

August 9, 2016

Subject: Thermo Scientific Linear Barcoded Tubes  
 NNI Catalog Nos. 5001-0020, 5001-0050 and 5001-1020

Dear Valued Customer:

Nalge Nunc International (“NNI”), part of Thermo Fisher, has discovered that certain lot numbers of barcoded tubes were inadvertently labeled with already used barcode numbers thus potentially creating situations where the same barcode number may exist on another barcoded tube from an earlier lot. **You are receiving this notification because you may have received product from:**

- (1) an original lot; or
- (2) an affected (repeated) lot; or
- (3) from both the original and the affected lots.

**AFFECTED PRODUCT DETAILS:**

The impacted products and respective lot numbers are listed below.

Original Lots	Affected Lots (may contain barcodes repeated from the Original Lots)	Quantity of Affected Lots Distributed within the EU (in cases)	Product Description	NNI SKU
1163820 1165358	1167716	4	5001-0020, 2ML BARCODED VIAL	5001-0020
1162762	1169844	8	5001-0050, 5ML BARCODED VIAL	5001-0050
1163817 1163838 1164344	1167260 1171457	12 4	5001-1020, 1.5ML BARCODED VIAL	5001-1020

**ISSUE:**

The root cause of this issue is the result of a software programming error during a recent software upgrade. Specifically, NNI upgraded its Vial Bar Coder system in December 2015. In connection with this system upgrade, the starting barcode numbers for each product in the new system were to continue numbering from the last barcodes from the existing system. During the development phase of the system upgrade, a file containing the then-current barcode numbers had been generated. Prior to launch of the new system, instead of installing the most current version of the file of barcode numbers, the software developer inadvertently installed the file provided during the development phase for the upgrade. This resulted in the repeat production of barcodes generated between the two file versions.

**INSTRUCTION:**

Please distribute this information to your customers for notification of the potential quality issue and place the lot on quarantine.

**PRODUCT CORRECTION:**

Please note that vials being printed today are not impacted, and the newly-installed Vial Bar Coder system actively checks to ensure it does not print a duplicate. Even so, we are taking all necessary actions to ensure that this situation does not reoccur.

**PRODUCT RETURN AND REPLACEMENT:**

**If you received products from both the Original Lot and the corresponding Affected Lot, you may be in possession of duplicate barcoded vials.** If you only received product from either the Original Lot or the Affected Lots (but **not both** lots), you will not have duplicative barcode numbers and there is no action for you to take.

If you have both Original Lot and Affected Lot products in your possession and would like to receive replacement product, please make arrangements through your distributor to do so, or you may contact us directly by email at [Rocregsupport@thermofisher.com](mailto:Rocregsupport@thermofisher.com). Replacement product will be provided at no charge.

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You can choose either of two (2) options concerning return of the products, depending on suitability:

1) Shipment of the unused product is handled via courier; please contact us directly by email at [ROCRegSupport@thermofisher.com](mailto:ROCRegSupport@thermofisher.com) and we will support with the arrangement, or

2) Alternatively you can choose to destroy any unused product if you can provide valid evidence that the specific lot number and amount of cases has been destroyed, making it possible for us to perform a reconciliation justifying that that all unused product has been destroyed. Please contact us directly by email at [ROCRegSupport@thermofisher.com](mailto:ROCRegSupport@thermofisher.com).

We deeply regret any inconvenience this may cause. If you require additional information related to this notification, please contact Barry Srolis at [barry.srolis@thermofisher.com](mailto:barry.srolis@thermofisher.com) or [ROCRegSupport@thermofisher.com](mailto:ROCRegSupport@thermofisher.com).

Sincerely,



Vikram Chandra  
Senior Director of Quality  
Laboratory Consumables Division