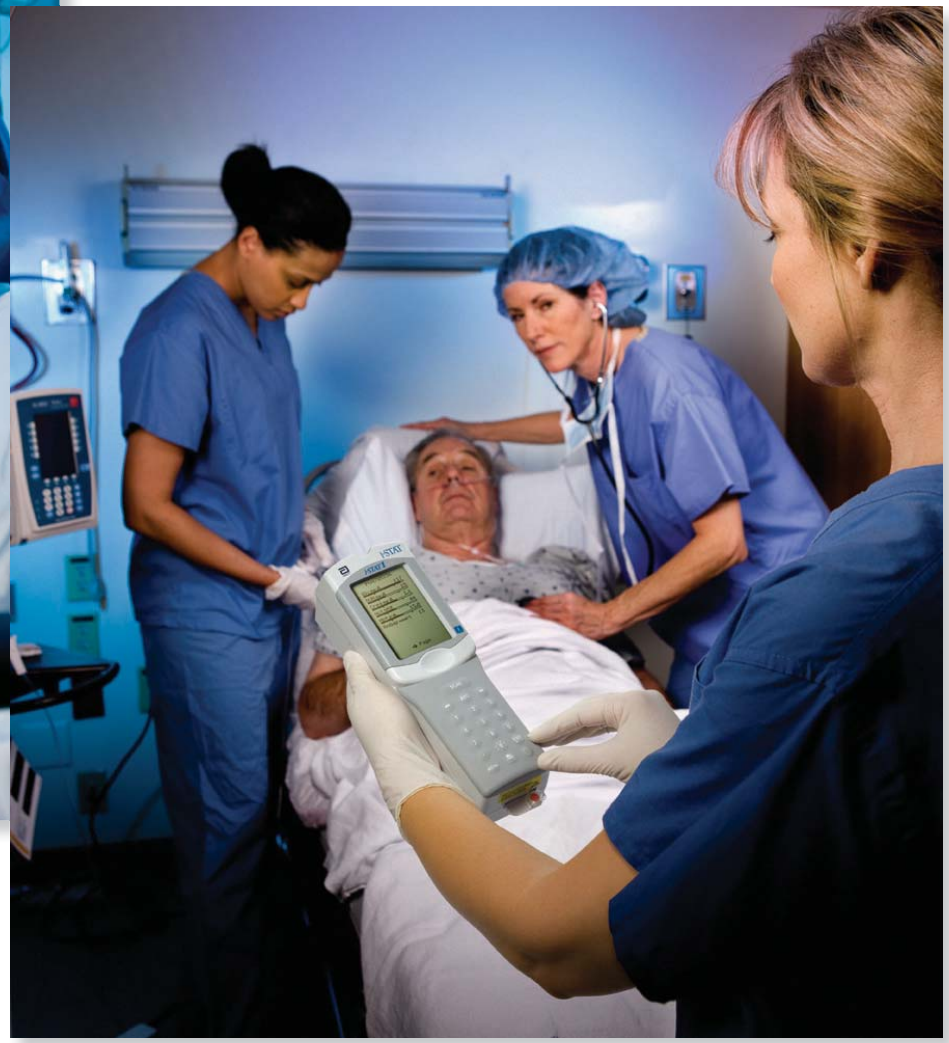
Welcome!



Why the i-STAT® System?

Expedites the delivery of information when every minute counts.

- Reduces the number of steps required to obtain lab results
- Brings testing to the bedside
- Requires smaller sample size
- Decreases wait time for lab-quality results

For additional instructions on using the i-STAT System please reference the *i-STAT 1 System Manual*.

Agenda

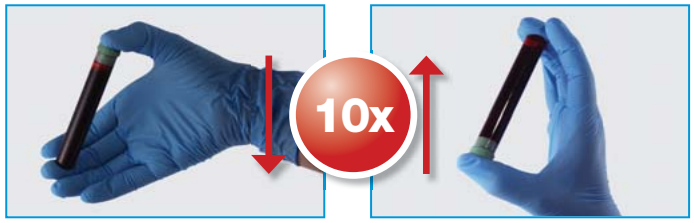
- Overview of the i-STAT Testing Process
- Sample Collection and Handling
- Cartridge Overview
- Performing a Patient Test
- Test Results
- Hands On
- Test / Q & A

i-STAT Testing Process

1 Prepare handheld

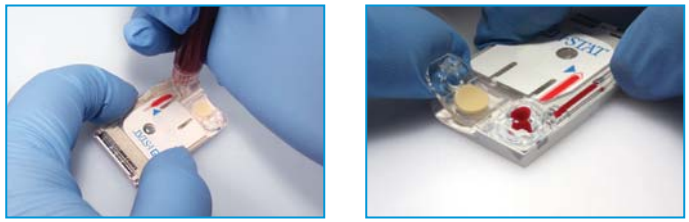
2 Collect sample

3 Mix sample



4 Discard first few drops of blood

5 Fill and close the cartridge



6 Insert cartridge

...Results appear within minutes

Sample Collection and Handling: Evacuated Tubes

- Avoid drawing from an arm with an IV line

- Avoid Hemolysis

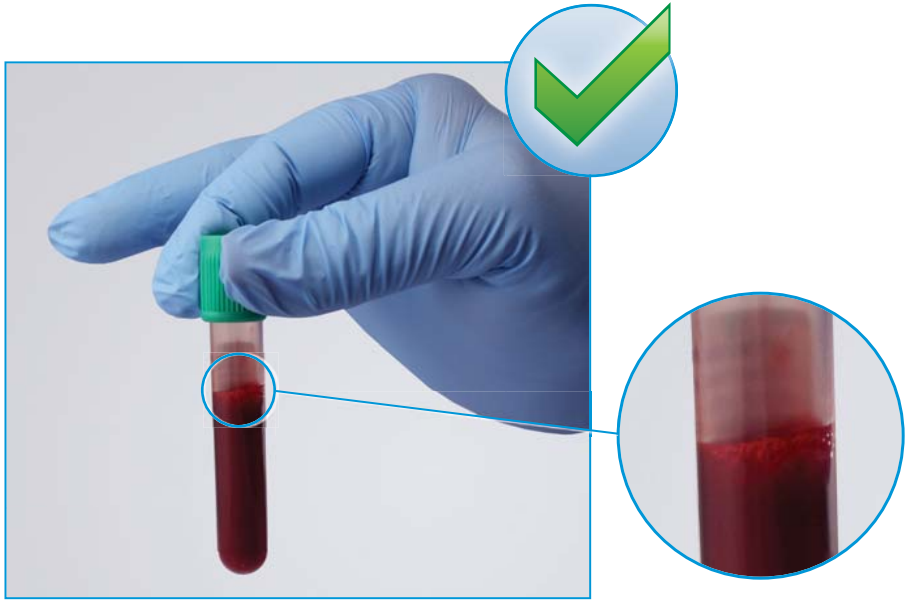
- **Do not** leave a tourniquet on for more than 1 minute

