GLUCOFIX® TECH

Accuracy Information

Technical Specification Summary

Parameter:	Specification:
Sample	0.5 microlitre
Test time	5 second test time
Memory	730 not deletable
Open vial expiry	12 months
Temp Range	5 - 45° C
Battery Life	1,000 tests
Heamatocrit Range	10 – 70%
Test Averages	1, 7, 14, 30, 60, 90 day
Downloadable	NFC to Diasend / Glucolog software

GlucoMen® The Diabetes Diagnostics Company

GLUCOFIX® TECH

Performance: Accuracy and Reproducibility

- GlucoFix TECH Sensors exceed the performance required by EN ISO 15197:2015

Accuracy. A comparison of the results of the GLUCOFIX® TECH Sensor with those obtained using capillary plasma tested with the glucose oxidase method performed on a laboratory analyser (YSI Model 2300 STAT Plus), indicated a high level of accuracy. The results were obtained by testing samples from 100 diabetic subjects (*Fig. 2*). 100% of individual glucose measured values falls within zones A and B of the Consensus Error Grid for type 1 diabetes.

ACCURACY	
Glucose concentration < 5.6 mmol/L (N=186)	
Within ± 0.28 mmol/L	128/186 (68.8%)
Within ± 0.56 mmol/L	180/186 (96.8%)
Within ± 0.83 mmol/L	186/186 (100%)
Glucose concentration ≥ 5.6 mmol/L (N=414)	
Within ± 5%	329/414 (79.5%)
Within ± 10%	409/414 (98.8%)
Within ± 15%	414/414 (100%)
Combined results (N=600)	
Within ± 0.83 mmol/L or 15%	600/600 (100%)

Fig. 2

Precision. Repeatability and intermediate precision results are shown in *Fig. 1*.

	REPEATABILITY (Blood Samples, N=300 per level)					INTERMEDIATE PRECISION (Control Material, N=300 per level)		
Glucose Level mmol/L	1.7-2.8	2.8-6.1	6.2-8.3	8.4-13.9	13.9-22.2	1.7-2.8	5.3-8.0	15.5-23.3
Average mmol/L	3.1	4.5	6.8	12.3	20.4	2.2	6.7	21.2
SD mmol/L	0.1	0.1	0.2	0.3	0.4	0.2	0.2	0.6
CV%	NA	NA	2.7	2.3	1.9	NA	3.3	3.0

Fig. 1

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Performance: Interference Testing

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Interference Testing. The substances listed in *Fig. 3* have been tested for interference with the system. The table reports the maximum concentration with no interfering effect according to EN ISO 15197:2015.

Substance	Test Concentration	Substance	Test Concentration
Acetaminophen	10 mg/dL	Heparin	3000 U/L
Acetylsalicylic acid	40 mg/dL	Ibuprofen	40 mg/dL
Ascorbic acid	6 mg/dL	Icodextrin	1094 mg/dL
Bilirubin	20 mg/dL	L-DOPA	3 mg/dL
Cholesterol	500 mg/dL	Maltose	280 mg/dL
Creatinine	5 mg/dL	Methyl-Dopa	15 mg/dL
Dopamine	0.1 mg/dL	Pralidoxime Iodide (PAM)	50 mg/dL
EDTA	0.5 mg/dL	Tolazamide	23 mg/dL
Galactose	15 mg/dL	Tolbutamide	10 mg/dL
Gentisic acid	2 mg/dL	Triglycerides	1500 mg/dL
Glutathione	1.5 mmol/L	Uric Acid	15 mg/dL
Hemoglobin	200 mg/dL	Xylose	25 mg/dL

Fig. 3

Performance: User Evaluation

- GlucoFix TECH Sensors exceed the performance required by EN ISO 15197:2015

User performance evaluation with GLUCOFIX® TECH meter. A study evaluating glucose values from fingertip capillary blood sample obtained by 105 lay persons showed the following results: 100% within ± 0.83 mmol/L of the reference values at glucose concentration < 5.6 mmol/L and 98.9% within ± 15% of the reference values at glucose concentration ≥ 5.6 mmol/L.