User Evaluation of Acceptability of a Reagent Lot Change Implementation Guide

EP26-Ed2-IG

Introduction

This implementation guide describes the minimum procedures necessary for a medical laboratory to verify that new reagent lots, when received and implemented by the laboratory, will produce results consistent with previous reagent lots. Reagent lot performance is validated by the developer before release and distribution; however, the laboratory needs to verify each new reagent lot it receives. Changes in performance with a new reagent lot could be due to:

- Changes in reagent component materials
- Instability of a component in a reagent
- Reagents that were compromised in transportation or storage
- Incorrect calibration of the new reagent lot

Verifying that these potential changes have not occurred is important to ensure the quality of laboratory results. For additional information on the acceptability of a reagent lot change, see CLSI document EP26.[1]

NOTE: For the purposes of this implementation guide, a "candidate" reagent lot is any reagent lot that will be used for the first time in a medical laboratory. The "current" reagent lot is the reagent lot that has been in routine use for patient sample testing, was previously verified as producing acceptable patient sample results, and will be replaced by the "candidate" lot. The terms "current" and "candidate" in this context refer only to the sequence in which the reagent lots are used in a medical laboratory.

IMPORTANT NOTE: The study outlined in this implementation guide is not intended for use by a test developer to establish or validate reagent lot variability for a new commercial or laboratory-developed test. Instead, test developers should use CLSI document EP05[2] for guidance on establishing or validating reagent lot variability. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.