PART III E

METHODS OF ANALYSIS/ STOP TESTING PROCEDURES and NEGATIVE/INDICATIVE RESULTS

The purpose of PART III E is to provide an analysis and reporting framework for laboratories when relevant analytes are not conclusively identified. A reported negative or indicative result depends on the use of an appropriate analytical scheme by competent analysts in a quality-controlled process.

IIIE.1 Introduction

IIIE.1.1 The decision to stop analysis and report negative or indicative findings is contingent upon the question being asked, which establishes the relevant analytes and may require different types of testing.

IIIE.1.2 Results from seized drug analysis can be used for a variety of reasons, such as:

IIIE.1.2.1 Criminal charges (e.g., possession of statutorily listed compounds, drug distribution resulting in death)

IIIE.1.2.2 Pharmacological relevance (e.g., death investigation, sexual assault investigation, non-controlled drug of abuse, epidemiological interest)

IIIE.1.2.3 Determination of all ingredients of a formulation (e.g., tablet binders, diluents, colorants).

IIIE.1.2.4 Suspected tampering of pharmaceutical preparations (e.g., dilution of an injectable commercial solution).

IIIE.1.3 The laboratory shall ensure testing is sufficient and employs an analytical scheme that is fit for purpose to answer the question being asked.

IIIE.1.4 Negative results convey the lack of a conclusive identification of a drug of interest and indicative results convey the possible presence of a compound which has not been conclusively identified by the laboratory.

IIIE.2 Stop-Testing Procedures

IIIE.2.1 The laboratory shall establish procedures to address when testing has not produced results sufficient to identify analyte(s) of interest.

IIIE.2.2 The laboratory shall establish criteria for when to cease analysis and report negative or indicative results.

IIIE.2.2.1 Negative and indicative findings shall be defined by the laboratory.

IIIE.2.3 The procedure should account for the sample type and matrix, analytical capability of the laboratory, available reference materials for conclusive identification, and the question being asked.

IIIE.3 Additional Testing When Stop Testing Criteria Are Not Met

IIIE.3.1 When analysis neither provides a conclusion nor satisfies stop-testing criteria, the analyst shall perform further testing. The additional testing shall be based on and address the specific case circumstances and the limitations of the previous testing conducted.

IIIE.3.2 Testing examples

IIIE.3.2.1 Increase the concentration of the sample analyzed (e.g., using more sample for analysis, decreasing extraction volume).

IIIE.3.2.2 Adjust instrumental parameters to increase sensitivity or utilize more sensitive techniques.

IIIE.3.2.3 Resample to address possible heterogeneity of the sample.

IIIE.3.2.4 Utilize instrument methods that detect the full range of relevant compounds for general screening (e.g., early/late-eluting compounds, positive and negative mode soft/ambient ionization).

IIIE.3.2.5 Utilize additional techniques to address different chemical principles or sample stability issues. For example, analysis for labile compounds should include techniques such as:

IIIE.3.2.5.1 non-thermal instrumental methods

IIIE.3.2.5.2 protecting group chemistry by derivatization

IIIE.3.2.5.3 soft/ambient ionization

IIIE.3.2.6 Utilize additional sample preparation techniques to facilitate analysis of different chemical affinities or address potential masking/interfering compounds in the sample, such as:

IIIE.3.2.6.1 acid/base chemistry to remove diluents or additives

IIIE.3.2.6.2 specific extraction to remove drug of interest from interfering matrix

IIIE.3.2.7 Utilize targeted analysis for specific compounds to ensure the question being asked has been addressed. Examples include:

IIIE.3.2.7.1 extraction for diphenhydramine in baby formula with a validated limit of detection.

IIIE.3.2.7.2 incorporating a Selected Ion Monitoring (SIM) method for low level opioid screening.

IIIE.4 Reports and Conclusions[1]

IIIE.4.1 The language used for negative and indicative statements shall be clear and understandable, and address the limitations of analysis.

IIIE.4.2 The report shall not imply the absolute lack of a substance if not supported by the testing (e.g., no controlled substances present). Examples of appropriate reporting statements include:

IIIE.4.2.1 No controlled substances identified.

IIIE.4.2.2 No controlled or related substances detected.

IIIE.4.2.3 No drugs of interest found.

IIIE.4.2.4 No substances identified.

IIIE.4.3 If a targeted analysis is applied to answer a specific question and results in a negative conclusion, the report shall reflect the scope of the testing performed.

IIIE.4.3.1 Example: No diphenhydramine identified at a level of 1 ppm or higher.

IIIE.4.3.2 Example: Ephedrine/pseudoephedrine identified. No methamphetamine identified at a level of 5 ppm or higher.

[1] Reporting requirements and styles differ among agencies. The examples listed are drawn from laboratories with varied requirements.

IIIE.4.4 If testing is stopped prior to conclusive identification and a compound is still reported, the reason for the indicative result should be reported and the reporting language must clearly state that the results have not been confirmed.

IIIE.4.4.1 Example: Caffeine indicated. Analytical data showed the possible presence of this substance, but further analysis was not performed to support conclusive identification because the substance is not controlled.

IIIE.4.4.2 Example: Human growth hormone indicated. Indication based on pharmaceutical label/identifier only. Confirmation is not possible by the laboratory due to the analytical scope of the laboratory.

IIIE.4.4.3 Example: Protonitazepyne indicated but not conclusively identified. Confirmation is not possible due to a lack of available reference material as required by this laboratory's policy.

IIIE.4.4.4 Example: Cocaine identified. Testing also indicates the possible presence of methamphetamine, not confirmed due to identification of cocaine.

