

American  
National  
Standard



ANSI/AAMI  
ST72:2019

Bacterial endotoxins—  
Test methods, routine  
monitoring, and  
alternatives to batch testing

## ***Erratum***

American National Standard  
*Bacterial endotoxin -Test methods, routine monitoring and alternatives to batch testing*

***TECHNICAL CORRIGENDUM 1***

(ANSI/AAMI/ISO ST72:2019)

*Erratum* issued: 16 April 2020

***Page 7, Equation 2 and Equation 3***

On each equation replace the denominator, "1", with a lambda, "λ".

# Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing

Approved 11 July 2019 by  
**AAMI**

Approved 19 November 2019 by  
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**Abstract:** Specifies general criteria to be applied in the determination of bacterial endotoxins on or in medical devices, components, or raw materials employing bacterial endotoxins test (BET) methods using amebocyte lysate reagents from *Limulus polyphemus* or *Tachypleus tridentatus*. The document is not applicable to the evaluation of pyrogens other than bacterial endotoxins.

**Keywords:** Limulus amebocyte lysate, LAL, pyrogenic labeling, maximum valid dilution, MVD, RSE:CSE standardization, analyst qualification, product qualification, gel-clot technique, chromogenic technique, turbidimetric technique, medical device, batch testing, laboratory quality system, product family, set, sample frequency, kinetic assay