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Standard Specification for Field Screening Devices Used for Identification of Biological Agents¹

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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* 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* 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](#)

[holderia 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.

3.1.8.1 *Discussion*—The environmental panel is determined by the entity directing testing and will include samples representative of aerosol backgrounds in the locations of interest. This specification does not include discussion of aerosol filter sample collection, sample preparation conditions, or methods that may be necessary to extract collected material into a suitable liquid for analysis using nucleic acid-based methods. The environmental panel is used as a more “real-world” test of a detection system’s performance when it is spiked with a whole biological agent. The environmental panel should not result in false positive or false negative results and should not cause failure of control samples.

3.1.9 *exclusivity panel, n*—collection of near-neighbor biological agents, viruses, or nucleic acids used during testing. **E3131**

3.1.9.1 *Discussion*—Results from tests involving members of the exclusivity panel, if carried out, are subject to the same statistical analysis and performance requirements described in this specification as samples containing biological agents of interest.

3.1.10 *false negative, n*—failure to detect a compound within a sample when it is present at a concentration well above the limit of detection. **E3289**

3.1.10.1 *Discussion*—This definition differs slightly from the one in Guide **E3289** by emphasizing concentrations above the limit of detection.

3.1.11 *false positive, n*—detection of a compound within a sample when it is not present. **E3289**

3.1.12 *field screening, n*—analysis conducted at a location, other than in a laboratory, to provide preliminary results for the presence a biological threat agent within a sample at the species level.

3.1.12.1 *Discussion*—The result from this analysis is referred to as a field screen result.

3.1.13 *field screening device, n*—a portable analytical platform to be used by field or facility personnel for onsite analysis.

3.1.14 *field screen result, n*—the initial discovery produced from field screening.

3.1.15 *genome, n*—the complete set of genetic material of a human, animal, plant, or other living thing.⁶

3.1.16 *genome equivalents, GE, n*—number of genome copies present in a given mass of nucleic acid (deoxyribonucleic acid (DNA) or ribonucleic acid (RNA)) that can be calculated by converting the size of a genome in base pairs to micrograms of DNA or RNA.

3.1.17 *inclusivity panel, n*—collection of closely related biological agents, viruses or nucleic acids used during testing. **E3131**

3.1.17.1 *Discussion*—Tests involving members of the inclusivity panel, if carried out, are subject to the statistical analysis and performance requirements described in this specification.

3.1.18 *limit of detection, LOD, n*—lowest amount of analyte in a sample that can be detected with stated probability. **E3131**

3.1.19 *lower confidence bound, LCB, n*—lowest value of a one-sided CI created using a procedure that, when repeated many times on distinct data sets generated from the same underlying stochastic process, will include the true measure of performance a proportion of times equal to the stated probability. **E3131**

3.1.19.1 *Discussion*—The LCB ensures that the POD attains a satisfactory value for the CL selected and determines the minimum number of samples that shall be analyzed. Slight modification from Specification **E3131**.

3.1.20 *measurement process, n*—step, or series of systematic steps, used to detect a material or determine if a system or instrument performs as intended. **E3289**

3.1.21 *multiplex assay, n*—assay that is capable of measuring multiple biological agents or multiple targets for a single agent in a single test sample. **E3131**

3.1.21.1 *Discussion*—This definition differs slightly from the one in Specification **E3131** by including multiple targets.

3.1.22 *near neighbor, n*—organism, virus, or nucleic acid that is similar to a desired target biological agent but should not result in a positive detection result. **E3131**

3.1.22.1 *Discussion*—Exclusivity panel members include near neighbors.

3.1.22.2 *Discussion*—Results from tests involving near neighbors, if carried out, are subject to the same statistical analysis and performance requirements described in this specification as samples containing biological agents of interest.

3.1.23 *operator, n*—person operating an on-site field screening device. **E3131**

3.1.24 *panel, n*—collection of samples used during testing.

3.1.24.1 *Discussion*—Examples of panels include inclusivity panel, exclusivity panel, and environmental panel.

3.1.25 *probability of detection, POD, n*—proportion of positive analytical outcomes in a stated number of tests for a qualitative method for a given matrix at a given concentration.

3.1.26 *risk, n*—the probability of suffering a loss or harm or injury; peril. **E2458**

3.1.27 *sensitivity, n*—ability of a measurement procedure to correctly yield a positive result or detection for a compound of interest when it is present in a test sample.

3.1.28 *serovar, n*—a group of closely related microorganisms differentiated by their surface antigens.

3.1.29 *stochastic process, n*—term used to describe observations governed by a random mechanism which cannot be precisely predicted.

3.1.30 *strain, n*—isolates or variants of the target biological agent(s) that the method can detect (inclusivity strains) or should not detect (exclusivity strains). **E3131**

3.1.31 *test sample, n*—amount and identity of a particular substance (target and non-target compounds) prepared for testing. **E3290**

3.1.32 *true negative, n*—correctly reporting the absence of a compound within a sample when it is not present.