- Avoid extra muscular activity
- Allow residual alcohol to dry over puncture site
- Discard sample from traumatic draw

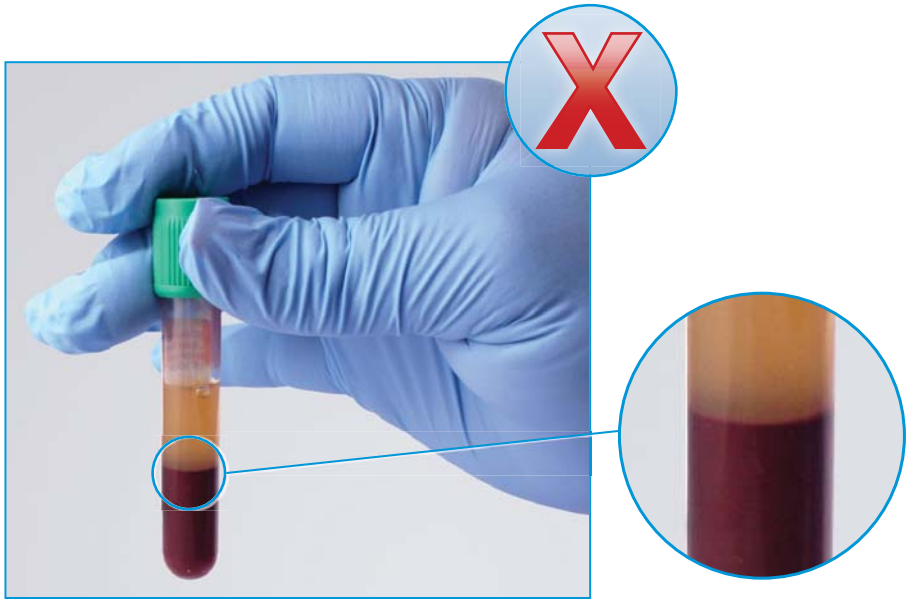
Sample Collection and Handling: Evacuated Tubes

Ensure evacuated tubes are filled to capacity

Sample Collection and Handling: Evacuated Tubes



Always mix properly!



Improper mixing may affect results

Sample Collection and Handling: Evacuated Tubes

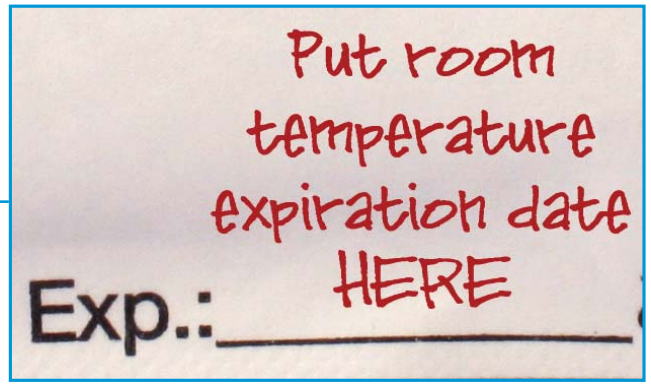
MIXING MATTERS!

