

RealFast™ Assays, Statement on stability testing

ViennaLab Diagnostics GmbH, manufacturer of the RealFast™ Assays, hereby declares that a risk analysis was performed to identify boundary condition for stability tests reflecting the specific device intended purpose as well as the stated shelf life. Tests were planned and performed according to EN ISO 23640:2015; In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents. Some results are listed below, more tests are ongoing.

1. Tests on freeze-thaw cycles

Use of the RealFast™ Assay involves repeated freeze/thaw cycles. For experiments regarding freeze/thaw cycles, reagents of the same kit lot were exposed to various cycles of freezing at -20°C and thawing at ambient temperature. The RealFast™ Assay withstands up to 30 freeze/thaw cycles with no loss of quality performance tested 10 months later (evaluation ongoing).

2. Storage at conditions other than recommended

Long-term storage of RealFast™ Assays at 2-8°C for up to 12 months was evaluated. Scale and amplification plots were identical compared to reagents of the same lot stored at -20°C.

3. In use stability

RealFast Assays™ are used at ambient temperature. Prolonged exposure to intense light should be avoided, however, during normal set up of PCR protection from light is not necessary. After use, all reagents should be stored at -20°C for long-term or at 2 to 8°C for short-term intervals of use.

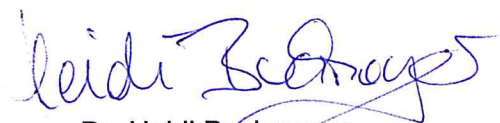
4. Transport stability (elevated temperature)

The influence of temperature stress was simulated by exposing RealFast™ Assay reagents up to 48 hours to 45°C followed by storage -20°C. Testing after 10 months resulted in identical scale of amplification plots for all samples (ongoing evaluation).

5. Long-term stability

Ongoing stability testing by the quality control lab demonstrate that RealFast™ Assays stored under the recommended storage conditions (-20°C) maintain performance characteristics. Additional test will be performed to verify the possibility of shelf life extension.

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