

**SUMMARY: Estimation of MU for a Glucose Measurement Procedure Ignoring Bias Uncertainty**

**Roche Accu-Chek**

**Inform II Meters**

**July – December 2020**

**IMPRECISION:**

<b>QC LEVEL 1</b>	Date Range
DATA POINTS (N)	1987
MEAN (mmol/L)	2.42
SD (uImp)	0.08
CV (%)	3.3%

<b>QC LEVEL 2</b>	Date Range
DATA POINTS (N)	1975
MEAN (mmol/L)	16.61
SD (uImp)	0.31
CV (%)	1.9%

**Bias** Not accessed

**PLASMA GLUCOSE**

	2.42	mmol/L, uProc =		
		CV =		3.3%
	16.61	mmol/L, uProc =		
		CV =		1.9%

**EXPANDED UNCERTAINTY (U)**

$k=1.96$

Multiplication of  $u_{Proc}$  by a coverage factor of 1.96 provides an interval of values that is believed to include the true value with a coverage probability of 95%.

2.42	mmol/L	<b>U=</b>	6.5%
16.61	mmol/L	<b>U=</b>	3.7%

**COVERAGE INTERVALS**

	<b>U (%)</b>	<b>CV<sub>i</sub> (%)</b>	<b>Minimal U Goal (%)</b>	<b>Desirable U Goal (%)</b>	<b>Optimum U Goal (%)</b>
1.7 - 3.3 mmol/L	<b>6.5%</b>	9.0	<b>6.8</b>	<b>4.5</b>	<b>2.3</b>
14.5 - 19.6 mmol/L	<b>3.7%</b>	9.0	<b>6.8</b>	<b>4.5</b>	<b>2.3</b>

**Conclusion:**

<b>Low Range</b>	Between Desirable and Minimal Goal	<b>Acceptable</b>
<b>High Range</b>	Between Desirable and Optimum Goal	<b>Acceptable</b>