Mix sample by gently **inverting tube at least 10 times**

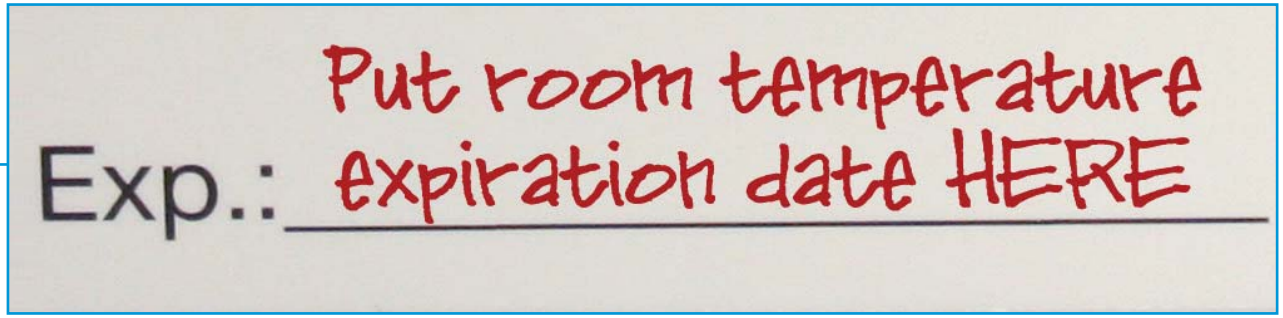
Cartridges: Room Temperature Storage

Number 14 and a “d” = 14 days room temperature storage

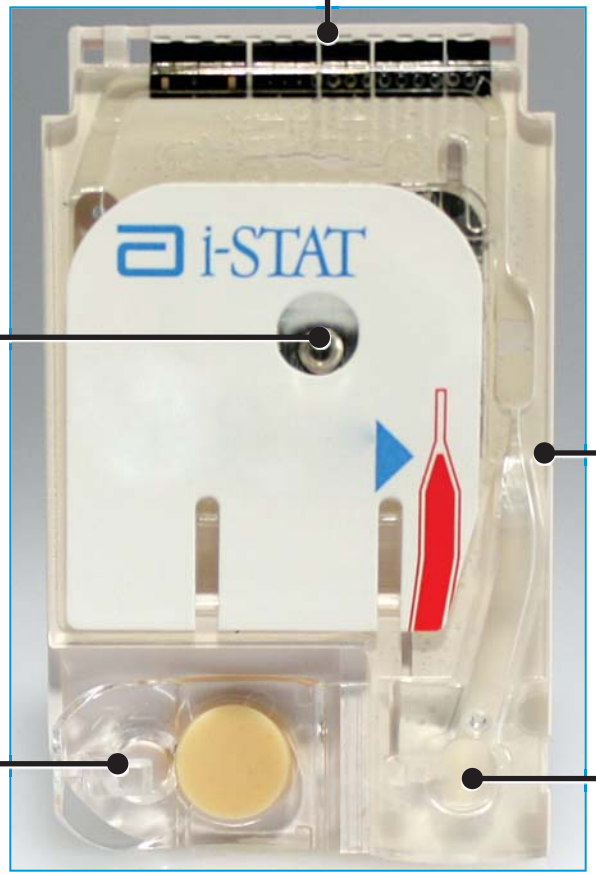
Cartridges: Room Temperature Storage



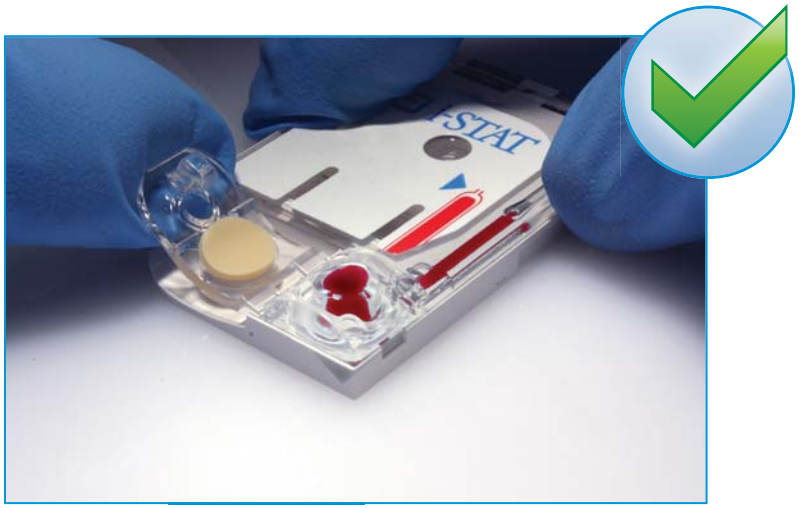
Cartridges: Room Temperature Storage



Cartridge Labeling



Cartridge Handling



Hold cartridge from the sides or bottom

Cartridge Handling

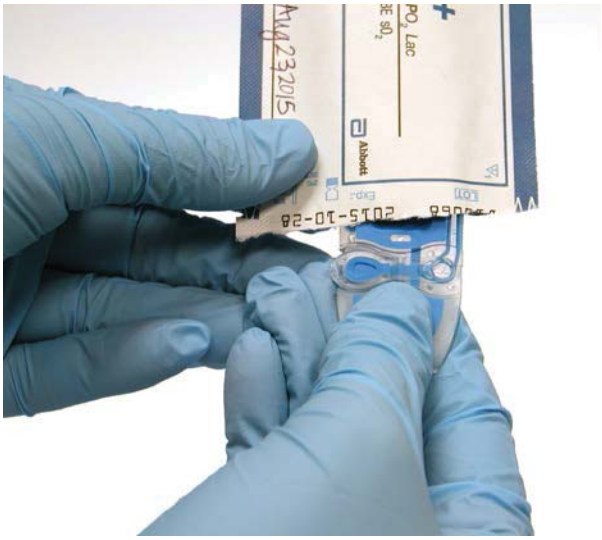
Failure to handle the cartridge properly may cause Quality Check Codes

Do not touch center of the cartridge or the sensors

TRAINING GUIDANCE- HANDLING and FILLING i-STAT® CARTRIDGES

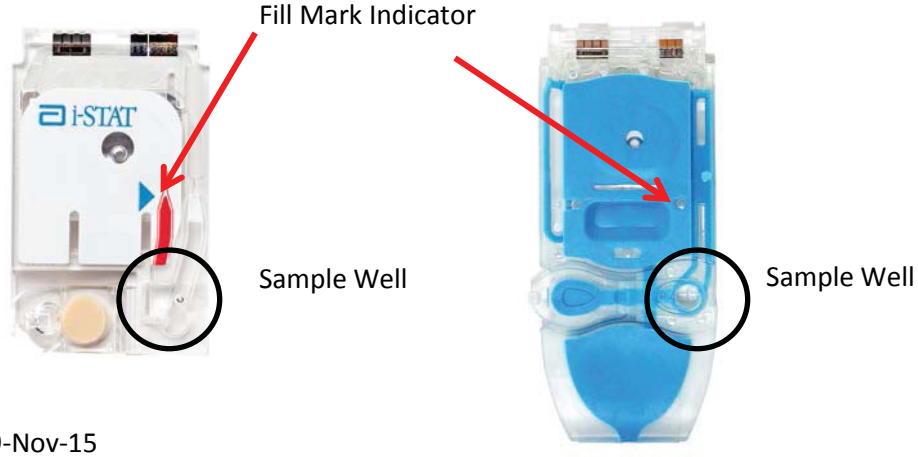
- Each cartridge is sealed in a foil pouch or clear plastic portion pack for protection during storage. If the pouch/portion pack has been punctured, the cartridge should not be used
- Do not remove cartridge from its protective pouch until it is at room temperature (18°–30°C or 64°–86°F). If removing a cartridge or box from refrigeration storage, allow a single cartridge to stand for 5 minutes and a box of cartridges for 1 hour at room temperature before use
- When removing and handling the cartridge,
  - avoid touching the contact pads, as this may cause contamination and prevent the analyzer from making proper contact with the cartridge
  - avoid touching the sensors on the top
  - avoid touching the calibrant solution pack in the middle of the cartridge
- After removing the cartridge from its protective pouch, use it immediately—prolonged exposure may cause it to fail a Quality Check

Removing Cartridge From Packaging



Filling and Sealing Cartridge

1. Place the cartridge on a flat surface. Note the location of the sample well and fill mark indicator, as identified in the images at right.



Artwork: 745570-00A Rev. Date: 09-Nov-15

2. Mix the sample thoroughly.
   a. Invert a blood collection tube at least 10 times.
   b. Roll a syringe repeatedly between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Note that it may be difficult to properly mix a sample in a 1.0 cc syringe
   c. Expel a few drops of sample from the transfer device before filling the cartridge

3. Direct the tip of the transfer device (syringe or dispensing tip)* into the sample well/inlet port, as shown below.
   a. *Not* directing the transfer device into the sample well could result in a sample not filling the cartridge or pooling on the sample well/inlet port

4. Dispense a small amount of sample, ensuring it travels toward the fill mark before applying additional sample. Avoid creating a bubble on the sample well.
   a. Continue dispensing until the sample reaches the fill mark indicated on the cartridge
   b. Ensure that there is sample in the inlet port, as well as the sample chamber

*For a complete list of recommended transfer devices, refer to Section 10 -Sample Collection of the i-STAT1 System Manual.

