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User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline

This document provides a protocol designed to optimize the experimental design for the evaluation of qualitative tests; to better measure performance; and to provide a structured data analysis.

A guideline for global application developed through the NCCLS consensus process.

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User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline

Abstract

NCCLS document EP12-A—*User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline* provides the user with a consistent approach for protocol design and data analysis when evaluating qualitative diagnostic tests. Guidance is provided for both reproducibility and method-comparison studies.

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User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline

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Contents

Contents (Continued)

Foreword

Qualitative diagnostic tests have been used since the early days of laboratory medicine for the screening, diagnosis, and management of a variety of diseases. These tests are found in many specialties of the clinical laboratory. Method evaluation procedures for such tests are diverse, with each laboratory specialty often emphasizing different issues in both the experimental design and in the data analysis and interpretation of such studies.

There have been two key published efforts to standardize both the experimental details as well as the data analysis of qualitative information.[1,2] The International Federation of Clinical Chemistry published a guideline in 1989 on protocol design and data analysis, featuring examples for urinary glucose and albumin by visually read reagent strips. [1] The European Committee for Clinical Laboratory Standards published a guideline in 1990 that focused on the evaluation of qualitative tests.[2] A very prominent work on the assessment of both quantitative and qualitative laboratory tests was written by Gambino and Galen in 1975, *Beyond Normality: The Predictive Value and Efficiency of Medical Diagnosis*. NCCLS document GP10— *Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots* describes the assessment of the accuracy of a test compared to the clinical status of the patient.

The latter two references both focus on the relation of the test result to the clinical status of the patient, for either qualitative or quantitative tests. In many laboratories, the clinical information is not readily available, so it is important that protocols for evaluations be established that enable comparison of a new test to other laboratory procedures, in much the same way that most method evaluation studies are performed for quantitative tests. Ideally, the comparison should be made to a "reference" procedure or "gold standard." However, comparison with a method in current use is also of interest. This guideline describes two different situations for these studies: the first is when the laboratory knows the diagnosis of each patient specimen in the study, and the second is when the laboratory does not know the clinical diagnosis of each patient specimen. These are treated separately, to enable appropriate data analysis. Parameters such as specificity, sensitivity, and predictive value for the test method are estimated in the former situation, and agreement measures are estimated in the latter situation.

This guideline is intended to promote uniformity in performance assessment of qualitative testing among

- laboratories of all types that perform qualitative tests;
- manufacturers of qualitative diagnostic kits, for design of the studies they use to demonstrate kit performance, as well as the way kit performance is described; and
- regulatory agencies and laboratory surveyors.

Key Words

Analytical goals, qualitative test, semiquantitative test

The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1- *A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

QSEs

Documents & Records	Information Management
Organization	Occurrence Management
Personnel	Assessment
Equipment	Process Improvement
Purchasing & Inventory	Service & Satisfaction
Process Control	Facilities & Safety

EP12-A Addresses the Following Quality System Essentials (QSEs)

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
					X						

Adapted from NCCLS document HS1— *A Quality System Model for Health Care*

User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline

1 Introduction

Qualitative diagnostic tests, which are found in many specialties of the clinical laboratory, have been used for the screening, diagnosis, and management of a variety of diseases. Method evaluation procedures for such tests are diverse, with each laboratory specialty often emphasizing different issues in the experimental design as well as the data analysis and interpretation of such studies.

A new qualitative test can be implemented in the clinical laboratory for a number of reasons. The new test might be easier to use, more economical, have enhanced performance, or otherwise better meet the user's needs. Before patient test results are reported with a new qualitative test, users must document the test performance in their clinical laboratories. Documentation of test performance is not limited to comparison with another method. Laboratory staff training and proficiency with the new qualitative test, preparation of proper specimen collection and handling, and documentation of a quality control system are necessary before implementation of any new test.

Although universal evaluation guidelines for all qualitative tests are not feasible or practical, several common features do exist. Before collecting performance evaluation data, proper familiarization, training, and a quality assurance plan should be completed. Any qualitative test must provide the user with consistent and correct results, and reproducibility studies and comparison of methods studies with patient specimens are used to demonstrate the test's performance capabilities.

This guideline is intended to promote uniformity in performance assessment of qualitative testing among laboratories of all types that perform qualitative tests; manufacturers of qualitative diagnostic kits, for design of the studies they use to demonstrate kit performance, as well as the way kit performance is described; and regulatory agencies and laboratory surveyors.

2 Scope

This guideline provides evaluation protocols for the demonstration of qualitative test performance. Here, a qualitative test is restricted to those tests that have only two possible outcomes. Future revisions may be expanded to include qualitative tests that have more than two outcomes. EP12 is written for clinical laboratory personnel who are the end users of such tests. Demonstration of test performance by the user can satisfy internal (as well as external) expectations that the test performs acceptably in meeting the user's clinical and analytical goals. This guideline for test performance may help the user meet documentation and regulatory needs, but it is not intended to meet all of the user's goals and requirements, because regulatory and documentation needs vary.

3 Clinical Utility

Qualitative tests may be used clinically for screening, diagnostic, confirmatory, or monitoring purposes. The test's sensitivity, specificity, predictive values, and efficiency, and the prevalence of the disease or condition in the population being tested, determine the clinical utility of the qualitative test just as for a quantitative test.

3.1 Screening Tests

Clinically, screening methods are used to test entire populations (or subsets of such populations) for the presence of the analyte or agent. Examples may be the detection of blood in feces or the use of the Venereal Disease Research Laboratory (VDRL) syphilis serology test. As a rule, these qualitative tests

