

**Stability Statement for  
TaqPath™ 1-Step RT-qPCR Master Mix, CG**

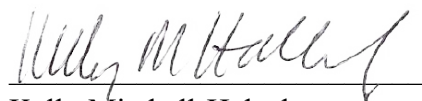
Thermo Fisher Scientific confirms that the stability for TaqPath™ 1-Step RT-qPCR Master Mix, CG was evaluated by performing accelerated aging, in-use and transportation studies. The expiration date was determined based on performance characteristics of material stored under specified experimental conditions per EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents.

As it relates to the accelerated aging study, three lots of TaqPath™ 1-Step RT-qPCR Master Mix, CG A15299 and A15300 were stored at  $5\pm 3^{\circ}\text{C}$  and tested after 7, 14, and 21 weeks. At this elevated storage temperature, accelerated degradation of the master mix and its components is used to model and project product stability at  $-20\pm 5^{\circ}\text{C}$  (recommended storage condition) for at least 12 months. Based on the testing performed and associated stability report, TaqPath™ 1-Step RT-qPCR Master Mix is stable and maintain its performance for at least 12 months post manufacturing, at its recommended storage of  $-20\pm 5^{\circ}\text{C}$ . 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:

Catalog No.	Quantity	Storage condition
A15299	5 × 1 mL	Store at $-25^{\circ}\text{C}$ to $-15^{\circ}\text{C}$ <sup>(1)</sup>
A15300	1 × 10 mL	

<sup>(1)</sup> The TaqPath™ 1-Step RT-qPCR Master Mix will not freeze at  $-20^{\circ}\text{C}$ ; gelling may occur.



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