Properly Filled Cartridge
(Chemistry/Electrolyte)

These images display properly filled cartridges. In the images at the top, you will notice the sample fills the sample chamber to the fill mark indicator.

In the images at the bottom, the sample well is full and no bubble appears in the sample pathway.

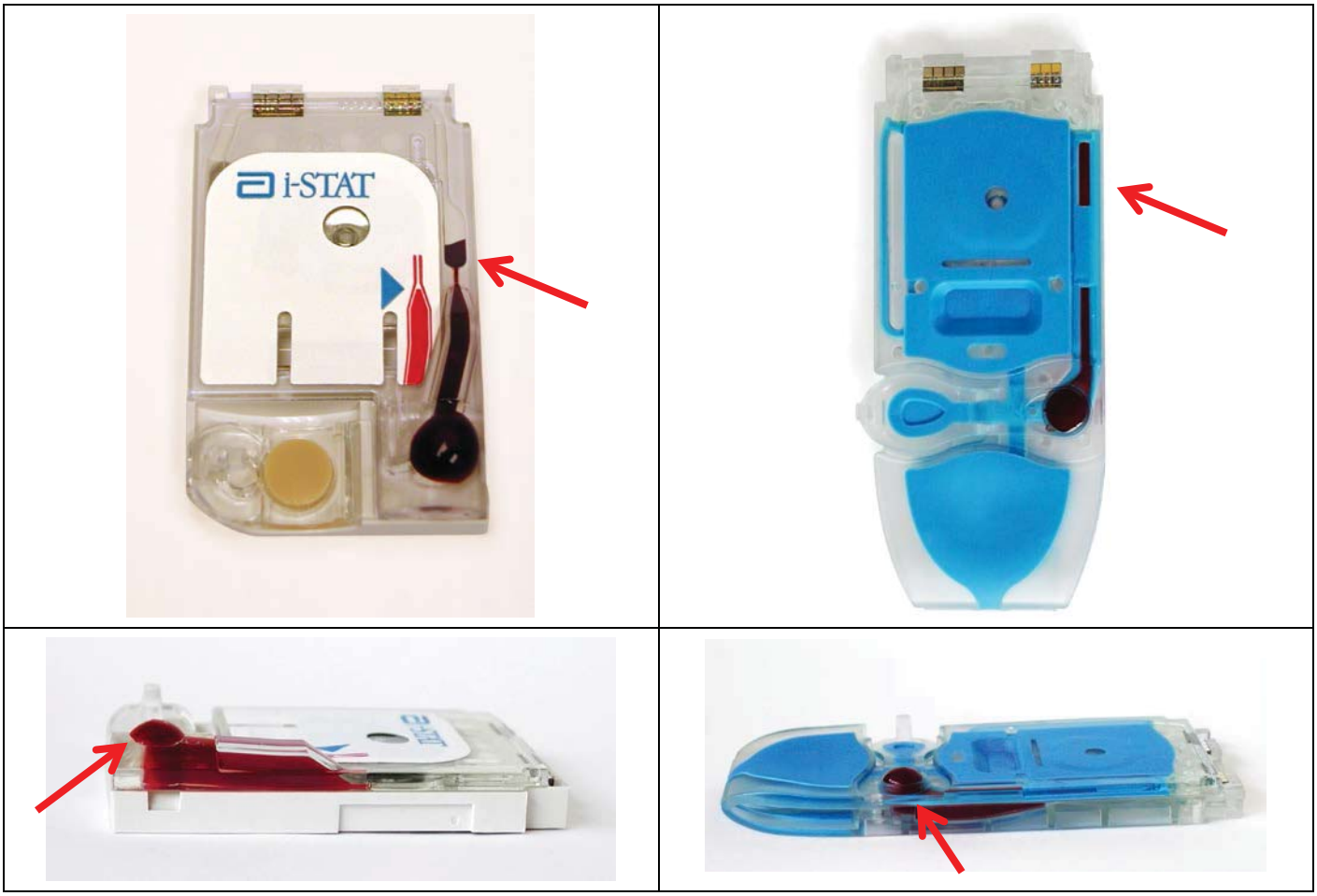
5. Fold the snap closure over the sample well.
   a. Keeping your thumb or finger on the outside edge of the closure clasp, press the rounded end of the closure until it snaps into place
   b. Ensure that the cartridge is completely closed before inserting it into the device

   To close the immunoassay cartridge with the plastic closure clip
   a. First anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cartridge from its side edges away from the sample inlet.
   b. Use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well.

Properly Closed Cartridge

These images display properly filled and closed cartridges. As such, they may be inserted into the handheld.

