

# QuikRead go HbA1c test fulfils the German quality requirements for laboratory measurements

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## Introduction

Glycated hemoglobin A1c (HbA1c) is an important laboratory marker in diagnosis and therapy management of diabetes mellitus. Measurement of HbA1c at the point-of-care (POC) is beneficial as results can immediately be discussed with the patient. The Aidian QuikRead go HbA1c constitutes a quantitative immunoturbidimetric HbA1c POC test performed on the QuikRead go device (both from AidianOy, Espoo, Finland). The aim of the study was to evaluate the precision of the QuikRead go HbA1c assay (QRgo) and compare it to a certified HPLC method.

## Materials and Methods

**Precision** was determined employing the **CLSI EP05-A3** protocol: normal and high QuikRead go HbA1c controls were measured as four replicates in one run per day for 10 days using two instruments. **Accuracy** of the QRgo was evaluated by comparing the results of fresh patient samples distributed around the clinically relevant range to the IFCC and NGSP certified Tosoh G8 cation-exchange HPLC analyzer (TG8, Tosoh Bioscience, Griesheim, Germany) in accordance with the **CLSI EP09C-ED3:2018** protocol. All measurements were performed in the Institut für Klinische Chemie und Pathobiochemie of the Klinikum rechts der Isar.

## Results

HbA1c control (mean: 45.8 mmol/mol)	SD [mmol/mol]	CV [%]	95% CI [%]	% of Total
<b>Repeatability</b>	1.2	2.5	2.2 – 3.1	78.0
<b>Between instrument</b>	0.5	1.0	0.0 – 2.5	12.4
<b>Within day</b>	1.3	2.7	2.4 – 3.7	90.3
<b>Between day</b>	0.4	0.9	0.0 – 2.4	9.7
<b>Within laboratory</b>	1.3	2.9	2.5 – 3.8	100.0

Table 1. Precision of QRgo with normal control level.

HbA1c control high (mean: 83.6 mmol/mol)	SD [mmol/mol]	CV [%]	95% CI [%]	% of Total
<b>Repeatability</b>	1.8	2.1	1.8 – 2.6	85.0
<b>Between instrument</b>	0.0	0.0	0.0 – 1.4	0.0
<b>Within day</b>	1.8	2.1	1.8 – 2.6	85.0
<b>Between day</b>	0.7	0.9	0.0 – 1.9	15.0
<b>Within laboratory</b>	1.9	2.3	2.0 – 2.9	100.0

Table 2. Precision of QRgo with high control level.

