

Dear Valued Distributor,

Charles River strives to provide the highest level of support 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 associated with Celsis® product codes and labeling**.

Description of Changes:

We have completed our planned move of the Charles River Microbial Solutions GmbH facility from Neuss Germany to Kaarst Germany. As was previously communicated, due to this change in manufacturing location, individual reagent labels, kit labels, Certificates of Analysis, and package inserts will be revised to reflect the address of our new manufacturing location in Kaarst.

In addition to the address change, we will be updating certain labels for Celsis® reagents, kits, components, and consumables; Certificates of Analysis; and package inserts to harmonize Celsis® alphanumeric ordering codes and part numbers. Historically, certain Celsis® labels and documents have utilized the legacy Celsis® code, which is a numeric code.

The current ordering codes and component part numbers for impacted products are alphanumeric codes beginning with the letter "C." These label and document changes impact most current Celsis® reagent kits and accessory products, and some customized reagents. The Celsis AMPiScreen® Pharma 400 Assay Kit (Product Code: RST400) and the product codes in the Celsis Adapt™ portfolio are not impacted. If you have questions about which products are impacted by this change, please contact Charles River Technical Support at Celsis-Support@crl.com.

Here is an example of how this labeling and documentation change will look in practice:

The Celsis® Monthly Maintenance & Cleaning Kit currently lists Product Code 92828 on its kit label and product documentation. This code will change from "92828" to "C92828" on its label and product documentation. The labels for the individual reagent bottles inside this kit will also have a "C" added to their component product codes.

Implementation Date:

The changes to the labeling and documentation identified above will begin in March 2022. Please be advised that this transition will occur over time based on component stock levels and production schedules. For a period of time, certain Celsis® kits may have a mix of reagent components with updated labels and some which do not, depending on when the component was manufactured.

These changes **do not impact** your ordering process with Charles River, and there are no other changes to the impacted products other than those described above. The Celsis® reagents continue to be formulated, filled, freeze-dried, labeled, and packaged using the same or similar equipment, the same raw materials provided by approved suppliers, and documented on approved batch records. The methods and procedures



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used for quality control testing of each product and the process used by Quality Assurance to perform final release also remain unchanged.

The above changes have been made to ensure business continuity and Charles River's ongoing efforts for continuous improvement for Microbial Solutions products. There are many factors that contribute to our overall decision-making process regarding product changes, which include, but are not limited to, operational efficiencies and waste reduction. If you have any questions, please contact Charles River Technical Support at Celsis-Support@crl.com.

Sincerely,

Allen Rudis

Allen Rudis
Associate Director, Regulatory Compliance