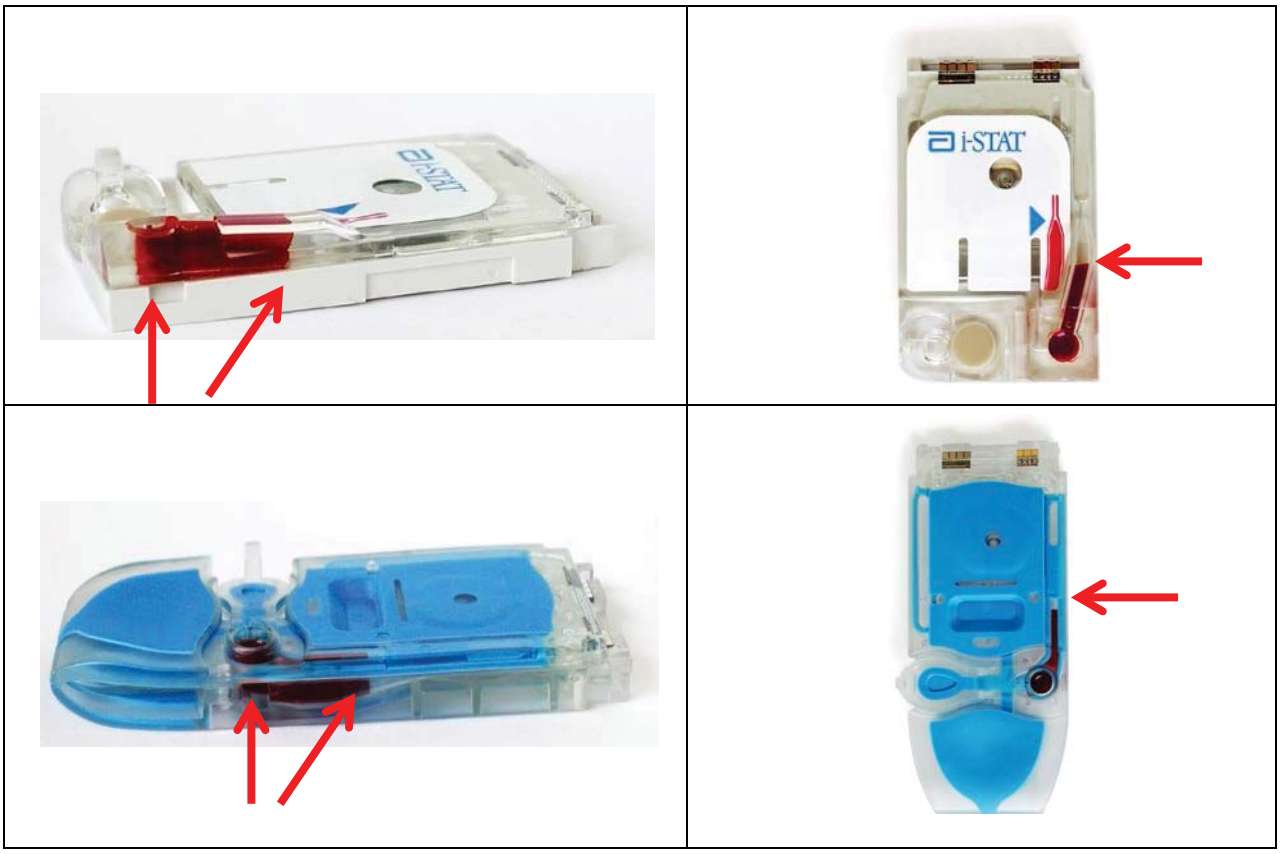
Examples of Overfilled Cartridges



These images display overfilled cartridges. In the images at the top, the sample exceeds the fill mark indicator. In the images at the bottom, you will notice a bubble in the sample well.

Every effort should be made to fill cartridges properly before inserting into the handheld device.

Examples of Under-Filled Cartridges



These images display under-filled cartridges. In the images on the left, the sample well is insufficiently filled, and the sample does not reach the fill mark indicator.

In the images on the right, the sample well is sufficiently filled, but the sample does not reach the fill mark indicator.

Every effort should be made to fill cartridges properly before inserting into the handheld device.

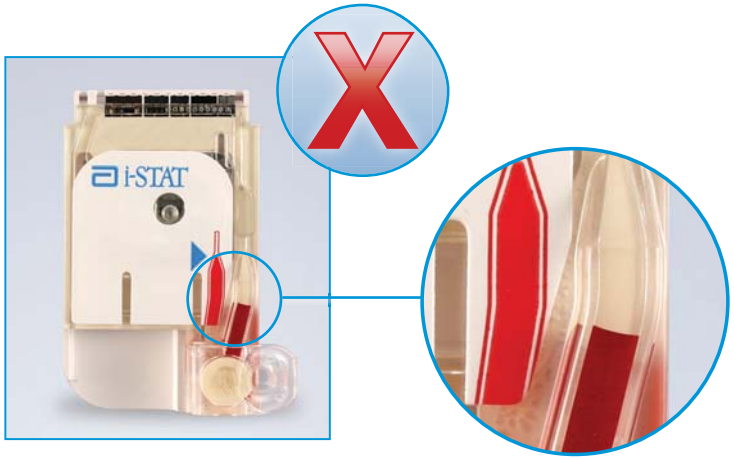
Examples of Improperly Closed Cartridges

These images display improperly closed cartridges. Although they were properly filled, they must be closed sufficiently before they may be inserted into the device.

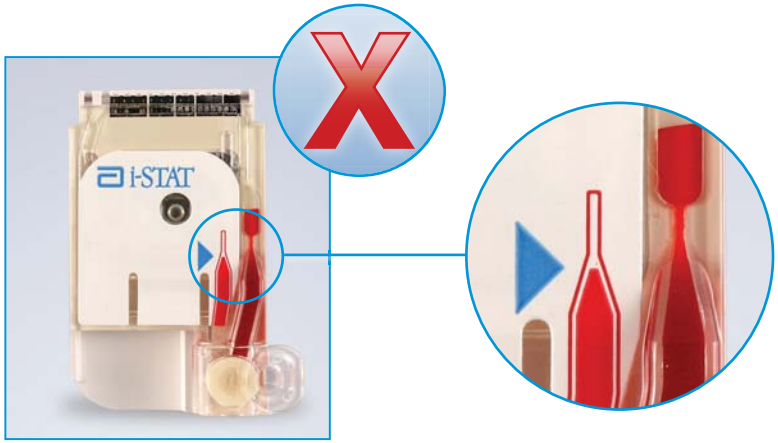
For *in vitro* diagnostic use only.

Cartridge Filling and Handling Document

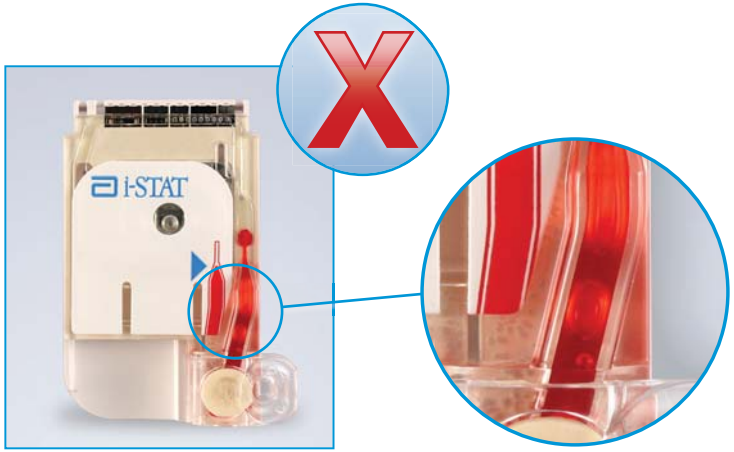
Avoiding Cartridge Filling Quality Check Codes



