The New Glucose Standard POCT12-A3 Misses the Mark

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Abstract

POCT12-A3 is a Clinical Laboratory Standards Institute standard for hospitals about hospital glucose meter procedures and performance standards. I have reviewed this standard based on the attributes of an ideal performance standard. POCT12-A3 has tighter limits than its predecessor for 95% of results, the limits widen for 98% of results, and there are no limits for 2% of results. It is hard to fathom that 2% of the results are unspecified and could cause life-threatening results, as glucose meters do not perform this poorly. There should be a specification for unreported results since, by definition, point-of-care-testing assays are time sensitive. POCT12-A3 provides useful advice about the glucose testing procedure but provides evaluation guidance only about analytical performance. Moreover, the recommended protocol to assess meter performance is biased and likely to underestimate the observed performance. The guideline would be improved if its specification were based on an error grid and contained evaluation protocols for user errors.