

30 March 2018

This notice serves as a change control notice that we are making to the production of Process Challenge Devices (PCDs). Nelson Laboratories is relocating PCD manufacturing operations from Salt Lake City, Utah to South Beloit, Illinois. This change notification impacts the following products: NLI-PCD-001, NLI-PCD-002, NLI-PCD-003, NLI-PCD-004, NLI-PCD-005, NLI-PCD-006, NLI-PCD-007, NLI-PCD-008, NLI-PCD-009, NLI-PCD-010, NLI-PCD-011, NLI-PCD-012, and NLI-PCD-013.

The new facility will start production on May 1, 2018, with the first production batches available starting May 15, 2018. We anticipate that you will not see any delays in production during this transition.

This change is being made to support the increased demand of PCDs, and it will not impact the manufacturing process, raw materials, or final product. The same standard operating procedure (SOP0180) used for preparing PCDs will remain effective. Validation work performed to assess the change demonstrated the resistance of the final product is the same. All Nelson Labs quality system requirements have been verified for both manufacturing locations. The Certificate of Compliance will denote the manufacturing facility location within the batch order number as follows: PCDs manufactured in Salt Lake City will include the prefix "BO" and PCDs made in South Beloit, Illinois will include the prefix "PL" in the batch number.

Thank you for working with us as we optimize this system to better deliver this critical sterilization process component. Please feel free to reach out to me with any questions.

Thank you,



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