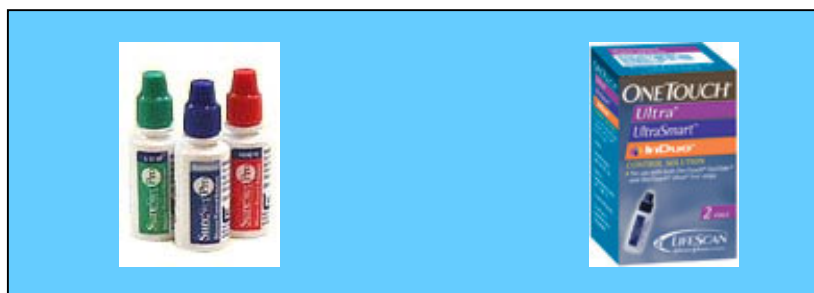


CONTROL SOLUTIONS

Control solutions are substances intended by a manufacturer to be used to verify the performance characteristics of an in vitro diagnostic medical device ¹.

Control materials can be classified as (1) 'primary controls' (reference materials that have assigned values by definitive methods), (2) 'secondary controls' (non-standard materials that have assigned values by reference methods), or (3) 'tertiary controls' (non-standard materials that have assigned values by repetitive routine measurements) ². LifeScan's control solutions are 'tertiary' controls – as are control solutions offered by most other meter manufacturers.



Tertiary controls are not traceable to higher order reference materials and cannot be used to assess the absolute accuracy of a meter system. However, control solutions provide a valuable function. Their value lies in that the customer can use control solutions to assess their SMBG system for:

- **Recovery – comparison of a customer result to an expected (i.e. initial manufacturing) result**
- **Use error – identifying a testing mistake**
- **Stability – observing results over product's shelf-life**
- **Imprecision – the degree of reproducibility of repeated tests**

Without control solutions, customers would not be able to conveniently check the reliability of their glucose meter systems and, instead, would have to compare meter values to a laboratory method using glucose in human blood and plasma – a complex task that is inconvenient, expensive, and a potential biohazard.

Control solutions are complex mixtures of various compounds. In addition to β -D-glucose, they may contain flow modifiers, preservatives, coloring agents, and buffers. These compounds cause a 'matrix effect' to occur which means that the

response can vary depending on how the material is tested and what method (e.g. meter, lab analyzer) is used to measure it. The performance of control solution mimics some of the characteristics of human blood but there are factors (temperature, humidity, sample volume, etc.) that can affect control materials differently than human blood.

LifeScan determines an acceptance range for each test strip lot by testing control solution with a specific set of meters and calculating an average response. The acceptance range is then assigned to the test strip lot that has this average as its midpoint. Therefore, whenever you test control solutions and observe a value that is exactly in the middle of the range, you are 'recovering' the response that was observed during manufacturing. The QC range is 'lot-specific' which means that each test strip lot can have a slightly different average response and a slightly different assigned range. The range accounts for expected variation due to analytical (meter-to-meter, strip-to-strip, bottle-to-bottle) environmental, and other product uses and claims. Therefore, values that fall outside the control solution range should be investigated.

Control solution testing should be carefully performed. The response of the solution may be temperature sensitive so the temperature of the solution and the environment may be important. The contents may settle inside the bottle so mixing may be necessary. The first drop from the tip of the bottle, or the tip of the bottle itself, may contain remnants of glucose from a previous test – this glucose may contaminate the next test unless wiped clean. Customers should carefully follow directions supplied in the Owner's booklet when performing control solution testing.

¹ ISO 15197 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. First edition dated 2003-05-01. ISO 15197:2003(E) International Standards Organization, Geneva, Switzerland.

² Maas AHJ. IFCC reference methods and materials for measurement of pH, gases and electrolytes in blood. Scand J Clin Lab Invest 1993; 53[Supplement] 214:83-94.