

Change Notification

To: Whom It May Concern
From: Karvi Vera
Date: 07/01/2022
Re: PeproGMP® Cytokines Mycoplasma Test Method

This change notification is to inform all PeperoTech clients that a change has been made to one or more Certificates of Analysis (CoA) or Data Sheets. Please make a note of this change for all future purchases.

Previously, the Certificate of Analysis (CoA) stated the following as the Mycoplasma Test Method:

“Quantitative Fluorescence PCR- 28 day”

Beginning September 1, 2022, newly issued Certificates of Analysis (CoAs) will be updated to state the following as the Mycoplasma Test Method:

“According to United States Pharmacopeia (USP) <63> and the European Pharmacopeia (EP) General Chapter 2.6.7”

This change was made for the purpose of testing compliance with USP <63> and the EP chapter 2.6.7. The change is being made because there is no general approval for PCR-based mycoplasma testing by regulation agencies. This change has no product impact and applies to all future lots.

Please feel free to contact our Quality Assurance Department should you have any questions or concerns.

Sincerely,

QUALITY ASSURANCE DEPARTMENT

Tel: (609) 497-0253, prompt number 4

Email: QualityAssurance@PeperoTech.com



Quality Assurance Representative