

Lyophilization & Post-Lyophilization User Guideline



The guidelines in this document can help users avoid problems in lyophilization. For storage and stability, expiry and general handling of these product pre-lyophilization, please refer to the individual Product Handling Guides.

Safety precautions:

Read and understand the SDS (Safety Data Sheets) before handling the reagents. Copies of these SDSs are available on our website or upon request.

There are several advantages for lyophilization, including room temperature shipping and storage, extended shelf-life and increased flexibility in sample volume. In order to be compatible with lyophilization however, enzyme preparations must be glycerol-free and include specialized lyophilization-excipients that preserve the mixture as it is exposed to various lyophilization conditions including freezing, temperature ramps, vacuum and dehydration. An ideal lyophilization formulation should stabilize an enzyme in a freeze-dried format and allow very fast rehydration and reactivation of the enzyme preparations, without impacting its performance post rehydration. The MDX products listed in table 3 are suitable for lyophilization.

Lyophilization

- The lyophilization cycle protocol in Table 1 is suitable for lyophilization of the Lyo-Ready™ qPCR mix and 1-step RT-qPCR mix in standard PCR tubes and plates. These parameters are provided as a guidance only and should be optimized to different user formats and systems.
- An annealing step can be added during the freezing step to assist crystallization of amorphous material.
- Combined primary and secondary drying time can be extended up to 24 hours.
- For product containing excipients, there should be no need to add any further excipients to assist lyophilization.

Table 1. Lyophilization guidelines

Step	Temperature	Time	Description
Freezing	+4 °C	10 min	Hold
	-45 °C	1.0 °C/min	Ramp
Primary Drying	-45 °C	180 min	Hold
	-40 °C	0.5 °C/min	Ramp
	-40 °C	720 min	Hold
Secondary Drying	+25 °C	0.5 °C/min	Ramp
	+25 °C	240 min	Hold

Critical Temperatures

Glass transition for frozen state (Tg') Collapsing (Tc) and Glass Transition for dried state (Tg^d) critical temperatures for Lyo-Ready™ qPCR Mix, Lyo-Ready™ 1-Step RT-qPCR Mix and Lyo-Ready™ 1-Step RT-qPCR Virus Mix are listed in table 2.

Table 2. Tg', Tc and Tg^d critical temperatures

Types of Mix	Tg'	Tc	Tg ^d
Lyo-Ready™ qPCR Mix	-36.3 °C	-33.6 °C	45 °C
Lyo-Ready™ 1-Step RT-qPCR Mix	-33 °C	-29.4 °C	45 °C
Lyo-Ready™ 1-Step RT-qPCR Virus Mix	-33 °C	-29.4 °C	45 °C

Post-Lyophilization

For maximum shelf-life, we suggest packaging lyophilized material under inert gas conditions (e.g. nitrogen or argon) and insert a desiccant sachet to improve stability. Pouches should be heat-sealed and labelled.

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Lyophilization compatible MDX products

Table 3. Lyophilization compatible products

Product	Catalog number	Product	Catalog number
Glycerol-Free Taq HS 50 U/μL	MDX011	Lyo-Ready™ Genotyping Direct qPCR Blood, 4x	MDX128
Aptamer Taq HS (Glycerol-Free)	MDX015	Lyo-Ready™ Direct DNA qPCR Saliva, 4x	MDX132
Glycerol-Free Bst	MDX017	Lyo-Ready™ Direct RNA/DNA qPCR Saliva, 4x	MDX133
Lyo-Ready™ qPCR Mix	MDX021	Lyo-Ready™ Direct DNA LAMP Saliva, 4x	MDX134
Lyo-Ready™ qPCR Buffer, 2.5x	MDX022	Lyo-Ready™ Direct RNA/DNA LAMP Saliva, 4x	MDX135
Lyo-Ready™ qPCR Mix 2.6x	MDX023	Lyo-Ready™ Direct DNA qPCR Stool, 4x	MDX142
Lyo-Ready™ 1-Step RT-qPCR Mix	MDX024	Lyo-Ready™ Direct RNA/DNA qPCR Stool, 4x	MDX143
Lyo-compatible MMLV-RT	MDX042	Lyo-Ready™ Direct DNA LAMP Stool, 4x	MDX144
Lyo-Ready™ 1-Step RT-qPCR Buffer	MDX052	Lyo-Ready™ Direct RNA/DNA LAMP Stool, 4x	MDX145
Lyo-Ready™ qPCR Buffer w/o Excipients, 4x	MDX061	Lyo-Ready™ Genotyping Direct qPCR Stool, 4x	MDX148
Lyo-Ready™ 1-Step RT-qPCR Virus Mix	MDX062	Lyo-Ready™ Direct DNA qPCR Urine, 4x	MDX152
Lyo-Ready™ LAMP Mix, 4x	MDX097	Lyo-Ready™ Direct RNA/DNA qPCR Urine, 4x	MDX153
Lyo-Ready™ RT-LAMP 1-Step Mix, 4x	MDX108	Lyo-Ready™ Direct DNA LAMP Urine, 4x	MDX154
Lyo-Ready™ Direct DNA qPCR Blood, 4x	MDX122	Lyo-Ready™ Direct RNA/DNA LAMP Urine, 4x	MDX155
Lyo-Ready™ Direct RNA/DNA qPCR Blood, 4x	MDX123	Lyo-Ready™ Genotyping Direct qPCR Urine, 4x	MDX158
Lyo-Ready™ Direct DNA LAMP Blood, 4x	MDX124	Lyo-Ready™ Genotyping Direct qPCR FFPE, 4x	MDX168
Lyo-Ready™ Direct RNA/DNA LAMP Blood, 4x	MDX125		