Technical Note: Effect of Maltose interference on Glucose Test Strip Results: Interference with Octagam and Icodextrin

Background

Diabetes is the most common cause of end stage renal failure. Those patients undergoing peritoneal dialysis to treat renal failure often suffer from problems with removing fluid. This can be improved with an osmotic agent based on a polymer of glucose - **icodextrin**. During circulation in the body icodextrin is mainly metabolised into **maltose** consisting of two glucose molecules, which accumulates in the body due to a lack of the enzyme needed to break it up (maltase). This accumulation of these metabolites of **icodextrin** is though to give rise to serious interference problems with some glucose test strips (1,2). In a similar manner some immunoglobulin solutions (e.g. **Octagam**) are administered to the patient intravenously and contain high levels of **maltose**. Once again, due to the lack of maltase in the circulation, the level of maltose builds up in the bloodstream.

The Problem

Some glucose test systems using a glucose dehydrogenase dependent on the co-enzyme pyrroloquinone (GDH-PQQ) show a high degree of cross reactivity with maltose. Hence patients who are hypoglycaemic have been reported to test as hyperglycaemic (2), with potentially life threatening consequences. Indeed, in both the USA and UK fatalities have already occurred (1). Strips that use this enzyme include the **Accu-Chek Advantage II (Roche), Freestyle (Abbott) and Ascensia (Bayer).**

In the USA the FDA has issued a warning regarding the use of such strips in situations in which the patient has been exposed to maltose (1).

The Microdot® System

The **Microdot® System** uses a different enzyme than the strips discussed above – a NAD dependent glucose dyehydrogenase (GHD-NAD) which shows no significant cross reactivity with **maltose**. Laboratory tests with **maltose** and **Octagam** have confirmed this. See attached results. Further clinical studies are ongoing. Other test strip systems that use the same type of enzyme (e.g. HaemoCue), similarly, show no interference with **maltose, Octagam or Icodextrin** (3).

(1) Gaines et al; Fatal Iatrogenic Hypoglycaemia: Falsely Elevated Blood Glucose Readings with a Point of Care Meter due to a Maltose Containing Intravenous Immune Globulin Product: www.fda.gov/cber/safety/glucfalse.htm.

(2) Disse E; C Thivolet: Hypoglycemic Coma in a Diabetic Patient on Peritoneal Dialysis due to Interference of Icodextrin Metabolites with Capillary Blood Glucose Measurements: Diabetes Care 27:2279;2004-09-03

(3) Riley S et al: Spurious Hyperglycaemia and Icodextrin in Peritoneal Dialysis Fluid: BMJ 608-9:327;2003

(4) Laboratorytalk, Product News: 5th September 2003: www.laboratorytalk.com/nes/hem/hem108.html

Whole Blood Testing of Microdot® Blood Glucose Sensors with Whole Blood Samples

Method: Maltose was added to samples of whole venous blood from a volunteer donor and the results on the Microdot® system were compared to controls. There was no interference even at high maltose levels. The tests were carried out on strips at high and low glucose levels.

Low Glucose levels: Approximately 60 mg/dl or 3.3 mM glucose

	Control	Maltose @20mg/dl	Maltose @100mg/dl
Number of tests	5	5	5
Average glucose reading (mg/dl)	62.0	63.4	63.2
Standard deviation	2.35	3.51	4.67
CV%	3.78	5.53	4.67

High Glucose levels: Approximately180mg/dl or 10 mM glucose

	Control	Maltose @20mg/dl	Maltose @100mg/dl
Number of tests	5	5	5
Average glucose reading (mg/dl)	173.25	176.4	175.8
Standard deviation	1.71	5.18	4.66
CV%	0.99	2.93	2.65

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