

Clinical Precision Evaluation of FORA Blood Glucose Monitoring System

OBJECTIVE

This report is intended to examine the precision including intermediate precision and repeatability of the FORA blood glucose monitoring system.

INTRODUCTION

This test is following ISO-guide 15197 [1]. The FDA recommending guideline, EP5-A [2], is also involved as a reference. Precision includes intermediate precision (day-to-day precision) and repeatability (within-day precision). Intermediate precision is defined as the test results was obtained by the same method on identical test item in the same location but in other variable condition such as day, operators, environmental conditions and equipment. Repeatability is defined as test results were derived with the same method on identical item in the same location, operators, environmental conditions and equipment but within a short interval of time.

MATERIALS AND METHODS

Intermediate precision

For intermediate precision, three level glucose control solutions which are respectively low level from 60 to 92 mg/dL, normal level from 109 to 165 mg/dL and high level from 259 to 389 mg/dL, was used instead of blood specimen to prevent glucose degradation effect (glycolysis). This evaluation was performed by three of each lot with duplicated measurements. The test was performed each day and last for ten day.

Repeatability precision

As for repeatability was performed as five concentration with spiking dextrose in venous blood samples as possible as short period (30 minutes) to minimize the effect of glycolysis. Five glucose concentrations for repeatability test were 30 to 50 mg/dL, 51 to 110 mg/dL, 111 to 150 mg/dL, 151 to 250 mg/dL and 251 to 400 mg/dL. The evaluation was performed by three of each lot with five times measurements. The test was developed within only 30 minutes.

RESULTS

Intermediate Precision

For three level control solutions, two measurements were tested for each of three lots. The test was performed every day lasted for ten days. This gave a total sixty different determinations for each level. From these sixty determinations, mean value (mean), standard deviation (SD) and correlation value (CV) was calculated as below. The following is the result of

intermediate precision using FORA glucose monitoring system.

Control solution	Low*	Normal*	High*
Mean [#]	79.8	138.2	327.6
SD [#]	1.91	4.11	7.83
CV [#]	2.39%	2.98%	2.39%

*Control solution: low, normal and high concentration was 60-90 mg/dL, 109-165 mg/dL and 259-389 mg/dL, respectively.

[#]Each mean, SD and CV were obtained by duplicated measurements of three lots for each day of ten days.

Repeatability Precision

For five glucose interval concentrations, five measurements were tested for each of three lots. To prevent from glucose degradation, the test was completed in 30 minutes. Fifteen results from each interval were calculated its mean, SD and CV which were shown below. The following is the results of repeatability precision of FORA glucose monitoring system.

	Int.1*	Int.2*	Int.3*	Int.4*	Int.5*
Mean [#]	43.0	85.0	136.9	214.1	353.5
SD [#]	1.97	2.47	3.74	6.24	4.98
CV [#]	4.58%	2.91%	2.73%	2.92%	1.41%

*Int. presented interval glucose concentration prepared by spiking dextrose in venous blood specimen. The concentration was respectively 30-50, 51-110, 111-150, 151-250, 251-400 mg/dL.

[#]Each mean value, standard deviation (SD) and correlation value (CV) were obtained by duplicated measurements of three lots of each five concentration within 30 minute.

CONCLUSION

The FORA glucose monitoring system meets the precision requirement for the ISO 15197:2003 standard. The CV is less than 5% both in intermediate precision and repeatability precision.

REFERENCES

1. ISO15197, first edition 2003, 05, 01: In vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
2. NCCLS, Vol. 19, No. 2, 1999, EP5-A: Evaluation of precision performance of clinical chemistry devices; approved guideline.
3. Review criteria assessment of portable blood glucose monitoring in vitro diagnostic devices using glucose oxidase, dehydrogenase or hexokinase methodology, FDA draft document, version 02/14/96.

