

## Frequently Asked Questions

### **1. What is the FDA's public health notification about?**

The FDA's notification explains that patients undergoing drug therapies that contain or metabolize to maltose, galactose or xylose, such as immunoglobulin therapy or peritoneal dialysis, should not have their blood glucose monitored with devices that use the GDH-PQQ enzyme. These devices cannot distinguish between glucose and the other sugars used in these drug therapies, causing falsely elevated blood glucose results. This could lead to inappropriate dosing or administration of insulin.

### **2. What products are affected by this FDA notification?**

The Public Health Notification issued by the FDA affects:

- The Nipro Diagnostics TRUEresult® and TRUE2go® meters and TRUEtest™ strips
- ACCU-CHEK blood glucose meters and corresponding test strips
- Abbott FreeStyle meters and corresponding test strips
- Smiths Medical's CoZmonitor blood glucose module (for use with the Deltec Cozmo Insulin Pump) that is used with Abbott Diabetes Care Freestyle test strips
- Insulet's OmniPod Insulin Management System that is used with Abbott Diabetes Care Freestyle test strips

### **3. Who does this affect?**

Only patients undergoing the specific drug therapies listed in the above question should stop using the TRUEresult and TRUE2go. This applies to a small group of people with diabetes who are undergoing peritoneal dialysis using solutions containing icodextrin (Extraneal, Icodial) that are metabolized to maltose, or those who are receiving injections or infusions of solutions containing or metabolizing to galactose, maltose, or xylose. These drugs include some immunoglobulin preparations such as Octagam 5% and HepaGam B; WinRho SDF Liquid; Bexxar radioimmunotherapy agent; Adept adhesion reduction solution (4% icodextrin); Orenzia; and solutions used in xylose absorption testing. All of these medications are administered either intravenously or through peritoneal catheter for serious medical conditions, oftentimes in a hospital setting.

The FDA notes that "GDH-PQQ meters and strips are okay to use if you are not using an interfering drug product or therapy." People undergoing any of these therapies can use our other meter systems, such as TRUEtrack, TRUEbalance, Sidekick and TRUEread, which are based on the glucose oxidase (GO) enzyme.

### **4. Should I stop using my TRUE2go or TRUEresult meter?**

If you are **not** undergoing drug therapies that contain or metabolize to maltose, galactose or xylose, such as immunoglobulin therapy or specific peritoneal dialysis solutions, you may use the TRUE2go or TRUEresult meter system for accurately monitoring your blood glucose. If you are undergoing drug therapies that contain or metabolize to maltose, galactose or xylose, such as immunoglobulin therapy or peritoneal dialysis, do not use the TRUEresult or TRUE2go system. Use another type of blood glucose monitoring technology that utilizes a glucose oxidase (GO) enzyme. Nipro Diagnostics offers the TRUEtrack®, TRUEbalance™, Sidekick® and TRUEread® systems, which are based on the glucose oxidase (GO) enzyme.

### **5. I am currently receiving one or more of these drug therapies, what should I do?**

If you are undergoing drug therapies that contain or metabolize to maltose, galactose or xylose, such as immunoglobulin therapy or peritoneal dialysis, do not monitor your blood glucose with devices that use the GDH-PQQ enzyme because these devices cannot distinguish between glucose and the non-glucose sugars used in these drug therapies, causing falsely elevated blood glucose results. Instead, use another type of blood glucose monitoring technology to monitor your blood glucose. For further information, please review the FDA's recommendations in the public health notification:

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm176992.htm>

### **6. Is this a recall?**

No, this is not a recall. As the FDA notes in the notification, "GDH-PQQ meters and strips are okay to use if you are not using an interfering drug product or therapy."