Verification of an Extended Measuring Interval Implementation Guide

EP34-Ed1-IG

Introduction

This implementation guide describes the minimum procedures necessary for a medical laboratory to verify a developer's extended measuring interval (EMI) claim. For additional information on verifying EMIs, see CLSI document EP34.[1]

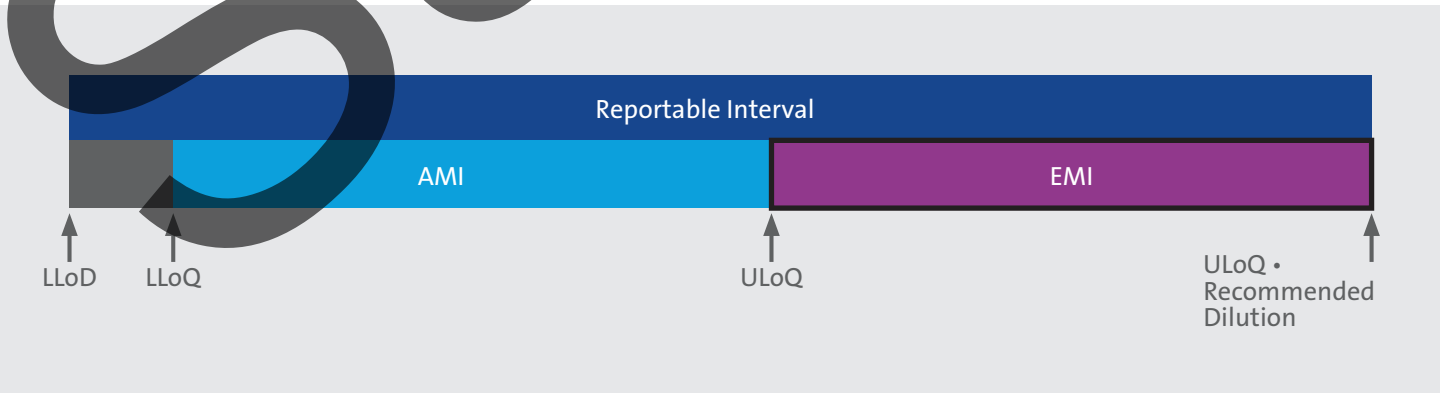
NOTE: This verification of EMI process can be used only when the measurement procedure produces quantitative numerical results.

IMPORTANT NOTE: The study outlined in this implementation guide and described in Chapter 4 of CLSI document EP34[1] is not intended for use by a test developer to establish or validate an EMI for a new commercial test or laboratory-developed test. Instead, test developers should consult Chapters 2 and 3 of CLSI document EP34[1] for guidance on establishing and validating an EMI. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

What Is an Extended Measuring Interval?

It is often medically necessary to provide results for samples with concentrations above the analytical measuring interval (AMI) of a measurement procedure. These results can be obtained by diluting the sample until the result is within the AMI and then multiplying the result by the dilution factor. Developers provide instructions for suitable diluents as well as the maximum dilution factor that provides acceptable results. The samples are diluted following the developer's instructions for diluting high-concentration samples, ie, manually or automatically by the instrumentation. Laboratories need to verify dilution instructions before putting them into practice.

The figure below shows the concentration intervals and limits that define a measurement procedure's AMI (also known as reportable interval). Typically, results are reported clinically when they fall within the AMI, from the lower limit of quantitation (LLoQ) to the upper limit of quantitation (ULoQ). With verified sample dilution procedures, results can be reported to the upper end of the EMI.



Abbreviations: AMI, analytical measuring interval; EMI, extended measuring interval; LLoD, lower limit of detection; LLoQ, lower limit of quantitation; ULoQ, upper limit of quantitation.

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The EMI verification process is outlined in the figure below.

Abbreviations: EMI, extended measuring interval; QC, quality control.