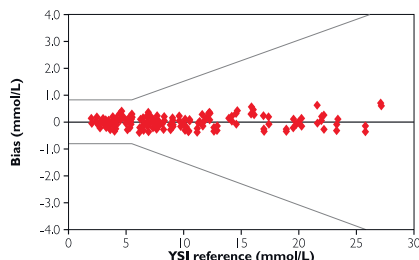


Requirement A: Accuracy

At glucose levels < 5.55 mmol/L, 95% of results should be within ± 0.83 mmol/L of laboratory results.

At glucose levels ≥ 5.55 mmol/L, 95% of results should be within $\pm 15\%$ of laboratory results.



Accuracy results for glucose < 5.5 mmol/L, n=198

Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
146 (198) 74%	196 (198) 99%	198 (198) 100%

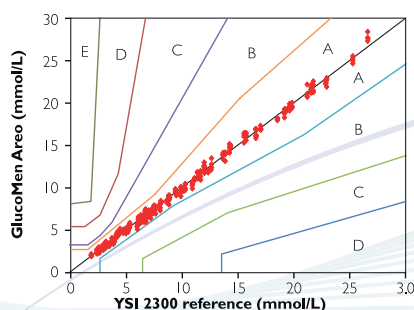
Accuracy results for glucose ≥ 5.55 mmol/L, n=402

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
317 (402) 78.9%	393 (402) 97.8%	401 (402) 99.8%

Results: 100% of results are within 0.83 mmol/L and 99.8% are within $\pm 15\%$ at respective glucose levels
Conclusion: GlucoMen Areo exceeds ISO 15197:2013 requirement of 95%

Requirement B: Accuracy

99% of results should fall within Zones A and B of the Consensus Error Grid.



ZONE	A	B	C	D	E
Cases	600	0	0	0	0
Percentage	100.0	0.0	0.0	0.0	0.0

Results: 100% of results are within Zone A
Conclusion: GlucoMen Areo exceeds ISO 15197:2013 requirement

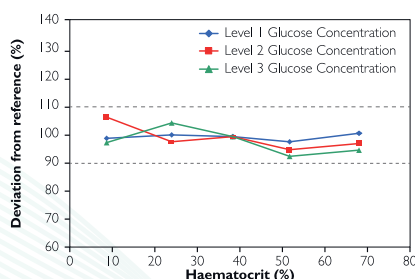
Requirement C: Haematocrit Interference Evaluation

For glucose levels < 5.55 mmol/L.

Results must be within 0.55 mmol/L of results obtained at reference haematocrit of 42%.

For glucose levels ≥ 5.55 mmol/L.

Bias must be less than 10% compared to results obtained at reference haematocrit of 42%.



The GlucoMen Areo sensor has a second electrode position which allows the system to measure haematocrit. The meter then removes the effect of varying haematocrit automatically.

Haematocrit Range 10%-70%.

Results: GlucoMen Areo exhibits an haematocrit interference effect of less than 10% at all levels
Conclusion: GlucoMen Areo exceeds ISO 15197:2013 requirement