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Clinical Accuracy of Blood Glucose Monitoring System

OBJECTIVE

The study was measured blood glucose of mice for evaluating the accuracy of the blood glucose.

INTRODUCTION

"Lab Gluco" offers a fast way which can be measured mice's blood glucose accurately. This study validated the accuracy of mice's blood glucose meter system.
Pet Glucose Meter has a convenient and portable feature which suit everything study program in the research laboratory. This model used the GDH test strip. The results indicate that blood glucose monitoring systems are reliable.

STUDY DESIGN AND METHODS

Study Design

Two of the models with two lots of test strips were tested in this study.

Glucose measurements were carried out in the laboratory. The reference method was used a blood glucose analyzer of Yellow Springs Instruments 2300. We were conducted 40 samples of the mice in this study.

Methods

The study collected blood samples via venipuncture performed accuracy test.

The sampling site of mice wiped with an alcohol pad saturated with 70% isopropyl alcohol before venipuncture. Insert the needle beveled up through the skin into the blood vessel carefully collected vein blood specimen. Technician applied a drop blood into test strip with the meter measured and gained glucose reading.

The reference method was performed using an equipment of YSI 2300 analyzer according to the ISO 15197 standard.

RESULTS

Accuracy

1. Difference Plot
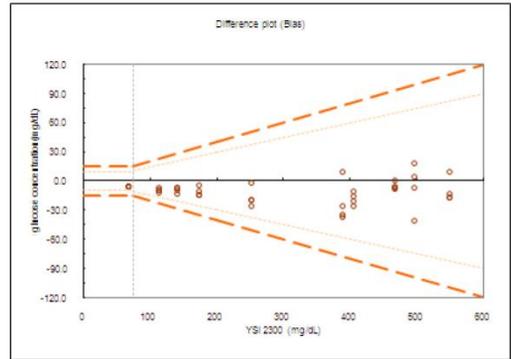
The red bold lines represented the acceptance criteria from ISO 15197, which is described in *Data presentation, 1*.

2. Difference Distribution

Tables below are the presentation of difference (between the meters and YSI-2300) results.

2.1 Difference distribution for glucose concentration <75mg/dL

Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
0/5(0.0%)	5/5(100%)	5/5(100%)

Assessment: 100% of the individual difference is within ±15mg/dL when glucose concentration < 75mg/dL.

Criteria from ISO 15197: 95% of the individual glucose results shall fall within ±15mg/dL.

Justification: Meet the requirement in ISO 15197.

#### 2.2 Difference distribution for glucose concentration ≧ 75 mg/dL

Difference within ±5%	Difference within ±10%	Difference within ±15%	Difference within ±20%
18/36(50%)	34/36(94.4%)	36/36(100%)	36/36(100%)

Assessment: 100% of the individual difference is within ±20% when glucose concentration ≧ 75 mg/dL.

Criteria from ISO 15197: 95% of the individual glucose results shall fall within ±15%

Justification: Meet the requirement in ISO15197.

3. EGA Plot and Analysis

Error Grid Analysis
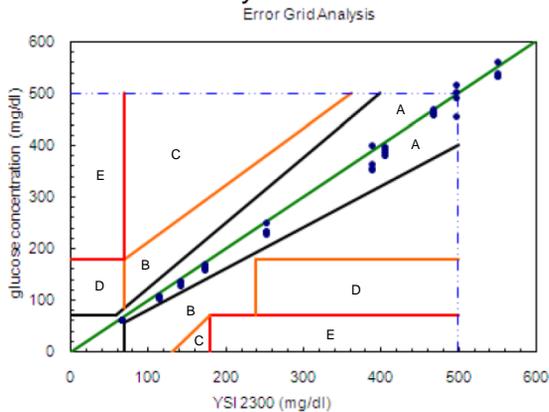
Zone	%	Indication
A	100%	clinically accurate
B	0	deviating from the reference method by more than 20% but would lead to benign or no treatment
C	0	deviating from the reference method by more than 20% and would lead to unnecessary corrective treatment errors
D	0	potentially dangerous failure to detect and treat blood glucose levels outside of desired target range
E	0	resulting in erroneous treatment

CONCLUSION

The study demonstrated the blood glucose monitoring systems to give clinically accurate results for glucose in whole blood samples accurate. The results obtained from using the blood glucose monitoring systems were compared well.

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. Melanie D. Thompsn. Ettinger & Feldman – Textbook of veterinary Internal Medicine. Home Monitoring of Blood Glucose

3. Cephalic and Saphenous Venipuncture. Clinical Textbook for Veterinary Technicians, 5th ed, 2002.

Meter Model Applied: Lab Gluco