Inaccurate High Glucose Values Involving Lifescan SureStep Glucometers and Hydrogen Peroxide Products

Glucose Oxidase based glucometers, such as the Lifescan SureStep, rely upon the generation of hydrogen peroxide via an enzymatic reaction to determine and measure blood glucose levels. Because of this reaction, it is understood that contamination of the test strips with hydrogen peroxide may lead to faulty results and as such, care by the healthcare provider or person performing the test should be taken to avoid contamination of the test strip, the strip holder and the optical area of the glucometer with H2O2. Accelerated Hydrogen Peroxide is one of, but not the only potential source of H2O2 within the home or healthcare setting that can potentially contaminate the test strips of glucose oxidase based glucometers. Regardless of the source of H2O2, there are procedures that can be implemented to prevent this reaction including stringent compliance with changing of gloves and hand hygiene and the rinsing of the glucometer after disinfection. If the potential risk for contamination is still deemed too high, Glucose Oxidase based glucometers can be replaced by those that utilize the Hexokinase or Glucose Dehydrogenase methods for glucose monitoring as their glucose monitoring methods are much less likely to be interfered with by outside contaminants.

Situation:

A memo identifying the concerns for the potential of a negative reaction with Accelerated Hydrogen Peroxide (AHP) disinfectants and the test strips of the Lifescan Sure Step Glucometers has recently been shared through a North American Patient Safety Listserv. Patient safety is absolutely paramount and therefore end-users should familiarize themselves with the potential cross reaction that can occur with all hydrogen peroxide-based products including the very common healthcare and household 3% topical antiseptic and the Lifescan glucose meters, however the information within the note is perhaps inappropriately narrow in its focus. The following bulletin has been drafted with the intention of providing concerned users with the most correct information.

Background:

Glucose meters are universally utilized in the management of hypoglycemic and hyperglycemic disorders in home and healthcare settings alike. Determination of glucose levels are a necessary tool in diagnosis and management of acutely ill patients and patients with chronic conditions such as diabetes mellitus. The measurement of blood glucose levels is determined by the use of enzymes which are special proteins that cause chemical reactions. These
enzymes react with the glucose in the blood in one of two ways; by causing a color change which is measured by the glucometer and translated into a glucose concentration or via a series of enzymes that cause glucose to react in such a way that a small amount of electricity is produced so that the glucometer translates the electrical activity into a glucose concentration.

At present there are three (3) enzyme methods used for the measurement of blood glucose:

**Glucose Oxidase (as used by the Lifescan SureStep)** is a two-step reaction where glucose is converted to gluconic acid and hydrogen peroxide (H2O2) in the presence of glucose oxidase and oxygen. The concentrations of gluconic acid and H2O2 are proportional to the amount of glucose originally present. The second part of this reaction utilizes peroxidase and a chromatogen where by the H2O2 is converted to H2O and the chromatogen produces a colour. The colour intensity is proportional to the concentration of H2O2 that was produced. This is measured and translated into a glucose concentration.

**Hexokinase** is also a two-step reaction, but has advantages over the glucose oxidase method because fewer substances interfere with the reaction and the reagents themselves are safer. In the first step, hexokinase in the presence of adenosine triphosphate (ATP) adds a phosphate to glucose to form glucose-6-phosphate (G6P). The second step G6P when in the presence of nicotinamid adenine diphosphate (NADP) and the enzyme glucose-6-phosphate dehydrogenase (G6PD) is converted to 6-phosphogluconate (6PG) with the production of reduced NADPH which is absorbed by ultraviolet light. The increase in the absorbance due to NADPH is proportional to the glucose concentration.

**Glucose Dehydrogenase (GDH)** uses the GDH enzyme to measure glucose and is another method that has few interferences. There are two different methods that utilize GDH. The first GDH method uses three enzymes; mutarotase, glucose dehydrogenase and diaphorase along with two colour reagents. In this method, glucose reacts with the reagents and enzymes to form gluconolactone, NADH and MTTH, which has a blue colour. The intensity of the blue colour is proportional to the glucose. The second method also utilizes the conversion of glucose to gluconolactone, however rather than reading the intensity of the colour created by the reaction, the electrical current produced during the reaction is measured.

