

STABILITY STATEMENT for

TaqPath™ BactoPure™ Microbial Detection Master Mix

Thermo Fisher Scientific confirms that the stability for TaqPath™ BactoPure Microbial Detection Master Mix and TaqPath™ BactoPure Microbial Detection Master Mix, No Rox was evaluated by performing accelerated, in-use and transportation stability studies (SS). The expiration date was determined based on the 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. 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, and transportation SS) and maintain their performance for at least 24 months post manufacturing when held at 5±3°C.**


Catalog SKUs in scope of this Stability Statement include:

TaqPath™ BactoPure™ Microbial Detection Master Mix with ROX™	TaqPath™ BactoPure™ Microbial Detection Master Mix No ROX™	Amount	Storage
A52699	A52703	1 x 1 mL	5±3°C
A52700	A52704	1 x 5 mL	
A52701	A52705	5 x 1 mL	
A52702	A52706	1 x 50 mL	

Authorized by:

Senior Quality Manager

Ana Mačernienė

 Electronically signed by: Ana Mačernienė
Reason: Approver of the GxP documents
Date: Dec 22, 2022 13:16 GMT+2