B BRAUN
SHARING EXPERTISE

Blood Glucose
Measurement

Omnitest® plus

ACCURACY TEST
INTERNATIONAL STANDARD ISO 15197:2013

Omnitest® plus
System Accuracy Evaluation

In accordance with the ISO 15197:2013 standard, new criteria for blood glucose meters have been published.

The aim of this document is to present how Omnitest® plus meets these new requirements.

TEST INFORMATION

SYSTEM ACCURACY

The accuracy of Omnitest® plus blood glucose monitoring system was assessed by comparing patients' blood glucose results obtained with Omnitest® plus with those of a standard laboratory instrument, the YSI 2300 auto analyzer.

1) Test date	November 26th, 2012 - December 12th, 2012
2) Test meter serial number	GKRBMC00034 - GKRBMC00039
3) Test strip lot numbers	B4MK07 (Lot #1), B4MK08 (Lot #2), B4MK09 (Lot #3)
4) Sample numbers	▪ 6 x Omnitest® plus meter ▪ 600 x Omnitest® plus test strips (three lots) ▪ 1 x YSI 2300 auto analyzer
5) Standard/guidance documents referenced	▪ ISO/DIS 15197:2010 In vitro diagnostic test systems Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus (during clinical trial) ▪ ISO 15197:2013 In vitro diagnostic test systems Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus (for data analysis) ▪ CLSI EP09-A2:2004 Method comparison and bias estimating using patient samples

SAMPLE DISTRIBUTION

SYSTEM ACCURACY

Glucose concentration mmol/L	Percentage of sample	Sample numbers	Preparation of sample
≤ 2.77	5 %	5	glycolyzed
> 2.77 – 4.44	15 %	15	unaltered
> 4.44 – 6.66	20 %	20	unaltered
> 6.66 – 11.10	30 %	30	unaltered
> 11.10 – 16.65	15 %	15	unaltered
> 16.65 – 22.20	10 %	10	unaltered
> 22.20	5 %	5	supplemented with glucose
Total	100 %	100	

Distribution of glucose concentrations in samples for system accuracy evaluation

System Accuracy Evaluation Difference Plot

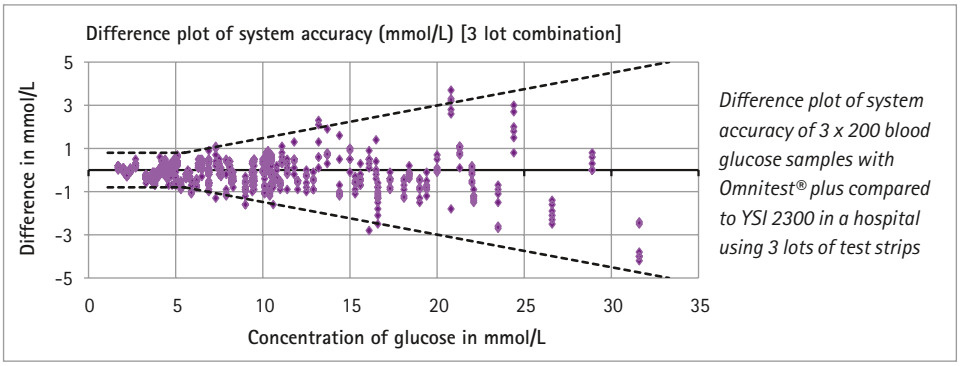
ACCEPTANCE CRITERIA

ACCURACY PLOT – PART 1

Blood glucose concentration & requirements	Tolerance range
< 5.55 mmol/L	± 0.83 mmol/L
≥ 5.55 mmol/L	± 15 %
Minimum requirement: 95 % of all results within tolerance range	

TEST RESULTS

SYSTEM ACCURACY PLOT



Difference plot of system accuracy of 3 x 200 blood glucose samples with Omnitest® plus compared to YSI 2300 in a hospital using 3 lots of test strips

DATA ANALYSIS

BIAS DISTRIBUTION ANALYSIS COMPARED WITH YSI 2300

System accuracy results for glucose concentration < 5.55 mmol/L

Strip lot	Within ±0.28 mmol/L	Within ±0.56 mmol/L	Within ±0.83 mmol/L	Combined lots within ± 0.83 mmol/L
Lot 1	**64.5 %** [40/62]	**88.7 %** [55/62]	**100.0 %** [62/62]	
Lot 2	**72.6 %** [45/62]	**93.5 %** [58/62]	**100.0 %** [62/62]	
Lot 3	**61.3 %** [38/62]	**91.9 %** [57/62]	**98.4 %** [61/62]	
Combined	**66.1 %** [123/186]	**91.4 %** [170/186]	**99.5 %** [185/186]	**99.5 %** [185/186]

