

Frequently Asked Questions regarding Control Solution Testing

What is the purpose of control solution testing?

Performing a glucose control test is an excellent way to check that your system (meter and strips) are working optimally to deliver accurate and precise results. Using manufacturer's control solution to test the system, the results will provide information to determine if the system passes or fails the test. If the system fails the test, further information needs to be obtained to troubleshoot the system.

What are the ingredients in control solution?

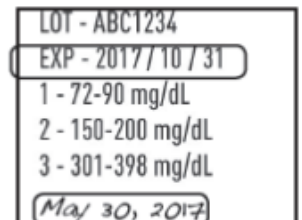
Control solution is a mixture of sugar, water and other stabilizers. Unlike a blood sample, control solution does not contain any blood cells, interferents, or blood products and is less viscous than blood. Control Solution necessarily reacts differently than blood (more viscous) when applied to the test strip. Therefore, the results of a glucose control test do not reflect a true blood glucose value. **DO NOT EVER DRINK OR INJECT THE CONTROL SOLUTION!**

How are control solutions ranges developed?

Manufacturers develop control solution(s) and assign acceptable ranges for each level of control solution (level 0, 1, 2, etc.). The ranges are based on regulatory guidelines, the accuracy and precision of test strips and glucose control solution.

What are the expiration dates for control solution?

Control solution has two expiration dates, (1) is the closed bottle expiration date which is printed on the glucose control bottle label and (2) is 3 months from the date the control solution bottle was first opened – please refer to the control solution Instructions for Use for more information. It is good practice to write the date when the solution was first opened on the bottle label.



How often should I use the control solution to test my meter?

We recommend using Control solution to test the meter:

- Before using the system to perform a blood test
- When opening a new vial of strips
- If blood results seem unusually high or low based on patients symptoms and condition
- If strip vial has been left open or exposed to extreme heat, cold or humidity (recommend replacement)
- Whenever a check on the performance of the system is needed
- If meter damage is suspected (Meter dropped, crushed, wet, etc.)

Should I shake the glucose control solution prior to using it?

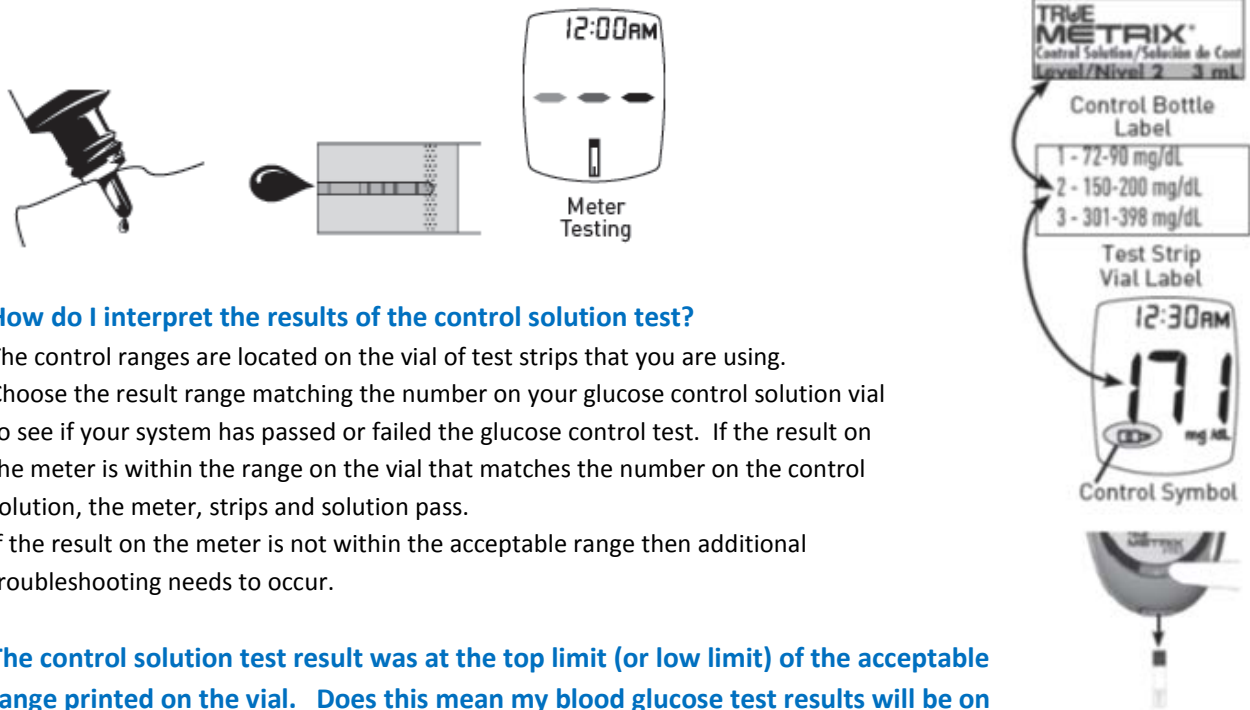
No, control solution should be gently swirled or inverted 2-3 times before use. DO NOT SHAKE! Shaking the vial of solution will introduce air bubbles into the solution, which may affect the results.

Does temperature affect the glucose control results?

The meter, test strips and control solution should to be at room temperature, (68-77°F) for at least 30 minutes prior to control testing. Control solution and the test strips are affected by temperatures below 68° F and above 77°F, as well as humidity. The solution can be stored at temperatures 36°-86°, but brought to room temperature at least 30 minutes prior to testing.

How do I perform a control test?

In order to get an accurate reading, first squeeze a drop of control solution onto a tissue, then wipe the tip of the bottle clean. The solution is basically sugar in water with a few additives, and can dry out in the bottle tip as the water evaporates, leaving a concentrated solution on the tip, which may result in an inaccurate reading. The next step should be to apply a drop of control solution onto a clean non-porous surface, such as aluminum foil or plastic wrap and touch the tip of the test strip into the solution. Remove the test strip from the drop of solution as soon as the meter beeps and begins testing.



How do I interpret the results of the control solution test?

The control ranges are located on the vial of test strips that you are using. Choose the result range matching the number on your glucose control solution vial to see if your system has passed or failed the glucose control test. If the result on the meter is within the range on the vial that matches the number on the control solution, the meter, strips and solution pass.

If the result on the meter is not within the acceptable range then additional troubleshooting needs to occur.

The control solution test result was at the top limit (or low limit) of the acceptable range printed on the vial. Does this mean my blood glucose test results will be on the high end (or low end) also?

No, the control solution result does not correlate with blood glucose results. Control testing must be interpreted as Pass/Fail. Where the control test results fall within the indicated test-range is in no way an indication of blood test results. Control solution has a completely different chemical and physical makeup compared to blood. These differences provide for stability and increased sensitivity to many conditions that could affect the blood glucose test system. Control solution's increased stability and sensitivity make it ideal for field assessment of the glucose measurement system. If the result is within the range printed on the test strip vial label, then the meter, strips and solution all pass the testing and are working properly.

The control solution test was either too high or too low and not within range

Ensure you are NOT matching the control solution test result against the range listed in the strip package insert (this is only an example and for reference only). Review question "How do I interpret the results of the control solution test?"