TECHNICAL NOTE

Lyo-ready qPCR master mixes for lyophilized assays

Master mixes now available in custom, lyo-compatible formulations

Molecular diagnostic tests are being increasingly developed in a lyophilized format. The enhanced stability of lyophilized reagents enables roomtemperature shipping and storage, extended shelf life, and allowance for increased volume of the sample. Our low-glycerol, lyophilization-ready qPCR master mixes are one-tube solutions that are ready to be mixed with primers, probes, and excipients, for the subsequent lyophilization step. There is no need for time-consuming development, optimization, and sourcing of multiple separate qPCR reaction components. These reagents retain the reproducibility, sensitivity, and specificity required for diagnostic assays (Figure 1). Once lyophilized, the assays demonstrate little to no loss of sensitivity or specificity, and have been shown to reproducibly detect

Applied Biosystems" TaqMan" XanoRNA" Gene Expression Assay TaqMan Lyo-Ready 1-Step Master Mix TaqMan FV 1-Step Master Mix 0.01 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32 34 36 38 40 Cycle

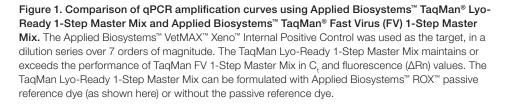
Lyo-ready master mix options

Applied Biosystems qPCR master mixes are available in a lyo-ready format on a custom basis to our commercial partners for genotyping, gene expression, and copy number variation applications. If you are interested in a lyo-ready master mix, contact us at MDxOEM@thermofisher.com, and we will work with you to deliver the right formulation for your unique assay.

single target copies per reaction and provide a linear dynamic range over 7 logarithmic units. Let our Custom Services team help you find the right Applied Biosystems™ lyo-ready master mix for your unique requirements. Customization is available, and all master mixes are available with or without a passive reference dye. Manufactured to the highest-quality standards and engineered for lot-to-lot consistency, you can rely on our lyo-ready master mixes and Custom Services team for your next qPCR-based diagnostics project.

Benefits of TaqMan lyo-ready master mixes

- High concentration—allows flexibility in final formulations with primers, probes, and excipients
- Convenience—optimized, readyto-use formulations for lyophilizing qPCR and 1-step RT-qPCR assays
- Customized—pack sizes and formulations tailor-made to your requirements
- Performance—reliable, reproducible results across a wide dynamic range





applied biosystems

Optimized for the rigors of lyophilization

The TaqMan lyo-ready master mixes are turnkey formulations that can be inserted into the lyophilization process with little-to-no optimization. They yield the sensitivity and linear dynamic range you have come to expect from Applied Biosystems qPCR master mixes (Figure 1), and post-lyophilization results are similar to those achieved pre-lyophilization. To demonstrate performance before and after lyophilization, the TaqMan Lyo Ready 1-Step Master Mix was first combined with excipients to form a pre-lyo master mix, and then lyophilized on an FTS Systems LyoStar™ II system. The performance of the TaqMan Lyo-Ready 1-Step Master Mix is retained with or without the added excipients, and after lyophilization (Figure 2).

Stability of reagents for convenience and cost savings

Lyophilized assays minimize stringent requirements for cold-chain storage and shipping, dramatically reducing cost to molecular diagnostics developers and their customers. Lyophilized assays also exhibit higher stability, thus reducing waste due to reagent and assay expiration. Figure 3 shows consistent stability of three batches of lyophilized assay using TaqMan Lyo-Ready 1-Step Master Mix for four targets tested.

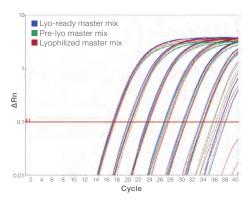


Figure 2. Performance comparison of lyoready, pre-lyo, and lyophilized master mixes to that of TaqMan Lyo-Ready 1-Step Master Mix, using a TaqMan XenoRNA™ Gene Expression Assay. C₁ values, PCR efficiency, and R² are consistent across the three variations of master mix.

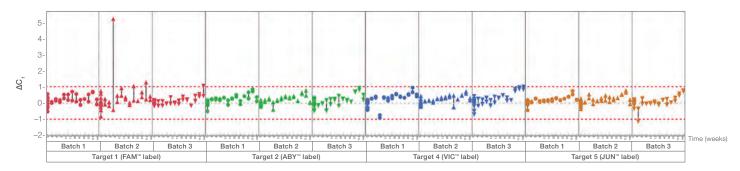


Figure 3. Stability testing of different batches of TaqMan Lyo-Ready 1-Step Master Mix. Three batches of a lyophilized multiplex arbovirus assay using TaqMan Lyo-Ready 1-Step Master Mix were stored at ambient temperature (24° C) and tested for their stability at regular intervals. Stability results for all batches of the lyophilized 1-step master mix with four targets showed that the ΔC_t values (C_t test point $-C_t$ time 0) remained within the specified metric of ± 1 over 146 weeks (2.8 years).

