

October 13, 2025

Version 1.1

LABWARE LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)

BIOBURDEN STANDARD STATEMENT

This memo is to serve as an explanation of the Bioburden specification analysis reporting changes with the implementation of BioSpectra's LabWare Laboratory Information Management System (LIMS). The term "Bioburden" is typically used for medical devices. According to the US Pharmacopeia USP <61>, the terminology for Bioburden is TAMC and TYMC. With the recently implemented LIMS program, the analysis name and specification will be updated to align with USP <61> terminology and will be reported as follows:

Microbial Content	TAMC
	TYMC

1. According to the US Pharmacopeia (USP) <61> states in the Interpretation of the Results section: "The total aerobic microbial count (TAMC) is considered to be equal to the number of cfu found using *Soybean-Casein Digest Agar*; if colonies of fungi are detected on this medium, they are counted as part of TAMC.... If the count is carried out by the MPN Method (Most-Probably-Number method) in USP <61>, the calculated value is TAMC."ⁱ The two analysis of TAMC and TYMC will be separated out to report results for that specific parameter.

For more information, please contact customer.service@biospectra.us

Sincerely,



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ⁱ 11/21/2016 34(6) Sixth Interim Revision Announcement: 61<61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS.