## **Dear Valued Customer,**

Charles River strives to provide the highest level of support to our global customers by delivering industry-leading scientific and technological advances. As part of our ongoing effort to better serve our customers, we want to inform you of upcoming changes to our Celsis<sup>®</sup> products. These changes do not alter the specifications or performance of any of our products.

## **Description of Change:**

Our Celsis<sup>®</sup> Wash and Rinse Kit (Product Code: 1290142N), containing Washing Solution (Product Code: 1290037N) and Rinsing Solution (Product Code: 1290036) use 31 mL glass vials. These glass vials are closed with a liquid stopper and a colored cap. We are replacing the glass vials with polypropylene vials in our Celsis<sup>®</sup> Wash and Rinse Kit starting in December 2018. The liquid stoppers and colored caps are not changed. In addition, starting in February 2019, we will be updating our Washing Solution (1290037N) and Rinsing Solution (1290036) bottle labels to reflect the fill volume of 25 mL.

## **Reason for Change:**

The use of polypropylene vials will reduce the risk of bottles cracking during shipment and routine handling and will lead to more efficient shipping solutions by reducing overall package weight. Waste disposal will be easier and less expensive for our end users.

## **Risk Assessment:**

Testing was performed to assess any risk associated with an interaction between the product and the polypropylene vials:

- Rinsing Solution samples were tested after 0 and 26 months by visual inspection and the bottles were tested for free and total ATP according to internal QC procedures. The Rinsing Solution was also plated on PCA to detect potential contamination.
- Washing Solution samples were tested after 0, 35, and 62 months by visual inspection, pH, and quenching, and the bottles were tested for free and total ATP according to internal QC procedures. The washing solution was also plated on PCA to detect potential contamination.

During the review of measured values, no significant differences between polypropylene and glass vials were observed.

At Charles River, we continue to develop and provide innovative solutions that allow our customers to improve their product quality and increase efficiency. This update will allow us to optimize our products to fulfill our goal of providing a complete QC solution for our customers. If you have any questions regarding this change, please do not hesitate to contact me.

Sincerely,

Brice Chasey Celsis<sup>®</sup> Senior Product Manager Charles River Microbial Solutions



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