

Date: May 3rd, 2022

Subject: **Thermo Scientific™ MAS™ Omni•IMMUNE™ and Omni•IMMUNE PRO™ Control Shelf-life Notification**

Catalog Numbers	OIM-101: Level 1 (6 x 5 mL)	Lot: OIM 24111
	OIM-202: Level 2 (6 x 5 mL)	Lot: OIM 24112
	OIM-303: Level 3 (6 x 5 mL)	Lot: OIM 24113
	OPRO-101: Level 1 (6 x 5 mL)	Lot: OPRO 24111
	OPRO-202: Level 2 (6 x 5 mL)	Lot: OPRO 24112
	OPRO-303: Level 3 (6 x 5 mL)	Lot: OPRO 24113

Dear Valued Customer:

We are glad to inform you that the Thermo Scientific MAS Omni•IMMUNE and Thermo Scientific MAS Omni•IMMUNE PRO Controls with lot numbers OIM2411 and OPRO2411 have received a 4-year shelf-life approval and will now expire on Nov 30, 2025, when stored at -25 to -15° C per the control package insert.

However, at the time of the filling of the control vials, we had not received the necessary approvals for the four-year shelf-life and consequently the product components, were labeled with a three-year dating.

To maintain the integrity of the product and retain the number of peer groups, we will not be changing the lot number for the product and the individual vials will not be relabeled. The kit insert will not be updated with the new expiration date. In addition, the control boxes, will also include a product stuffer notifying of the shelf-life change.

Catalog Number	Current Lot Number on component label	Current Expiration Date	New Expiration Date
OIM-101	OIM24111	11/30/2024	11/30/2025
OIM-202	OIM24112	11/30/2024	11/30/2025
OIM-303	OIM24113	11/30/2024	11/30/2025
OPRO-101	OPRO24111	11/30/2024	11/30/2025
OPRO-202	OPRO24112	11/30/2024	11/30/2025
OPRO-303	OPRO24113	11/30/2024	11/30/2025

Crossover Studies

Crossover studies may be required for customers transitioning to this lot from an existing on-market lot. Labs must follow internal SOPs as required and monitor the control ranges as established in their lab SOPs.

You may continue to use any inventory of lot OIM 2411 and or OPRO 2411 until the new expiration date of November 30, 2025.

If you have any questions, please feel free to contact your local Thermo Fisher Scientific Sales Representative or call Technical Service at toll free 1-800-232-3342 (USA only) or 510-979-5000 (International), Option 2, then 2 or by email: mas.controls@thermofisher.com
Clinical Diagnostics | Thermo Fisher Scientific

Sincerely,

Narayan Krishnaswami
Senior Manager- Global Product Marketing- QC Controls
Clinical Diagnostics | Thermo Fisher Scientific

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR:

If you are a distributor of the product, please contact your customers and advise them of the change and provide them with a copy of this letter.

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