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A common approach is a laboratory evaluation following standardized protocols, such as the Clinical & Laboratory Standards Institute (CLSI) guidelines. To meet WHO criteria, such evaluations should be undertaken using samples targeted to the Reference Measurement Procedure (RMP), which for HbA1c is the IFCC RMP.

Point-of-care testing for HbA1c: clinical need and ...
HbA1c measurements for samples with normal (4.4%), prediabetes (6.1%), and diabetes (7.9%) HbA1c levels that were stored at either 2□8 °C or □80 °C for up to 4 days were stable. For the samples stored at 2□8 °C, the relative increase in HbA1c was <0.1, <0.1, and 1.3% for normal, prediabetes, and diabetes HbA1c levels, respectively.

Evaluation of an Ion-Exchange HPLC Device for HbA1c ...
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The accuracy of A1C EZ 2.0 analyzer was evaluated following the guidelines described by the CLSI EP09-A3.17 We used 40 EDTA- anticoagulatedvenous whole-blood specimens to cover the mea-surement range of the A1C EZ 2.0: 10 specimens with an HbA1c level between 20 and 42mmol/mol (4.0%- 6.0%), 10 specimens be -

Evaluation of a new hemoglobin A1c analyzer for point□of ...
These guidelines for acceptable performance can be used as Analytical Quality Requirements in the Westgard QC Design and Planning process. The Poor Lab's Guide to the Regulations The tables below contain information on CLIA proficiency testing criteria for acceptable analytical performance, as printed in the Federal Register February 28, 1992;57(40):7002-186.

CLIA Requirements for Analytical Quality - Westgard
CLSI EP05-A3 (R2019) Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition. This document provides guidance for evaluating the precision performance of quantitative measurement procedures. It is intended for manufacturers of quantitative measurement procedures and for laboratories that develop or ...

CLSI EP05-A3 (R2019) - American National Standards Institute
Approved Guideline□Third Edition. CLSI document POCT12-A3 (ISBN 1-56238-867-3 [Print]; 1-56238-868-1 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013.

POCT12-A3 - Clinical and Laboratory Standards Institute
CLSI LINK. PREVIOUSLY RELEASED PUBLICATIONS C49-A: Analysis of Body Fluids in Clinical Chemistry; Approved Guideline This document provides guidance for the application of widely available measurement procedures for testing body fluids and for reporting and interpreting those results. It emphasizes defining the common clinical situations for ...

CLSI-IFCC Joint Projects - IFCC
This guideline provides recommendations to users and manufacturers of point-of-care coagulation testing devices for monitoring heparin and vitamin K antagonist therapy and for the evaluation of hemostasis, as well as to ensure reliable results comparable with those obtained by routine medical laboratory testing.

CLSI Standards & Guidelines: Shop for CLSI Standards
For example, for HbA1c, an AL of 10% is recommended in the new proposed rule. Compare that to the criteria that have been employed in the CAP PT surveys, where the AL was 15% in 2007, tightened to 12% in 2008, 10% in 2009, 8% in 2010, 7% in 2011, 6.0% in 2014, and is currently 5.0%.

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