System accuracy results for glucose concentration ≥ 5.55 mmol/L

Strip lot	Within ±5 %	Within ±10 %	Within ±15 %	Combined lots within ± 15 %
Lot 1	**55.8 %** [77/138]	**89.1 %** [123/138]	**96.4 %** [133/138]	
Lot 2	**56.5 %** [78/138]	**89.9 %** [124/138]	**97.1 %** [134/138]	
Lot 3	**52.2 %** [72/138]	**87.0 %** [120/138]	**95.7 %** [132/138]	
Combined	**54.8 %** [227/414]	**88.6 %** [367/414]	**96.4 %** [399/414]	**96.4 %** [399/414]

System accuracy results for glucose concentrations between 1.7 mmol/L and 31.6 mmol/L **Within ± 0.83 mmol/L or ± 15 %**	**97.3 %** [584/600]

RESULT

97.3 % of results are within ± 0.83 mmol/L or ± 15 % for combined lots.

CONCLUSION

Omnitest® plus exceeds the minimum requirement of 95 % system accuracy.

System Accuracy Evaluation
Consensus Error Grid

ACCEPTANCE CRITERIA

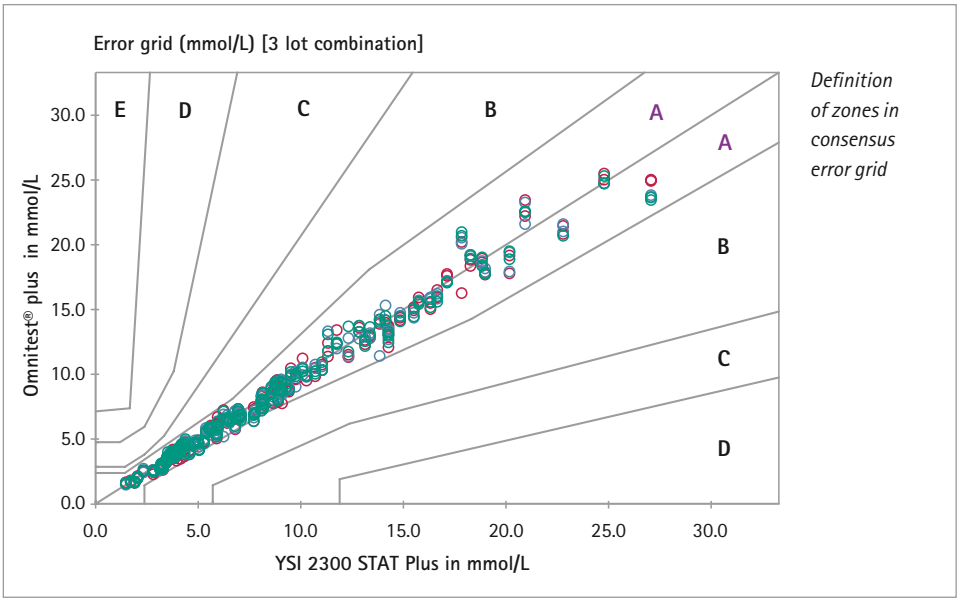
ACCURACY PLOT – PART 2

Test criteria	Tolerance range
Consensus error grid	99 % of results within zones A and B of the consensus error grid for type 1 diabetes

Zone	Classification
A	No effect on clinical action.
B	Altered clinical action – little or no effect on clinical outcome.
C	Altered clinical action – likely to affect clinical outcome.
D	Altered clinical action – could have significant medical risk.
E	Altered clinical action – could have dangerous consequences.

TEST RESULTS

CONSENSUS ERROR GRID



DATA ANALYSIS

CONSENSUS ERROR GRID

Strip lot	Zone A	Zone B	Zone C	Zone D	Zone E	Total
Lot 1	**99.5 %** [199/200]	**0.5 %** [1/200]	0 % [0/200]	0 % [0/200]	0 % [0/200]	**100 %** [200/200]
Lot 2	**100 %** [200/200]	**0.0 %** [0/200]	0 % [0/200]	0 % [0/200]	0 % [0/200]	**100 %** [200/200]
Lot 3	**99.5 %** [199/200]	**0.5 %** [1/200]	0 % [0/200]	0 % [0/200]	0 % [0/200]	**100 %** [200/200]
Combined	**99.7 %** [598/600]	**0.3 %** [2/600]	0 % [0/600]	0 % [0/600]	0 % [0/600]	**100 %** [600/600]

RESULT

100 % of results are within zones A and B of the consensus error grid.

CONCLUSION

Omnitest® plus exceeds the system accuracy requirement that 99 % of results are within zones A and B.