

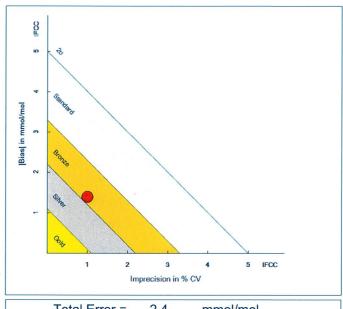
Certificate

EKF Diagnostic GmbH

using

Quo-Test HbA1c

participated in the IFCC HbA1c Certification Programme to demonstrate traceability to the IFCC Reference Measurement Procedure and performed as shown below.



| Total Error = | 2.4 | mmol/mol |
|---------------|--------|----------|
| Bias = | +1.4 | mmol/mol |
| Imprecision = | 1.0 | % |
| Grade = | Bronze | |

Criteria derived from the IFCC model for Quality Targets HbA1c (Clin Chem 2015;61: 752-59)

Date of Certification: 01 June 2018

Date of Expiry: 01 June 2019

IFCC Network Coordinator Dr. C.W. Weykamp



Summary Analytical Performance

Organisation EKF Diagnostic GmbH

Instrument Quo-Test HbA1c

Date Of Certification 01 June 2018

Bias at 30 mmol/mol 0.9 mmol/mol at 50 mmol/mol 1.4 mmol/mol at 70 mmol/mol mmol/mol 2.0 **Imprecision** CV 1.0 % Linearity 0.9996 r

Total Error TE 2.4 mmol/mol

Analytical Performance Individual Samples

| Sample ID | Target Value | Your Result | Your Bias |
|-----------|--------------|-------------|-----------|
| 01 | 58.6 | 60.0 | 1.4 |
| 02 | 53.0 | 55.0 | 2.0 |
| 03 | 94.3 | 97.6 | 3.3 |
| 04 | 55.8 | 57.4 | 1.6 |
| 05 | 83.8 | 86.7 | 2.9 |
| 06 | 39.9 | 40.7 | 0.8 |
| 07 | 31.7 | 32.2 | 0.5 |
| 08 | 67.7 | 70.2 | 2.5 |
| 09 | 37.6 | 39.3 | 1.7 |
| 10 | 48.5 | 50.6 | 2.1 |
| 11 | 45.4 | 45.9 | 0.5 |
| 12 | 73.3 | 76.0 | 2.7 |
| 13 | 48.5 | 49.7 | 1.2 |
| 14 | 50.7 | 51.6 | 0.9 |
| 15 | 88.8 | 89.8 | 1.0 |
| 16 | 63.1 | 65.0 | 1.9 |
| 17 | 53.0 | 55.2 | 2.2 |
| 18 | 34.6 | 35.3 | 0.7 |
| 19 | 42.3 | 43.4 | 1.1 |
| 20 | 99.9 | 102.7 | 2.8 |
| 21 | 37.6 | 38.8 | 1.2 |
| 22 | 58.6 | 60.9 | 2.3 |
| 23 | 78.7 | 80.9 | 2.2 |
| 24 | 67.7 | 68.9 | 1.2 |

^{*} Only if applicable: Blunder, excluded from the calculations