remove a strip and insert into the meter (contact bars on sample receiving end) until it beeps.

Step 2: Prepare Control Solution

- Invert bottle several times. Open bottle and place cap upright on a flat surface.
- Discard the first 1–2 drops from bottle.
- Apply one drop to the cap.



Step 3: Apply Control Solution to Test Strip

- Touch the edge of the strip to the drop until the meter beeps.



Step 4: View Result

- Meter counts down from 7 to 1.
- Result is marked as a control test and stored.
- Compare result to range on test strip vial.

Step 5: Dispose of Strip

- Eject and discard safely.
- Meter turns off automatically.

Notes

Meter turns off if solution is not applied within 5 minutes. If control result is out of range, do not use the meter.

Out-of-range results may be due to:

- Improper mixing or expired solution.
- Components were exposed to temperature extremes.
- Contaminated solution or strip.

Repeat test or use new solution if needed.

To perform a control solution test at any other time and to reset the QC Lockout timer:

- When PCS does not appear on the screen, insert a test strip and then press and hold the center button for one second. The meter will be ready for a control solution test. Use the buttons to select the appropriate control solution level.
- Control solution can be run at any time, and the meter will autodetect it as a control solution test. However, you must follow the steps stated above to reset the QC Lockout timer.
- After selecting control solution level and performing control solution test, the control solution level associated with that test cannot be changed.

Cautions

- Control ranges are for solution only and not patient glucose.

Comparing the Control Solution Test Results

The test result of each control solution test should be within the range printed on the label of the test strip vial. Repeat the control solution test if the test result falls outside of this range. Out of range results may occur due to the following factors:

Situations	Actions
If the control solution bottle was not gently inverted several times. If the meter, test strip or the control solution were exposed to high or low temperatures. If the test strip is past the expiration date. If the first one or two drops of the control solution were not discarded or the top of the cap was not wiped clean. If the meter is not functioning properly.	Repeat the control solution test.
If the control solution is past the expiration date printed on the bottle. If the control solution is past its discard date (the date the bottle was opened plus three months (90 days)). If the control solution is contaminated.	Discard the used control solution and repeat the test using a new bottle of control solution.

If results continue to fall outside the range printed on the test strip vial, the test strip and meter may not be working properly.

Do not use your system and contact ARKRAY Technical Customer Service at 800.818.8877, 24 hours a day, 7 days a week.