

Stability Statement for


TaqPath™ 1-Step Multiplex Master Mixes

Thermo Fisher Scientific confirms that the stability for TaqPath™ 1-Step Multiplex Master Mixes were evaluated by performing Real-time stability. The expiration date was determined based on performance characteristics of material stored under specified experimental conditions per EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents.

Three lots for five of the six product SKUs (A28521, A28522, A28523, A28525 and A28526) were placed under controlled temperature storage conditions in accordance with product labeling. Two lots of the sixth product SKU (A28527) were placed under controlled temperature storage conditions in accordance with product labelling. The similarity of SKU A28527 to the SKUs within this report allow them to be treated as a product stability family. The stability claims applied to the other SKUs within the family can be applied to A28527 as per definition of a Product Family. Based on the testing performed and associated stability report, TaqPath™ 1-Step Multiplex Master Mixes are stable and maintain their performance for at least 12 months post manufacturing, at its recommended storage of -20±10°C. Exact expiry date is printed on the product label and reflected within the lot specific Certificate of Analysis (COA).

Catalog SKUs in scope of this Stability Statement include:

Product	Cat. No.	Amount	No. of 20-µL reactions	Storage
TaqPath™ 1-Step Multiplex Master Mix (No ROX™)	A28521	1 × 0.5 mL	100	-30°C to -10°C
	A28522	5 × 1 mL	1000	
	A28523	1 × 10 mL	2000	
TaqPath™ 1-Step Multiplex Master Mix	A28525	1 × 0.5 mL	100	
	A28526	5 × 1 mL	1000	
	A28527	1 × 10 mL	2000	


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