**Supplemental material**

**1. ISO 15197:2013 section 6.3.3 accuracy criteria**

For values <100 mg/dL, ≥95% of results for each test strip lot shall be within ±15 mg/dL of the reference value, and for values ≥100 mg/dL, ≥95% of results for each test strip lot shall be within ±15% of the reference value; and ≥99% of combined results for all three test strip lots shall be within Zones A and B of the Parkes-Consensus Error Grid [14].

**2. ISO 15197:2013 section 8.2 accuracy criteria**

For glucose concentrations <100 mg/dL, ≥95% of results shall be within ±15 mg/dL of reference values, and for concentrations ≥100 mg/dL, ≥95% of results shall be within ±15% of reference values [14].

**3. Process capability statistics (Cpk) calculation**

Cpk values were derived using the following formula:

|  |
| --- |
| Cpk = Minimum of USL – X or X – LSL |
| 3σ 3σ |

USL, Upper Specification limit

LSL, Lower Specification limit

σ, Sigma (Process)

X, process average

**4. Z-score calculation and interpretation**

Z-score values were derived from the Cpk (z-score = Cpk multiplied by three). The z-score represents the number of standard deviations between the mean value and the closest limit (i.e. +15% or +15 mg/dL for positive bias; -15% or -15 mg/dL for negative bias). Because 95% of the normal distribution is within ±1.96 standard deviations, a z-score >1.96 indicates with at least 95% probability that a second chance sampling result was within ±15% or ±15 mg/dL, for blood glucose values <100 and ≥100 mg/dL, respectively.