Underfilled cartridge



Overfilled cartridge



Air bubble

Test Menu and Administration Menu

Test Menu

Administration Menu

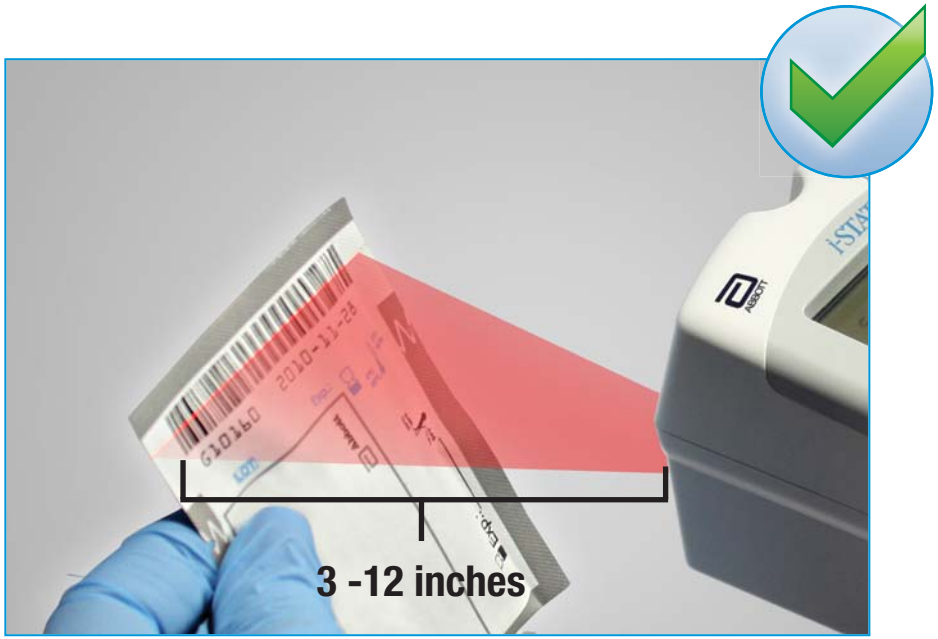
SCAN Your Operator ID

Laser beam must cover the entire length of the barcode

SCAN the Patient ID

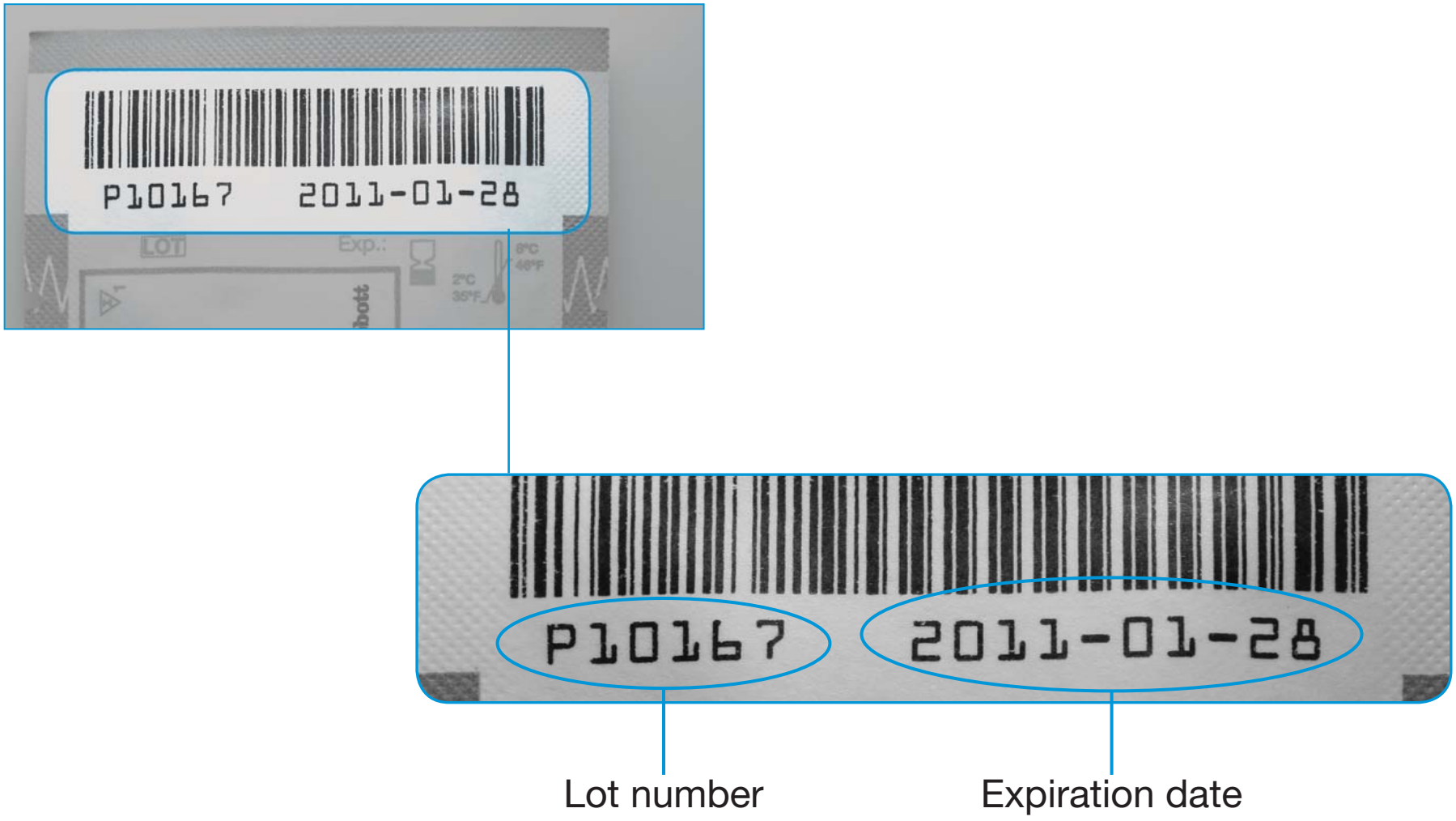
Laser beam must cover the entire length of the barcode

