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Standard Specification for Field Screening Devices Used for Identification of Biological Agents[1]

This standard is issued under the fixed designation E3394; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

Prompt and accurate identification of harmful biological agents on-scene is crucial to the public health mission. Inaccurate results can place public health and safety at risk and disrupt essential public services. In addition to utilizing instruments for screening for potential radiological, explosive, and chemical hazards, first responders also rely on field screening devices (FSDs) to obtain on-scene presumptive results of potential biological hazards, which can be later verified at a Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) facility. This specification covers such FSDs. Information regarding verification at an LRN is available at www.cdc.gov.

This specification describes a statistical testing approach for quantifying device performance and defines sample composition and amounts. It does not provide protocols for sample preparation or the testing of different types of devices, or reporting of results. These are described in the Test Method E3395, a companion to this specification. Only issues related to the statistical impact of replication are evaluated in this specification. Other issues, such as concerns over the biological, chemical, or other experimental variability and their impact on detection are not considered.

1. Scope

1.1 This specification provides system designers, manufacturers, integrators, procurement personnel, end users, practitioners, and other responsible authorities with a common set of criteria to match field screening device capabilities with user requirements for specific applications.

1.2 This specification describes the required test sample compositions and amounts, and provides a statistically-based testing approach for evaluating FSD performance for the detection of biological agents as described in Test Method E3395. This specification does not address the estimation of limit of detection.

1.3 *Units:*

1.3.1 Values stated in SI units are to be regarded as standard in this specification.

1.3.2 When creating test sample mixtures, all concentrations are stated as copies/mL or genome equivalents/mL (GE/mL).

1.4 *Operational Concepts:*

1.4.1 FSDs used for identifying potentially dangerous biological agents play an important role in the decision-making processes intended to protect responders and the general public. Suitable FSDs require low rates of false positives and false negatives. FSDs are used for surveillance and sample screening, and they are a particularly important tool in responding to incidents where a sample suspected of containing a biological agent is found. FSDs must be rugged enough to withstand storage and operating conditions that include, but are not limited to, temperature and humidity extremes, shock and vibration, radio frequency interference, and rapid thermal and humidity changes. This specification does not address testing to characterize operating limits or storage conditions.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use. Manufacturers, purchasers, and end-users will need to determine safety requirements including, but not limited to, use by hazardous material (HAZMAT) teams; use with personal protective equipment (PPE); use by firefighters, law enforcement officers, or the Federal Emergency Management Agency (FEMA) Urban Search & Rescue (US&R) teams, special*

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electromagnetic compatibility needs, extended usage periods, and extended mission time.

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E2458 Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biological Agents and Toxins from Nonporous Surfaces

E2771 Terminology for Homeland Security Applications

E3131 Specification for Nucleic Acid-Based Systems for Bacterial Pathogen Screening of Suspicious Visible Powders

E3289 Guide for Using Equipment and Assays for Field Detection of Fentanyl and Fentanyl-Related Compounds

E3290 Test Method for Establishing Performance of Equipment and Assays for Field Detection of Fentanyl and Fentanyl-Related Compounds

E3395 Test Method for Characterizing Performance of Field Screening Devices for the Identification of Biological Agents

2.2 *AOAC Standards:*[3]

AOAC SMPR 2010.001 Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of *Francisella tularensis*in Aerosol Collection Filters and/or Liquids

AOAC SMPR 2010.002 Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of *Yersinia pestis*in Aerosol Collection Filters and/or Liquids

AOAC SMPR 2010.003 Standard Method Performance Requirements for DNA-Based Methods of Detecting *Bacillus anthracis* in Field-Deployable, Department of Defense Aerosol Collection Devices

AOAC SMPR 2016.006 Standard Method Performance Requirements for DNA-Based Methods of Detecting *Bacillus anthracis* in Field-Deployable, Department of Defense Aerosol Collection Devices

AOAC SMPR 2016.007 Standard Method Performance Requirements for Detection of *Francisella tularensis* in Aerosol Collection Devices

AOAC SMPR 2016.008 Standard Method Performance Requirements for DNA-Based Methods of Detecting *Yersinia pestis* in Field-Deployable, Department of Defense Aerosol Collection Devices

AOAC SMPR 2016.010 Standard Method Performance Requirements for DNA-Based Methods of Detecting *Burkholderia pseudomallei* in Field-Deployable, Department of Defense Aerosol Collection Devices

AOAC SMPR 2016.012 Standard Method Performance Requirements for Detection and Identification of *Variola* Virus

2.3 *Other References:*

18 US Code 178 Definitions[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *accuracy, n*—closeness of agreement between a test result and the accepted reference value. **E2771**

3.1.2 *assay, n*—quantitative or qualitative test used to determine the presence or absence of a chemical or biological material. **E3131**

3.1.2.1 *Discussion*—Amended the definition from Specification E3131 to include chemical as well as biological material.

3.1.3 *biological agent, n*—any microorganism (including, but not limited to bacteria, viruses, fungi, rickettsia, or protozoa); infectious substance; or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance capable of causing: *(1)* death, disease, or other biological malfunction in a human, an animal, a plant, or other living organism; *(2)* deterioration of food, water, equipment, supplies, or material of any kind; or *(3)*, deleterious alteration of the environment. **18 USC 178**

3.1.3.1 *Discussion*—Also termed biothreat agent.

3.1.4 *biovar, n*—a group of microorganisms, usually bacteria, distinguishable from other strains of the same species based on physiological or biochemical characteristics.

3.1.5 *calibration, n*—set of operations that establish, under specified conditions, the relationship between the values of quantities indicated by a measurement instrument or measuring system, or values represented by a material measure, or a reference material, and the corresponding values realized by standards (**1**).[5]

3.1.6 *confidence interval, CI, n*—range of values created using a procedure that, when repeated many times, on distinct data sets, generated from the same underlying stochastic process, will bracket the true measure of performance, such as probability of detection (POD), the proportion of times stated in the confidence level. **E3131**

3.1.6.1 *Discussion*—This definition differs slightly from that in Specification E3131 by explicitly linking the interval to the confidence level.

3.1.7 *confidence level, CL, n*—probability value associated with a CI; the percentage of intervals that can be expected to include the true population parameter in the long run. **E3131**

3.1.8 *environmental panel, n*—collection of materials and compounds that can be found in the environment (indoor or outdoor).

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from AOAC International, 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250, http://www.aoac.org.

[4] Available from U.S. Government Publishing Office (GPO), 732 N. Capitol St., NW, Washington, DC 20401, http://www.gpo.gov.

[5] The boldface numbers in parentheses refer to a list of references at the end of this standard.