Prolongation of shelf life of CD8-APC-Vio770 (REA734)

Product | REF
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CD8-APC-Vio770 (REA734), IVD | 170-080-014
CD8-APC-Vio770 (REA734), ASR | 170-081-075

Category of change: Prolongation of shelf life

Current State: The shelf life of CD8-APC-Vio770 is 9 months at 2-8 °C.

Planned change: The shelf life of CD8-APC-Vio770 will be 12 months at 2-8 °C.

Justification/ Evaluation: The stability of CD8-APC-Vio770 was tested during stability study. All samples passed the respective specifications. Thus, the shelf life can be adjusted without any risks.

There is no change of raw material or manufacturing process. Therefore, no impact on the performance, quality and safety of the affected product could be identified.

Estimated Implementation: Mar.2022

Please share, if applicable, this information with relevant staff in your organization. If there are any further questions, do not hesitate to contact us.

06.Jan.2022

QA Audit/Customer/Supplier Management
Miltenyi Biotec B.V. & Co.KG