

Sentinel Automated Measurement IP Accuracy-Precision Studies

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Abstract

Introduction

Newly proposed and more stringent blood sugar measurement standards were proposed in 2014. Industry experts and health care professionals applauded the idea of requirements for greater accuracy, but were concerned that there was no existing technology or known innovations available that could meet the new specifications. To demonstrate the capability of our patented and patent pending automated Sentinel intellectual property ("Sentinel IP") to meet and exceed these newly proposed measurement specifications, an advanced instrument design incorporating TecMed, Inc.'s innovative IP was utilized to collect and analyze data from 27 studies.

Methods

Over four days, two researchers completed more than 30 automated studies using the same advanced device design and instrument. Glucose measurement data was collected and reported from 27 of those studies and the measurements from the remaining studies were utilized for calibration of the instrument. Two different lots of aqueous glucose standards comprised of seven glucose concentrations each ranging from 50mg/dL to 400mg/dL were measured in the studies. The studies provided variation data for day-to-day, multiple users, and lot-to-lot standard preparations.

Results

All of the measurements were within the FDA-preferred "A" area of the Clarke Error Grid Analysis and exceeded all existing and newly proposed specifications for glucose measurement for blood sugar management in hospitalized patients or consumer self blood glucose monitoring for diabetics. The current designs for the IP are focused on clinical use.

Conclusions

The automated optical measurement system (Sentinel IP) embodied in the advanced device design provided glucose measurement of aqueous standards that is the only known accurate, automated, realtime and cost effective blood glucose measurement and monitoring technology that exceeds all existing and proposed standards for blood glucose measurement.