

Evaluation of HbA1c Devices Using International Quality Targets

Please find attached the latest article published by Erna Lenters-Westra and Emma English in the Journal of Diabetes, Science and Technology last week. The authors are the two most significant Key Opinion Leaders in Europe right now and both sat on the IFCC Task Force on Implementation of HbA1c Standardization.

This article is the result of the work we have been carrying out with Erna's group based at ISALA hospital, Netherlands, which she presented during our February IDM in Berlin. This should be considered to be a significant achievement and testament to the continual improvement programme that was started @ Quotient and has taken significant leaps since the product was transferred to EKF Diagnostics GmbH.

Significant observations:

1. There is hardly any bias between the Quo-Lab and the mean of the 4 SRMPs (secondary reference measurement procedures).
2. Although not included in this particular study Erna felt it was important to include comment about the Quo-Test's improved performance which also has no bias anymore compared to the mean of 3 SRMPs.
3. The Quo-Lab passed all relevant criteria going far beyond what is required by NGSP and IFCC certification, whereas the HbA1c 501 (HemoCue) did not and the A1Care (i-SENS) did not even come close! The Afinion was almost same level with Quo-Lab.
4. The Quo-Lab showed no consistent clinically significant interference from the common Hb variants HbAS, HbAC, HbAD, HbAE, elevated A2.
5. The Quo-Lab achieved a 1.7% CV in DCCT units. We currently report CVs in DCCT units so this is a significant improvement on the status of all previous studies that declare the up to now performance of similar analyzers (excellent performance is everything below 3%).

Please share this information with the relevant Quo-Lab distributors and clients. We will be putting a new brochure based upon this data (and the previous studies).

Best regards

Gavin

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