

August 31, 2021

**RE: USP Particle Count Set Reference Standard, Catalog #1500502**

The purpose of this letter is to notify you that USP will be releasing a new lot of the USP Particle Count Set Reference Standard (RS).

After the recent release of Current Lot R138F0, it was brought to our attention that the labeled values may not be representative of all instruments currently being used in the market for particle count testing. The labeled values of this RS are determined through statistical analysis of results from multiple instruments obtained from several laboratories during a collaborative study. Based on customer feedback, USP conducted further collaborative testing of Lot R138F0 on additional instruments. The statistical analysis of all collaborative laboratories has resulted in an update to the labeled values. Lot R138F0 will be re-labeled as Lot R138F1 to reflect this update. This lot is projected to be released by the end of September.

It is important to note that Current Lot R138F0 remains suitable for use and the labeled values of this lot are correct based on the original collaborative testing results. However, users may not meet the acceptance value if using an instrument that was not adequately represented in the original study.

For technical questions or further guidance, please contact Reference Standard Technical Services at [rstech@usp.org](mailto:rstech@usp.org).

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