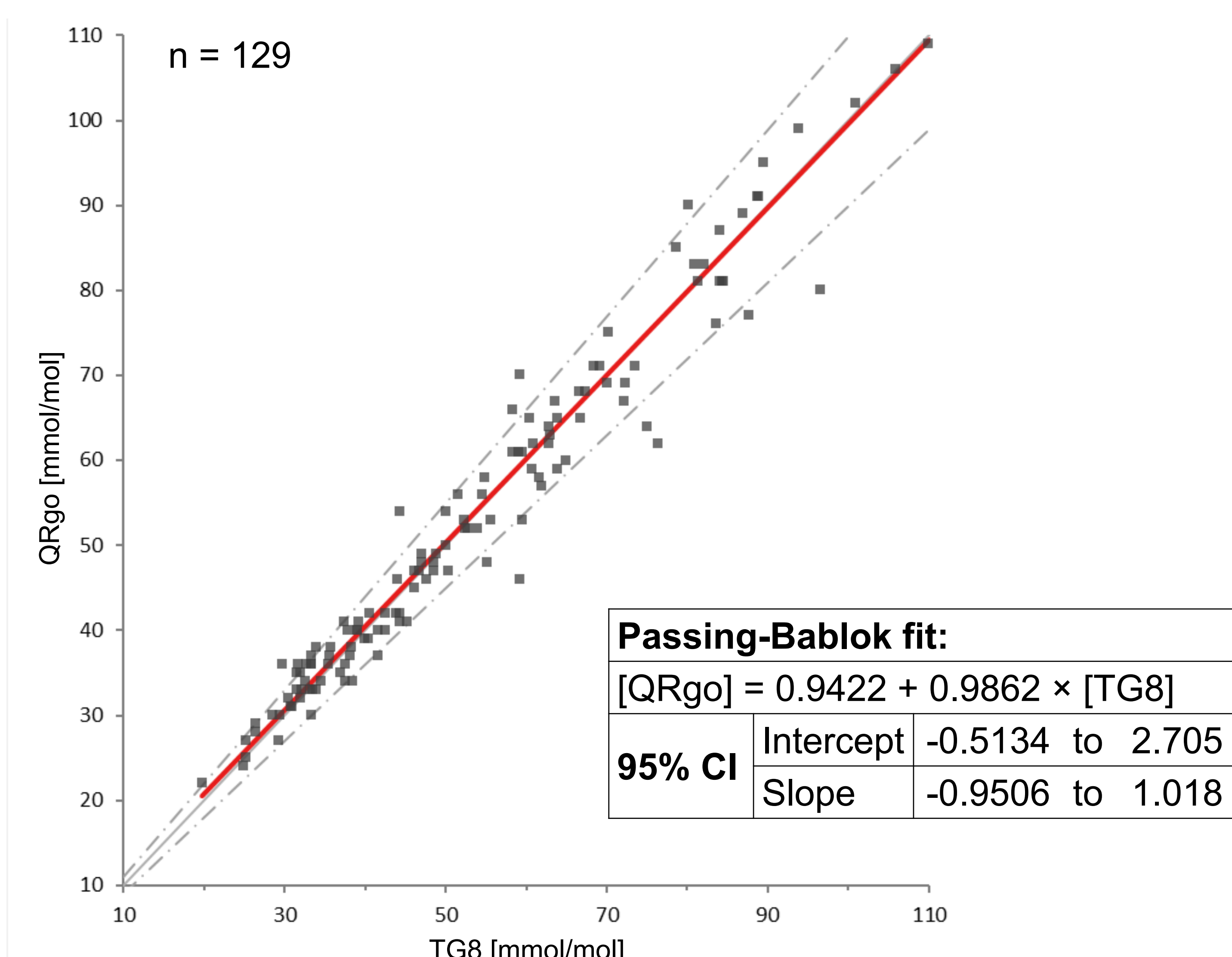


Fig. 1. Comparison QRgo vs. TG8: Passing-Bablok analysis.

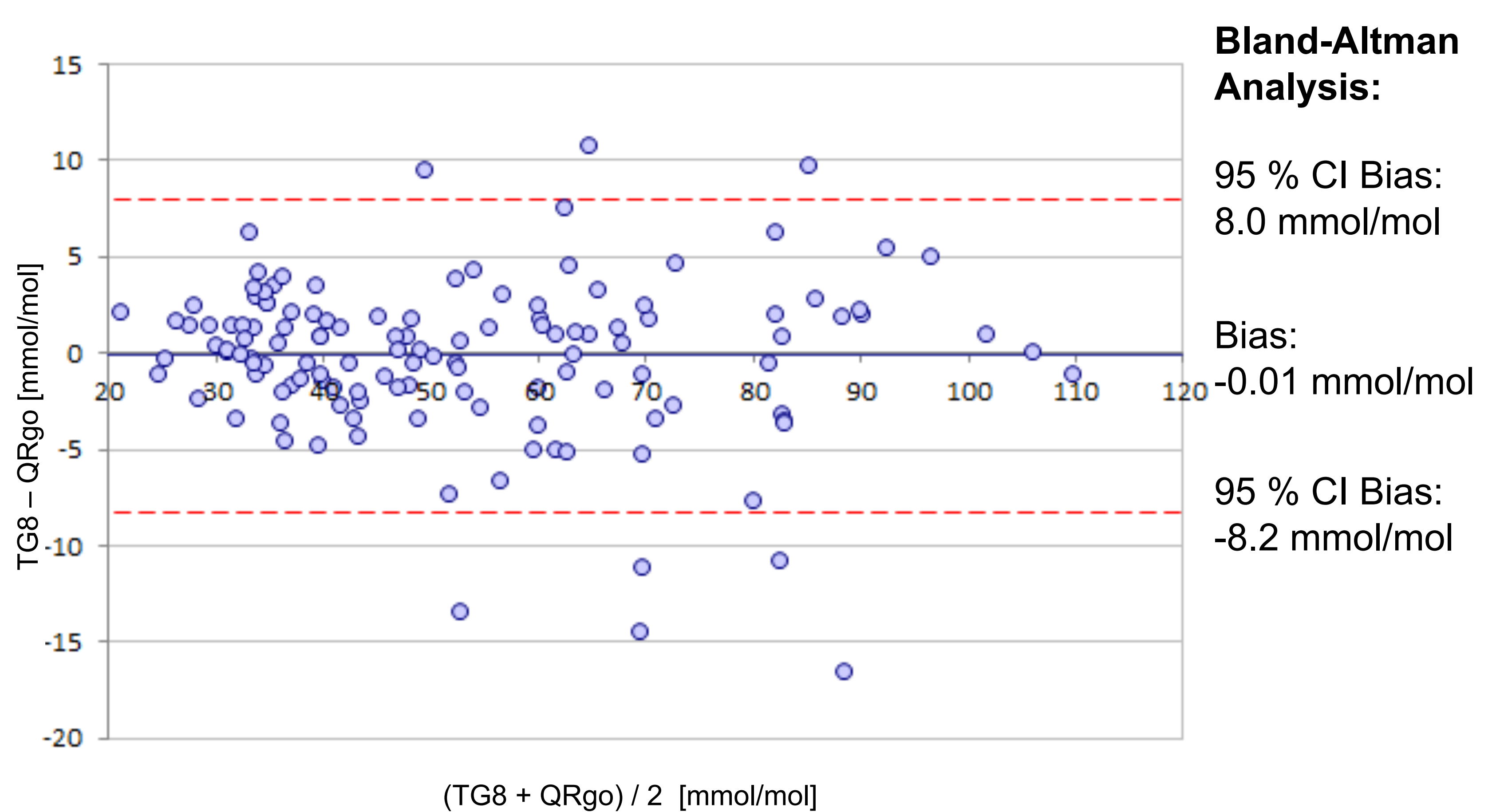


Fig. 2. Comparison QRgo vs. TG8: Bland-Altman plot.

## Conclusions

Before implementation into different healthcare settings, precision and accuracy requirements for HbA1c POC tests have to be considered carefully. We were able to demonstrate high precision for the QRgo with maximum within laboratory CVs of 2.9 %. Notably, the device meets the RilibÄK targets for precision of HbA1c assays allowing a maximum CV of 3.0 %. Furthermore, results of the the QRgo exhibited excellent agreement with a certified HPLC method. HbA1c POC tests such as the QRgo are therefore suitable for the diagnosis of diabetes mellitus and the successful management of diabetic patients.