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STABILITY STATEMENT for TagPath™ ProAmp™ Master Mix and TagPath™ ProAmp™ Multiplex Master Mix

Thermo Fisher Scientific confirms that the stability for TaqPath™ ProAmp™ and TaqPath™ ProAmp™ Multiplex Master Mix was evaluated by performing accelerated, in-use, transportation and long-term stability studies (SS). The expiration date was determined based on the performance characteristics of product stored under specified experimental conditions per EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents. Exact expiry date is printed on the product label and reflected within the lot specific Certificate of Analysis (CoA). The products remain stable under the described SS conditions (accelerated, in-use, transportation and long-term SS) and maintain their performance for at least 12 months post manufacturing when held at 5±3°C.

Catalog SKUs in scope of this Stability Statement include:

TaqPath™ ProAmp™ Master Mix	TaqPath™ ProAmp™ Multiplex Master Mix	Amount	Storage
with ROX™	with MUSTANG PURPLE™		Otorage
A30865	A30868	1 x 1 mL	
A30866	A30869	1 x 10 mL	
A30871	A30873	2 x 10 mL	5±3°C
A30867	A30870	1 x 50 mL	
A30872	A30874	2 x 50 mL	

Authorized by: Senior Quality Manager

Ana Mačernienė

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Electronically signed by Ana Mačerniene Reason: Approver of the GxP document Date: Jun 3, 2022 12:45