3.1.33 *true positive, n*—correctly detecting a compound within a sample when it is present.

⁶ From <https://dictionary.cambridge.org/us/dictionary/english/genome>.

3.2 Acronyms:

- 3.2.1 *BIT*—built-in test
- 3.2.2 *CDC*—Centers for Disease Control and Prevention
- 3.2.3 *CI*—confidence interval
- 3.2.4 *CL*—confidence level
- 3.2.5 *FEMA*—Federal Emergency Management Agency
- 3.2.6 *FSD*—field screening device
- 3.2.7 *GE*—genome equivalents
- 3.2.8 *GPS*—global positioning system
- 3.2.9 *IP*—ingress protection code, part of an alphanumeric code denoting the protection rating of an electrical or mechanical enclosure
- 3.2.10 *LCB*—lower confidence bound
- 3.2.11 *LRN*—Laboratory Response Network
- 3.2.12 *PCR*—polymerase chain reaction
- 3.2.13 *POD*—probability of detection
- 3.2.14 *PPE*—personal protective equipment
- 3.2.15 *RG*—risk group
- 3.2.16 *RH*—relative humidity
- 3.2.17 *UI*—user interface
- 3.2.18 *US&R*—urban search and rescue
- 3.2.19 *VNTR*—variable number tandem repeat
- 3.2.20 *WHO*—World Health Organization

4. Biological Agent Identification

4.1 Biological identification capabilities of FSDs shall be tested against the agents in the inclusivity, exclusivity, and environmental panels presented in [Annex A1](#). For an FSD to pass, identification performance, measured as the estimated LCB on the POD, shall meet or exceed the 0.85/80 % LCB/CL requirements as presented in Section [12](#).

5. Performance Requirements

5.1 General:

5.1.1 FSDs shall be capable of operating independently from any peripheral device, remote station, or external software, and shall be unaffected by any malfunction of a peripheral device.

5.1.2 FSDs shall be able to draw power from fixed electrical infrastructure or from batteries. FSDs that are capable of drawing power from either fixed electrical infrastructure or from batteries are also acceptable.

5.1.3 FSDs should be hand- or person-portable (see Section [7](#)) so that a single individual can handle the task of analyzing and interpreting results from testing.

5.1.4 FSD should be operable while in motion.

5.1.5 FSD identification methods should be automated, have multiplexed assay capability, and allow for integrated sample preparation and collection.

5.2 User Interface:

5.2.1 Input commands, status indicators, and results shall be presented in a manner interpretable by operators with a minimal level of training. Identification results shall be pre-

sented with a binary response by biological agent (for example, “[Agent] Identified” or “No biological agents identified”). Identified biological agents shall be reported by species.

5.2.2 Results shall not be presented in basic mode as numerical, spectral, colorimetric lines, or other means that require interpretation or analysis. Data that requires a higher skill level to interpret shall be accessible, separately from the basic operator UI.

5.2.3 The user interface shall provide state-of-health alerts (such as calibration needed, and possibly others), and the battery charge level. Separate indications shall be provided when the FSD is ready to process a sample and when a sample is being processed. The FSD should provide optional instructions that guide users to load samples.

5.3 Access Modes:

5.3.1 FSDs shall have at least two different access modes as follows:

5.3.1.1 *Basic Mode*—In basic mode, the FSD shall perform all instrument functions aside from those that affect alarm notifications, measurement sensitivity or thresholds, or identification results.

5.3.1.2 *Advanced Mode*—In advanced mode, a device administrator may control parameters that can affect the result of a measurement (for example, routine function control, calibration parameters, alarm thresholds). Access to advanced mode shall be protected via password or biometric authentication.

5.4 Warm-up Time:

5.4.1 From a cold start, the FSD shall be available to process samples within 10 min.

5.4.2 Upon startup, the FSD performs self-diagnosis or built-in test (BIT), if such test is available. A BIT may be comprised of internal negative or positive controls that indicate instrument readiness for sample processing.

5.5 Maximum Time-to-Result:

5.5.1 The time-to-result is the time after the sample has been collected and when the identification result is reported. The time-to-result shall not exceed 60 min. The time-to-result includes sample preparation or processing time needed after sample collection but prior to introduction to the instrument, if any.

5.6 Battery Power:

5.6.1 FSDs should have ability to run on battery power for field applications. On battery power, FSDs should be able to perform at least 3 assays or perform analyses of samples for 5 h, whichever is longer, per full battery charge.

5.7 Data Handling, Management, and Storage:

5.7.1 Specialized software shall not be necessary to store, transfer, access, view, or interpret identification data. Users shall have the ability to enter sample identifier information. However, entry of this information should not be required to accommodate use cases where this action becomes operationally impractical or difficult. Data shall be exportable in .csv or tab-delimited format to allow for short- or long-term archiving and retrieval. Exportable data shall, at a minimum, include the identification results and the time and date of measurement. Geospatial data should be recorded when instrument location