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Assessing the quality and reliability of the DEA drug identification process

S.E. Rodriguez-Cruz [a,*], R.S. Montreuil [b,1]

[a] DEA Southwest Laboratory, 2815 Scott Street, Vista, CA 92081, United States
[b] DEA Office of Forensic Sciences, 700 Army Navy Drive, Arlington, VA 22202, United States

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ABSTRACT

Seized drugs laboratory managers and analysts strive to produce results that are accurate and reliable by employing scientific techniques that are foundationally valid and appropriately applied. Laboratories can assess the quality and reliability of their processes by using historical performance data or by establishing quality assurance programs that include blind testing or sample re-analysis, among others. Here, an assessment of laboratory error rates within the DEA laboratory system is presented using historical proficiency test laboratory data generated during the years 2005–2016. Results indicate the DEA *drug identification process* is characterized by high sensitivity (99.90%) and specificity (99.12%), with very low type I (0.87%) and type II (0.092%) error rates. An overall positive likelihood ratio of 114 is calculated, providing an additional quantitative indicator of the laboratory process' performance. Using Bayes' theorem and population base rates estimated from historical data, a positive predictive value greater than 99.9% is obtained, further demonstrating the high *degree of certainty* associated with a positive drug finding.

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1. Introduction

The Drug Enforcement Administration (DEA) laboratory system processes thousands of suspected drug exhibits every year. These submissions are seized by federal, state, and local law enforcement officials through raids, undercover operations, traffic stops, smuggling interceptions, and border crossing arrests, among others. DEA laboratory personnel employ well-established practices for the handling, sampling, and analysis of such submissions, generating thousands of laboratory reports where conclusions and results of analyses are summarized and forwarded to the submitting investigative agency. Many of these laboratory reports are then used by government officials during court trials and sentencing hearings. It is therefore critical that the reports reflect accurate and scientifically supported results and conclusions, as incorrect decisions based on inaccurate reports could have significant legal consequences and place an individual's liberty at stake. Laboratory reports and any associated case documentation must also fulfill laboratory accreditation requirements and provide users in the judicial system, including attorneys, judges, and jurors, with information regarding the quality of laboratory processes and resulting drug identifications.

The DEA *drug identification process* can be separated into three phases (Fig. 1). Phase I includes evidence submission and chain-of-custody (COC) procedures such as barcoding, safety and security protocols, and the use of appropriate evidence storage facilities to avoid cross-contamination and ensure integrity of the evidence at all times. Phase II forms the core of the laboratory identification process, as it incorporates the *analytical scheme* – the combination of sampling protocols, chemical and instrumental tests, and observations performed by expert analysts in order to achieve an unambiguous and scientifically supported identification. Phase III of the DEA *drug identification process* includes preparation of the final laboratory reports by analysts, technical and administrative review of all reports by laboratory managers, and dissemination to customers. The review steps ensure that *analytical scheme* requirements have been met, that identification results are accurately reported, and that the analytical case file contains all the documentation required to support the analysis conclusions.

The *analytical scheme* employed throughout DEA laboratories is a well-established multitier analytical process that combines presumptive and confirmatory tests, using methods that are fit for the analysis of controlled and non-controlled substances. Each method uses well-established and scientifically based tests and techniques accepted in the chemistry and forensic fields. The knowledge, training, and expertise of DEA analysts are essential

* Corresponding author.
E-mail address: Sandra.E.Rodriguez-Cruz@usdoj.gov (S.E. Rodriguez-Cruz).
[1] Present address: DEA Southeast Laboratory, 2205 NW 132nd Place, Miami, FL 33182, United States.

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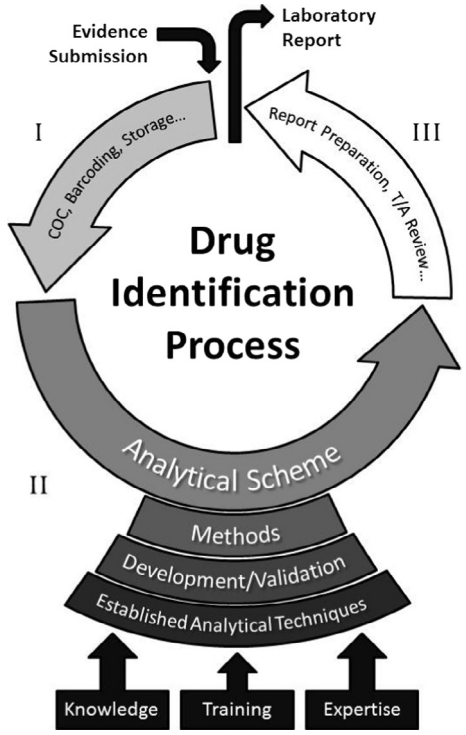

Fig. 1. General scheme illustrating the DEA drug identification process.

during the development of such test methods, as there are many recognized analytical techniques available for the analysis of seized drugs. Methods are developed to provide high selectivity and discrimination, and validated to fulfill international standards of accreditation, following protocols and principles analogous to those internationally recognized and recommended by the International Conference on Harmonization (ICH) [1], EURACHEM [2], and others.

