CLINICAL AND LABORATORY STANDARDS INSTITUTE®

ESTABLISHMENT GUIDE

CLSI EP06 EG: Developer Validation of Linearity

Developer Validation of Linearity Establishment Guide

EP06-Ed2-EG

Introduction

This establishment guide describes the minimum procedures necessary for a developer (either a manufacturer or a laboratory-developed test developer) to validate the linearity of a measurement procedure's analytical measuring interval (AMI). For additional information on validating linearity, see CLSI EP06.[1]

NOTE: This protocol to validate linearity can be used only when the measurement procedure produces quantitative numerical results. CLSI EP06-EG is not intended for qualitative test methods; see CLSI EP12.[2]

IMPORTANT NOTE: CLSI EP06-EG is not intended for laboratory verification of linearity. Instead, end users should consult Chapter 4 of CLSI EP06[1] as well as CLSI EP06-IG[3] for guidance and tools for verifying established linearity performance claims made by a developer.

What Is Linearity?

A measurement procedure is linear throughout a given interval when the results, on average, are proportional to the true values of the samples. In the graph below, both test 1 (orange line) and test 2 (blue line) are linear and proportional through the example interval but give very different values. Each line can be depicted in the following equations:

- Test 1: Y = X
- Test 2: Y = 2X

This concept of proportionality is important for patient decision-making. That is, when a patient sample is measured, a change in a test result over time (eg, a 40-mg/dL change in glucose results over a two-hour period) must reflect the change in the patient's condition.