Despite sophistication of glucose meters, critically ill patients whose homeostasis is severely compromised are likely to encounter extreme physiologic conditions, complicating the interpretation of results. The most common reason for errors is due to the mechanical stress applied to the test strips, however, site humidity can also prematurely rehydrate the enzymes. Furthermore, in the ICU, patients may have multiple medical problems that can affect glucose meter readings such as high pH, hypoxia and anemia which can falsely elevate glucose results for glucose-oxidase-based meters.
In the case of the Lifescan SureStep Glucometer, it utilizes the Glucose Oxidase reaction to measure blood glucose levels. As the Glucose Oxidase method requires glucose to be converted into gluconic acid and H2O2 it is understood that contamination of the test strips with hydrogen peroxide may lead to faulty results. As such, care by the healthcare provider or person performing the test should be taken to avoid contamination of the test strip, the strip holder and the optical area of the glucometer with H2O2. Although Clinical Biochemistry articles from 2006\(^2\) and 2010\(^3\) identify issues associated with Accelerated Hydrogen Peroxide disinfectant wipes, the potential for contamination is present with any source of H2O2. Hydrogen Peroxide is widely used in both the home and in healthcare facilities in such things as oral hygiene products, teeth whitening solutions, wound antiseptic, wound debridement, surface disinfectants; surgical instrument disinfectants and vaporized hydrogen peroxide room decontamination etc.

Regardless of the source of H2O2, it is exceptionally important that healthcare workers and individuals alike are cognizant to not contaminate their hands with H2O2 which could be transferred to the glucose test strip. In the healthcare environment, if the appropriate moments of hand hygiene are followed such as after touching the patient surroundings, before touching a patient and before a clean or aspetic procedure the hands/gloves of the healthcare workers would not run the risk of potential contamination. While hand hygiene compliance including auditing and reporting of a facility’s compliance is an integral part of patient safety, the compliance is often low. While compliance by healthcare workers has improved with respect to entry into a room, compliance with hand hygiene after touching the patient’s environment – for example putting down the bedrail or touching monitoring equipment – but before moving to the next task is low and difficult to assess. These are the instances however, when hands/gloves can be contaminated and can lead to transmission of pathogenic organisms or in the case of facilities that utilize hydrogen peroxide-based disinfectants or room decontamination devices can lead to potential contamination of hands/gloves and the potential contamination of glucose test strips prior to taking a patient’s blood glucose reading.

We believe it’s important to highlight that oxidizers such as hydrogen peroxide are becoming more and more popular for use as disinfectants in healthcare facilities as well as in the home due to many factors. They often carry preferred environmental profiles, synergies with other ingredients that provide good disinfection, superior cleaning efficacy and enhanced stability in soil loads. Furthermore, this excellent performance is balanced with a superior safety profile. “The future of disinfectants is in non-halogen based oxidizers such as Hydrogen Peroxide” (Block, 2001)\(^4\). For this reason, the manufacturers of glucometers based on the glucose oxidase method will need to put forth very clear and concise use protocols for those who choose to use these glucometers.

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Conclusion:

Accelerated Hydrogen Peroxide is one of, but not the only potential source of H2O2 within the home or healthcare setting that can potentially contaminate the test strips of glucose oxidase based glucometers. Regardless of the source of H2O2, there are procedures that can be implemented to prevent this reaction including stringent compliance with changing of gloves and hand hygiene. If the potential risk for contamination is still deemed too high, Glucose Oxidase based glucometers can be replaced by those that utilize the Hexokinase or Glucose Dehydrogenase methods for glucose monitoring as their glucose monitoring methods are much less likely to be interfered with by outside contaminants.

References: