Verification of Performance of a Qualitative, Binary Output Examination Implementation Guide

EP12-Ed3-IG

Introduction

This implementation guide describes the minimum procedures necessary for a medical laboratory to verify the performance of qualitative, binary output (yes or no, positive or negative, target condition present or absent) examinations. For additional information on verifying performance of qualitative examinations, see CLSI document EP12.[1]

NOTE: This verification process is intended to be used when the examination procedure produces qualitative, binary output results with no equivocal zone.

IMPORTANT NOTE: The study outlined in this implementation guide and described in Chapter 5 of CLSI document EP12[1] is not intended for use by a test developer to establish or validate performance of any examination method. Instead, test developers should consult CLSI document EP12[1] for guidance on establishing and validating qualitative, binary output examinations. Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

Why Is it Important to Verify Qualitative Examination Performance?

When a laboratory decides to offer any *in vitro* diagnostic examination, performance claims by the developer should be verified before patient results are reported. For qualitative examinations, the intended use and indications for use depend on meeting precision and clinical accuracy claims. Verification through testing within the laboratory confirms that the performance of the new examination is consistent with its established claims.

Additionally, the arrival of new reagent lots should trigger the need to verify the consistency of the new reagent lot compared with reagent lots currently in use before substitution can occur. This guidance is intended for products already cleared by regulatory agencies. If an examination procedure is modified in any way (including but not limited to the use of sample types not listed by the developer in the package insert), this new indication for use is subject to additional validation requirements as described in CLSI document EP12.[1]

Sample

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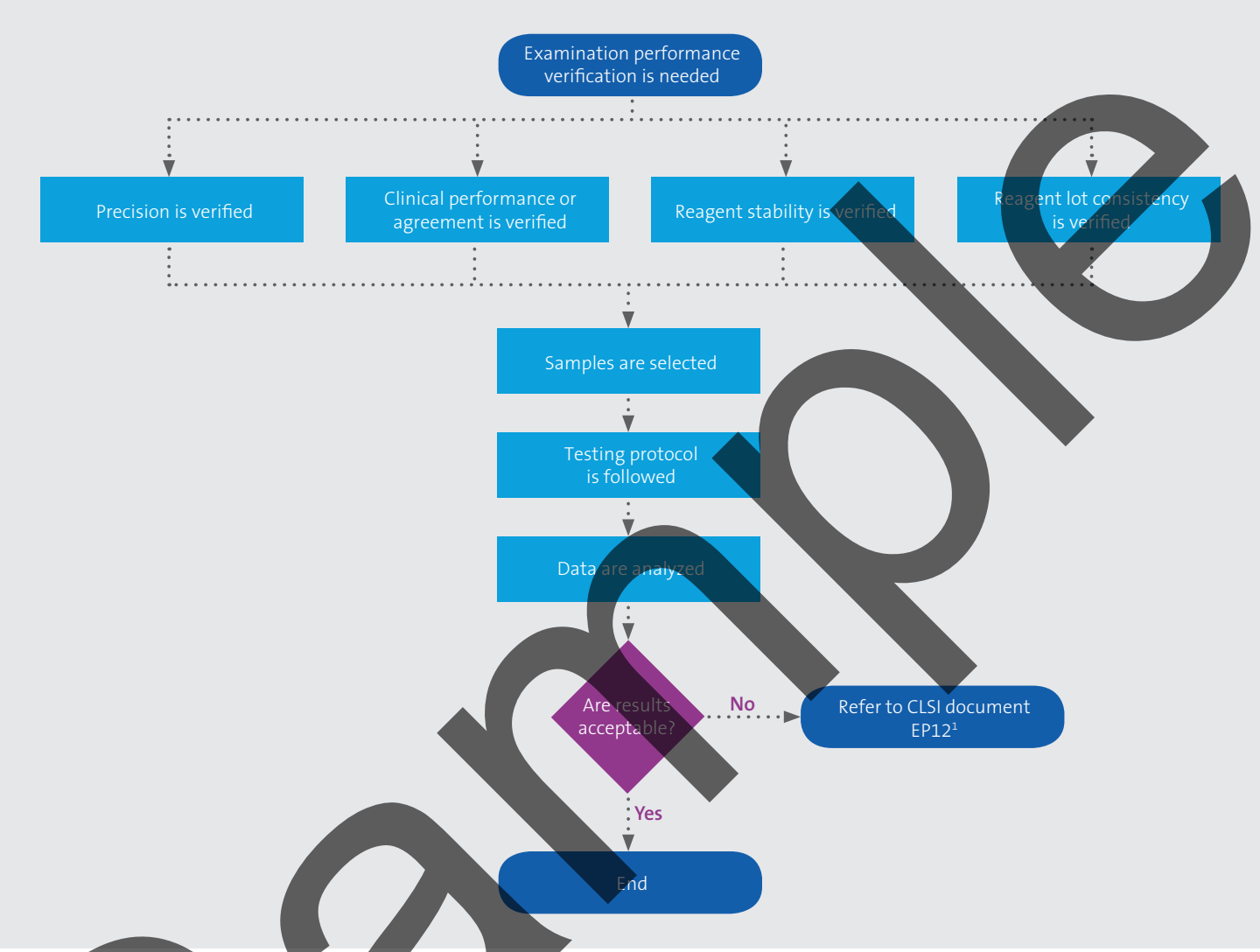
Verification of Performance

The performance verification process is outlined in the figure below.



Preparing for the Study

Before verification of a qualitative examination, it is necessary to review the factors that affect all phases of the examination process for which a verification study is being planned. The package insert should be reviewed to determine the performance characteristics claimed by the developer as well as to understand the examination's principle, methodology, limitations, and quality control (QC) recommendations. This review is essential to identify examination performance characteristics and to determine under what conditions the examination was validated and thus set up acceptance criteria. Once the review is completed, the verification protocol, working documents, controls, and verification samples can be prepared and the verification can begin.

Sample

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