

Problems and Practical Solutions in the External Quality Control of Point of Care Devices with Respect to the Measurement of Blood Glucose

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Abstract

Point of care testing (POCT) is evolving at an ever increasing rate. This article deals mainly with the aspect of POCT for blood glucose and the problems of external quality assessment (EQA) of point of care devices (POCD). At the present time it is only possible to control precision with EQA, independent of the matrix of the test materials (synthetic polymer-base, plasma/serum, or processed whole blood). The German Federal Medical Council guidelines for laboratory performance allow an interlaboratory imprecision of $\pm 16\%$. The majority of POCD fulfill these requirements. The long-term stability of results—tested by repeated distribution of the same materials over a 12-month period—is excellent, and the performance of POCD under routine conditions is usually excellent in terms of result-comparability. The problems of accuracy in terms of control materials have still to be mastered.

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Abbreviations: (cv) coefficient of variation, (EQA) external quality assessment, (EQAS) external quality assessment scheme, (GC) gas chromatography, (INSTAND) Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V., (IDMS) isotope-dilution mass spectrometry, (POCT) point of care testing, (POCD) point of care device, (RiliBÄK) Richtlinie der Bundesärztekammer, (RMV) reference method value

Keywords: accuracy, blood glucose, diabetes mellitus, evaluation, external quality assessment, external quality assessment schemes, home testing, point of care devices, point of care testing, precision, quality control

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