

Date: June 2nd, 2019

Subject: **Thermo Scientific™ MAS™ T-Marker Control Date Extension Notification**

Catalog Number	TUM-101: Level 1 (6 x 3 mL)	Lot: TM19061
	TUM-202: Level 2 (6 x 3 mL)	Lot: TM19062
	TUM-303: Level 3 (6 x 3 mL)	Lot: TM19063
	TUM-S1: Sample Pack (3 x 3 mL)	Lot: TM1906S

Dear Valued Customer:

We are pleased to inform you that MAS T-Marker Control lot TM1906 has been date extended 2 years and will now expire on June 30, 2021 when stored at -25 to -15°C per the control package insert.

To maintain the integrity of the product, the individual control vials will not be relabeled. However the kit insert will be updated denoting the new lot number and expiration date and the kits will also include a product stuffer notifying of the date extension.

Catalog Number	Current Lot Number	Current Expiration Date	New Lot Number	New Expiration Date
TUM-101	TM19061	06/30/2019	TM21061	06/30/2021
TUM-202	TM19062	06/30/2019	TM21062	06/30/2021
TUM-303	TM19063	06/30/2019	TM21063	06/30/2021
TUM-S1	TM1906S	06/30/2019	TM2106S	06/30/2021

Crossover Studies

No crossover studies are necessary, however, a careful review of your QC data and ranges is highly recommended as adjustments to your control ranges may be required. Labs must follow internal SOPs as required and monitor the control ranges as established in their lab SOPs.

You may continue to use your current inventory of lot TM1906 until the new expiration date of June 30, 2021.

LIMITATIONS:

If Insulin results fall below the lower limits provided below, do not use for Insulin.

Level 1 lower limit: 2.3 uIU/mL
Level 2 lower limit: 19.2 uIU/mL
Level 3 lower limit: 38.0 uIU/mL

If you have any questions, please contact your local Thermo Fisher Scientific Sales Representative or call Technical Support at toll free 1-800-232-3342 (USA only) or 510-979-5000 (International), Option 2, then 2 or email to mas.controls@thermofisher.com. Outside the USA, please contact your local distributor or local Thermo Fisher Scientific office.

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.