SCAN the Barcode on the Cartridge Pouch

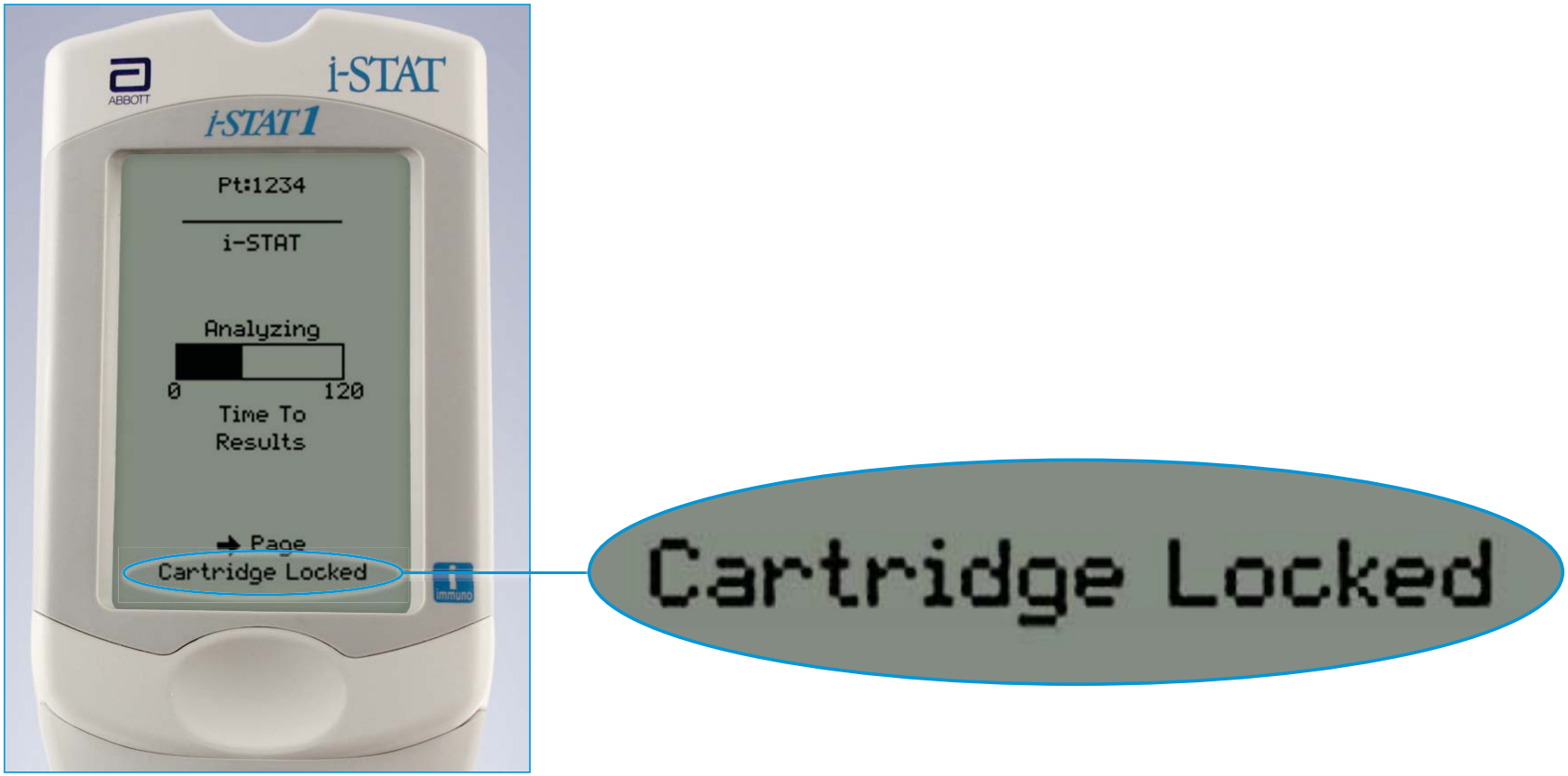


Laser beam must cover the entire length of the barcode

Cartridge Barcode

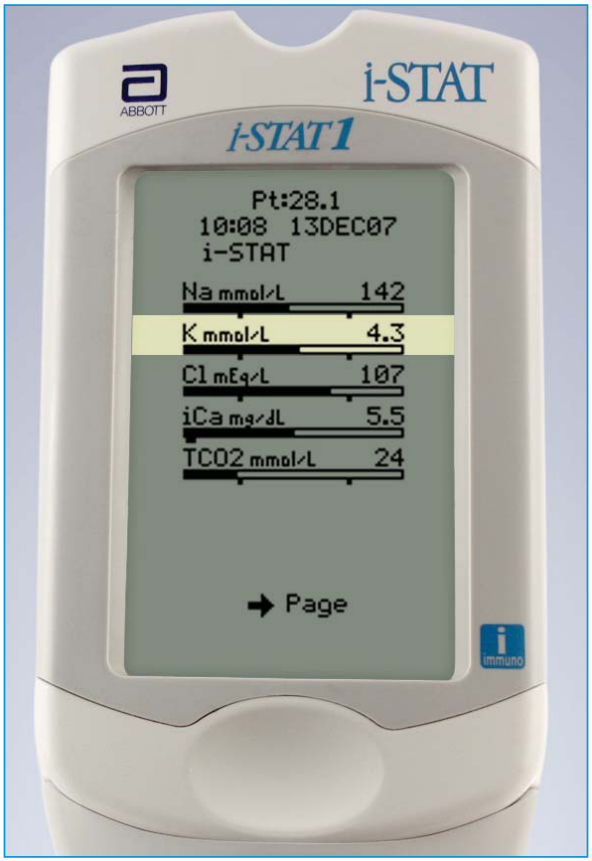


Cartridge Locked Message

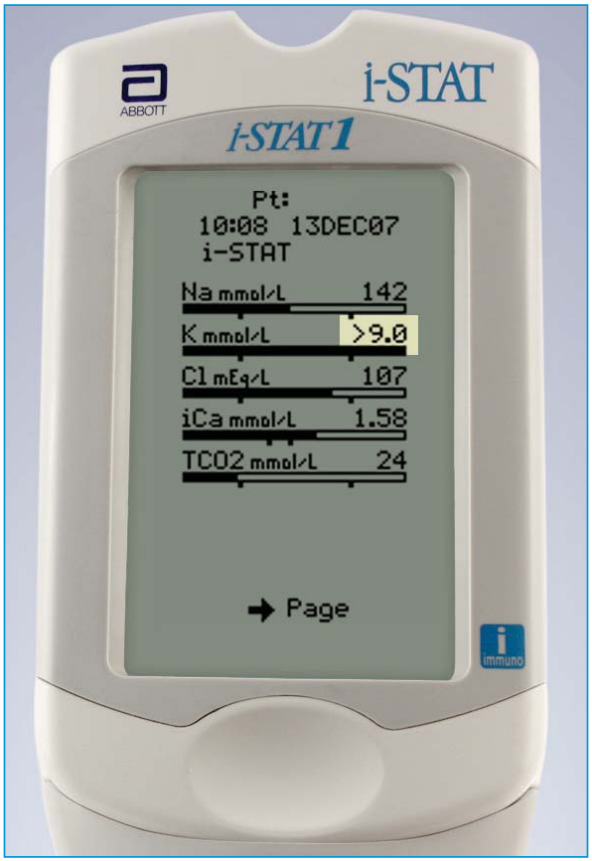


Quality Check Code: Dead Battery

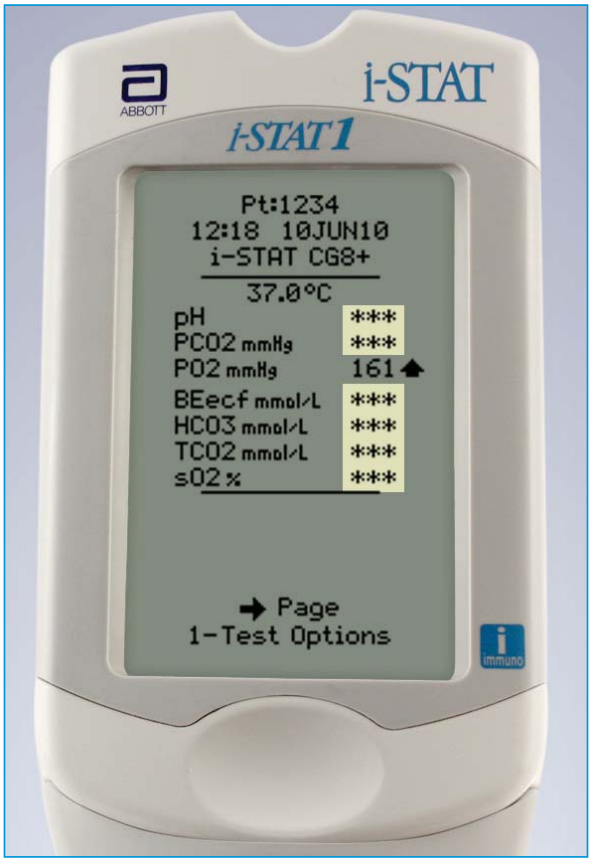
Test Results: Reference Range Graphs



Test Results: Out of Reportable Range Flags



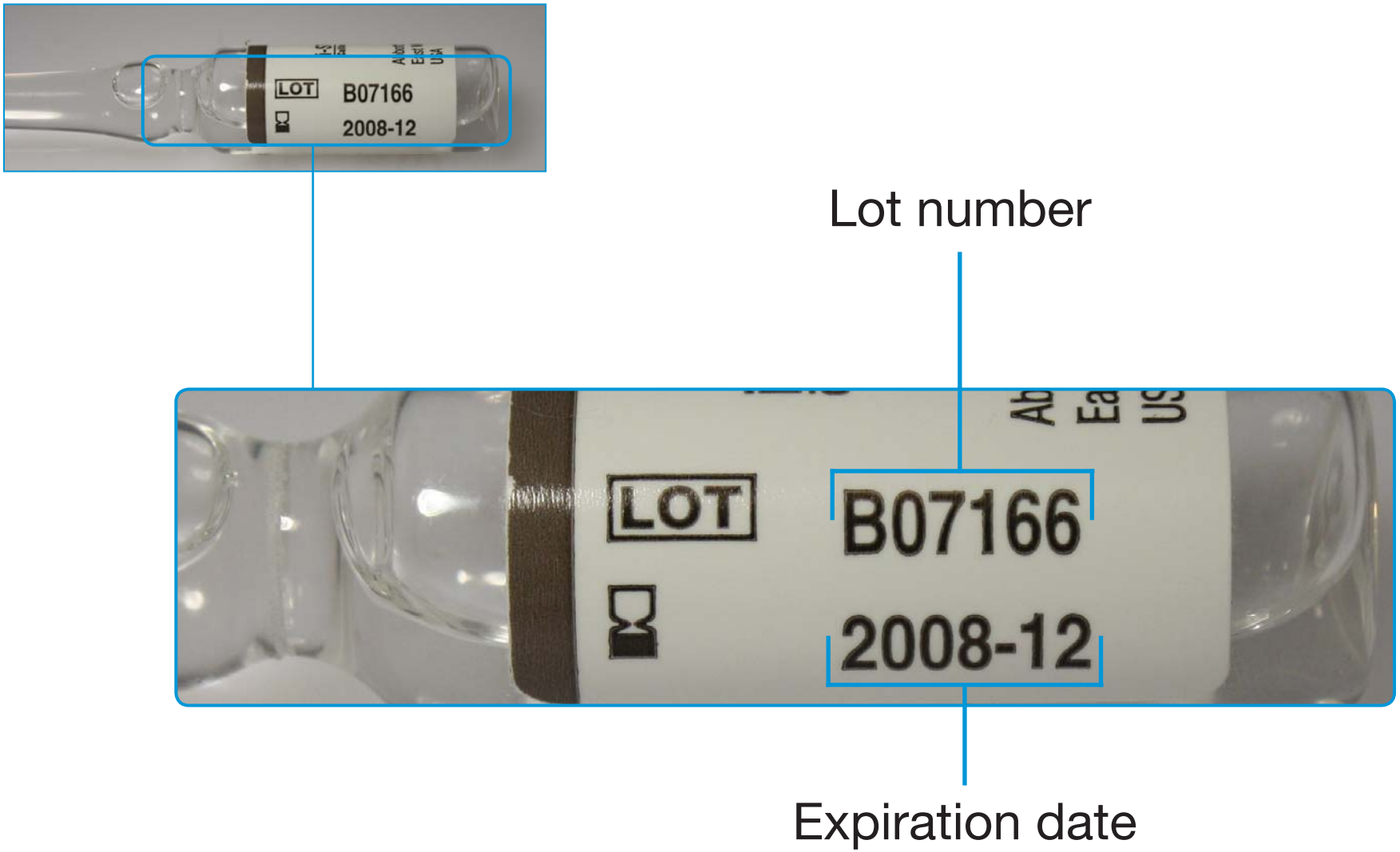
Test Results: Star Outs (***)



Downloader/Recharger

Printing Results with the i-STAT Portable Printer

Quality Control Material - Liquid Control Ampules



Summary

Ensure a quality sample is obtained:

- Failure to handle the cartridge properly may cause Quality Check Codes
- MIX, **MIX**, **MIX**……Always mix properly and test promptly!
- Place handheld on a level, nonvibrating surface or in the downloader
- Always correlate results with the status of the patient