AOAC SMPR® 2015.013

Standard Method Performance Requirements (SMPRs®) for Detection of Staphylococcal Enterotoxin B (SEB)

Intended Use: Laboratory or Field Use by Department of Defense Trained Operators

1 Applicability

Detection of SEB in liquid samples. The preferential method would be a field-deployable assay.

2 Analytical Technique

Any analytical method that can detect the protein and meets the requirements of this SMPR.

3 Definitions

Acceptable minimum detection level (AMDL).—Predetermined minimum level of an analyte, as specified by an expert committee which must be detected by the candidate method at a specified probability of detection (POD).

Maximum time-to-result.—Maximum time to complete an analysis starting with recovery of toxins from the collection matrix and ending with the assay result.

Probability of detection (POD).—Proportion of positive analytical outcomes for a qualitative method for a given matrix at a specified analyte level or concentration with a ≥0.95 confidence interval.

Selectivity study.—A study designed to demonstrate a candidate method's ability to detect SEB and, at the same time, demonstrate that a candidate method does not detect nontarget compounds and nontarget related toxins.

Staphylococcus enterotoxin.—A pyrogenic protein implicated in toxic shock and respiratory disorders and superantigenic response due to inhalation. Staphylococcal enterotoxin A (SEA), staphylococcal enterotoxin B (SEB), and staphylococcal enterotoxin C (SEC) are a part of a set of exotoxins produced by *S. aureus,* which comprises about 23 serologically distinct proteins that include SEA, SEB, SEC1, SEC2, SEC3, SED, SEE, SEH, SEG, SEI, SEJ, SEK, and SEU.

System false-negative rate.—Proportion of test results that are negative contained within a population of known positives.

System false-positive rate.—Proportion of test results that are positive contained within a population of known negatives.

4 Method Performance Requirements

See Table 1.

Table 1. Method performance requirements

Parameter	Minimum performance requirement
AMDL	0.25 ng/mL recovered SEB in liquid
POD	≥0.95 at AMDL for SEB
Selectivity study	SEB at the AMDL
	All nontarget compounds (Table 3 and OMA Appendix O, Part 1) must test negative at 10x the AMDL[a]
System false-negative rate using spiked aerosol environmental matrix at the AMDL	≤5% (OMA Appendix O, Part 2)
System false-positive rate using aerosol environmental matrix	≤5% (OMA Appendix O, Part 2)

[a] 100% correct analyses are expected. All discrepancies are to be retested following the *AOAC Guidelines for Validation of Biological Threat Agent Methods and/or Procedures* [*Official Methods of Analysis of AOAC INTERNATIONAL* (2019) 21st Ed., AOAC INTERNATIONAL, Rockville, MD, USA, Appendix I, http://www.eoma.aoac.org/app_i.pdf].

5 System Suitability Tests and/or Analytical Quality Control

Controls listed in Table 2 shall be made available in assays as appropriate. Manufacturer or method developer must provide written justification if controls are not available in the assay.

6 Validation Guidance

AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Biological Threat Agent Methods and/or Procedures [*Official Methods of Analysis of AOAC INTERNATIONAL* (2019) 21st Ed., Appendix I].

Use pristine collection buffer solution. Sample containers with target and nontarget compounds must be: (*1*) blind coded, (*2*) randomized, (*3*) evaluated at the same time, and (*4*) masked, so that the sample identity remains unknown to the analysts. Batches are permissible.

7 Maximum Time-to-Results

Within 2 h.

Environmental Panel Organisms

See Environmental Factors for Validating Biological Threat Agent Detection Assays [*Official Methods of Analysis of AOAC INTERNATIONAL* (2019) 21st Ed., Appendix O].

Approved by the AOAC Stakeholder Panel on Agent Detection Assays (SPADA). Final Version Date: September 2, 2015. Revised: October 2018 to replace sections on Environmental Panel Organisms with reference to OMA Appendix O: Environmental Factors for Validating Biological Threat Agent Detection Assays

Table 2. Controls

Control	Description	Implementation
Positive	Designed to demonstrate an appropriate test response. The positive control should be included at a low but easily detectable concentration, and should monitor the performance of the entire assay. The purpose of using a low concentration of positive control is to demonstrate that the assay sensitivity is performing at a previously determined level of sensitivity.	Single use per sample (or sample set) run
Negative	Designed to demonstrate that the assay itself does not produce detection in the absence of the target. The purpose of this control is to rule out causes of false positives, such as contamination in the assay or test.	Single use per sample (or sample set) run

Table 3. Nontarget toxins

SED
SEE
SEH
SEI
SEJ
SEK
SEA
SEC 1, SEC 2, SEC 3