DEA's *analytical scheme* requires analysts to test, at minimum, two different portions of an exhibit[2] (or of each selected unit within a multiunit exhibit); and to use at least two different and independent tests (one of them a category A – *confirmatory* – technique [3]) so that a high degree of selectivity, sensitivity, and specificity can be achieved. Analysts must also use negative and positive controls, corroborate the results of individual tests, and supplement all instrumental analyses with data obtained from traceable reference materials. Hence, the validity of the *analytical scheme* followed is further confirmed during analysis. These requirements fulfill minimum standards recommended by the Scientific Working Group for the Analysis of Seized Drugs (SWGDRUG) [3], recognized by ASTM International [4], and approved by the Organization of Scientific Area Committees (OSAC) [5]. DEA's *analytical scheme* is further supported by numerous quality assurance measures throughout the laboratory system. Routine instrument performance verification, standardization of methods, and the recurrent use of traceable reference materials ensure that analytical laboratory instrumentation is operated under reliable conditions, and that results are reproducible. Furthermore, a robust and well-established system-wide proficiency testing program offers routine assessment of the chemists' analytical and forensic skills, allowing evaluation of the effectiveness of the analysis scheme, and providing the platform for monitoring the performance of the laboratory system as a whole.

Even when best laboratory practices are in place and appropriate analytical schemes are followed, unforeseen errors may occur. Some of these errors may originate as a result of human behavior during any phase of the *drug identification process* (Phase I, II, or III) such as during evidence submission procedures, as a result of accidental sample swapping prior or during analysis, from mistakes during instrument operation, or during the report writing stages. Thus, the possibility of reporting a wrong conclusion or misidentification is always present. It is therefore important to assess the overall performance of a laboratory's identification process. Doing so provides a quantifiable metric of product quality to the stakeholders receiving the final reports; that is, a measure of the probative value of the scientific evidence that may be introduced in court proceedings. Moreover, understanding the quality of reported identifications and the origin and frequency of errors (false responses) would undeniably lead to the improvement of quality assurance measures throughout laboratories.

The subject of uncertainty (or error rates) in qualitative drug analysis has not received as much attention as that of uncertainty in quantitative analyses (measurement uncertainty). However, its importance has been highlighted by multiple authors during the last decades [6–10]. The discipline of seized drug analysis has not been under the same scrutiny as other forensic science areas due to its strong chemistry foundation and the use of well-known techniques with long-established validity. However, it is indisputable that errors can occur, and analysts should be aware of the nature and frequency of such errors and understand the limitations of laboratory procedures as well as the conditions that may lead to producing false positive and false negative outcomes.

Bayes' theorem has been extensively used for estimating probabilities when evaluating scenarios that are dichotomous in nature (e.g., yes/no, presence/absence, success/failure, etc.). In 1998, Ellison and co-workers demonstrated application of Bayes' theorem as a suitable framework for expressing uncertainty in classification scenarios [11]. More recently, Koehler suggested the use of proficiency tests to obtain "*reasonable first pass estimates for the rates at which various types of errors occur*", while addressing issues to consider when designing proficiency tests [12]. In this paper, the quality and reliability of the overall DEA *drug identification process* is assessed via the evaluation of historical DEA laboratory system-wide proficiency testing (PT) data. PT samples are processed by DEA laboratories and analysts using the same routine protocols and procedures as those used for all other evidence submissions. Each PT sample is received, documented, barcoded, stored, analyzed, and a final report of analysis is generated. That report is then submitted to the originating source for evaluation. Therefore, PT results provide a useful source of data and a reasonable approach for a baseline assessment or estimate of the accuracy of the overall *drug identification process*. Here, a summary and evaluation of over ten years of PT results are presented and used to estimate the error rates associated with DEA laboratory results. An estimated likelihood ratio, which can be used by triers of fact to assess the evidentiary value of the laboratory findings, is also discussed. Using Bayes' theorem, the likelihood ratio can be combined with prior probabilities estimated from historical data to obtain posterior probabilities known as positive predictive values (PPV) for correct and incorrect drug identifications, given a reported positive finding. As previously suggested by Ellison and collaborators [11], this PPV can be characterized as the *identification certainty*; and its complement can then be used to express the *uncertainty* associated with positive laboratory findings.

2. Material and methods

Qualitative analysis results used in this study were compiled from the DEA laboratory system PT program data archives maintained by the DEA Office of Forensic Sciences. Results evaluated

[2] Physical evidence submitted to the laboratory, which may consist of single or multiple items.