

Interference Test of FORA Blood Glucose Monitoring System

OBJECTIVE

To determine a quantitative error criterion for endogenous and exogenous substance for FORA glucose monitoring system.

INTRODUCTION

Twenty-eight analytes were selected and tested in vitro to observe interference on FORA glucose monitoring system. The test substances includes as follows:

1. Primary endogenous substance: Bilirubin, Cholesterol, Creatinine, Uric acid and Triglyceride
2. Primary used drugs: Acetaminophen, Ascorbic acid, Dopamine, Gentistic acid, Ibuprofen sodium, L-dopa, M-dopa, Salicylic acid, Tetracycline, Tolazamide, Tolbutamide and Warfarin
3. Primary used anticoagulants: K₃ EDTA, Heparin, Sodium Citrate and Sodium Fluoride
4. Sugar: Fructose, Galactose, β -Lactose, Maltose, Mannose, D-Sorbitol and Xylose

MATERIALS AND METHODS

The study was performed in accordance with guidelines of human subjects committee and NCCLS. Five endogenous substances, twelve exogenous substances, four anticoagulants and seven sugars were chosen and tested for FORA glucose monitoring system. The test concentrations were recommended by (1) NCCL (2) the toxic level or ten times the highest therapeutic or physiological concentration used, or if both the drug therapeutic and toxic levels were not known (3) test concentrations equivalent to the highest therapeutic dosage assumed to be distributed in 5L of blood volume. Parallel control was performed in the first screening to compared glucose measurements in the presence and absence of substance using heparinized venous blood. An error threshold for interference of ± 6 mg/dL was used

CONCLUSION TABLES

Interference test result of endogenous substances

Substances	Physiological level	Test concentration	FORA system
Bilirubin	0-2 mg/dL ^b	20 mg/dL	No Interference* up to test concentration
Cholesterol	<300 mg/dL ^b	500 mg/dL	No Interference* up to test concentration
Creatinine	<1.7 mg/dL ^b	30 mg/dL	No Interference* up to test concentration
Uric acid	< 8 mg/dL ^b	20 mg/dL	No Interference [#] at physiologic level and level <10 mg/dL
Triglyceride	190 mg/dL	2000 mg/dL	No Interference* up to test concentration

while glucose concentration is ~ 80 mg/dL. Each sample was measured in four replications and derived its mean value and mean difference.

If the mean difference in parallel testing more than ± 6 mg/dL. The substances were became potential interference and would be tested by a dose response at five concentration from therapeutic (physiological) level to test concentration at low glucose ~ 80 mg/dL and high glucose ~ 200 mg/dL (n=4). An error threshold for substance interference of bias $\pm 10\%$ was used. If the bias of glucose measurement greater than 10%, the substance would conclude to be the interference of FORA glucose monitoring system and vise versa.

RESULTS

Twenty-eight substances were chosen for the first interference screening including anticoagulant, sugar, endogenous and exogenous substances. Based on the stringent criterion (± 6 mg/dL at glucose conc. ~ 80 mg/dL) in the first screening, twenty-two substances were determined no interference with FORA glucose monitoring system at therapeutic or physiological level to the test concentration. Uric acid, Acetaminophen, Ascorbic acid, L-Dopa, Tolazamide and Mannose with mean difference greater than 6 mg/dL were followed by the dose response testing.

According to the results of second screening, it showed that no interference was observed in all interfering substances at therapeutic or physiological levels. The conclusion tables were listed as below.

REFERENCES

1. Powers DM, Boyd JC, Glick MR, Miller WG. *National Committee for Clinical Laboratory Standards. Interference testing in clinical chemistry; Approved Guideline. NCCLS publication EP7-A. Villanova, PA; USA 2002.*
2. *Tietz textbook of Clinical Chemistry, 4th edition.*

Interference test result of exogenous substances

Substances	Therapeutic level	Test concentration	FORA system
Acetaminophen	0.45-3 mg/dL ^a	25 mg/dL ^a	No Interference [#] at therapeutic level and level <5 mg/dL
Ascorbic acid	0.4-2 mg/dL ^a	4 mg/dL ^a	No Interference [#] at therapeutic level and level <3 mg/dL
Dopamine	0.03 mg/dL ^a	0.1 mg/dL ^a	No Interference* up to test concentration
Gentistic acid	0.2-0.6 mg/dL ^a	2 mg/dL ^a	No Interference* up to test concentration
Ibuprofen sodium	1-7 mg/dL ^a	55 mg/dL ^a	No Interference* up to test concentration
Levo-Dopa	0.02-0.3 mg/dL	4 mg/dL	No Interference [#] at therapeutic level and level <3 mg/dL
Methy-Dopa	0.1-0.75 mg/dL ^a	1.5 mg/dL ^a	No Interference* up to test concentration
Salicylic acid	10-30 mg/dL ^a	60 mg/dL ^a	No Interference* up to test concentration
Tetracycline	0.2-0.5 mg/dL ^a	1.5 mg/dL ^a	No Interference* up to test concentration
Tolazamide	2-2.5 mg/dL	100 mg/dL	No Interference [#] at therapeutic level and level <50 mg/dL
Tolbutamide	4.32-24 mg/dL ^a	64 mg/dL ^a	No Interference* up to test concentration
Warfarin	0.1-1 mg/dL ^a	2 mg/dL ^a	No Interference* up to test concentration

Interference test result of anticoagulants

Substances	Therapeutic level	Test concentration	FORA system
K ₃ EDTA	175 mg/dL	Blood drawing tube	No Interference*
Heparin	17 U/mL	Blood drawing tube	No Interference*
Sodium Citrate	500 mg/dL ^a	500 mg/dL ^a	No Interference*
Sodium Fluoride	250 mg/dL	250 mg/dL	No Interference*

Sugar nonspecific interference test result

Substances	Therapeutic level	Test concentration	FORA system
Fructose	-	1000 mg/dL	No Interference* up to test concentration
Galactose	-	1000 mg/dL	No Interference* up to test concentration
B-Lactose	-	1000 mg/dL	No Interference* up to test concentration
Maltose	-	1000 mg/dL	No Interference* up to test concentration
Mannose	-	1000 mg/dL	No Interference [#] at level <750 mg/dL
D-Sorbitol	-	1000 mg/dL	No Interference* up to test concentration
Xylose	-	1000 mg/dL	No Interference* up to test concentration

- * : An error threshold for analyte interference of $\pm 6\text{mg/dL}$ was used.
- # : An error threshold for analyte interference of bias $>10\%$ was used.
- ^a : referred by the national Committee for Clinical Laboratory Standards (NCCL).
- ^b : referred by Tietz textbook of Clinical Chemistry, 4th edition.