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June 23, 2021

Subject: Temperature excursions and assay stability

Dear Valued Customer:

To ensure that our customers receive product that meets expectations, Cepheid assay test kits are subjected to a shipping validation protocol followed by functional stability testing. The outcomes of these studies determine the shelf-life and shipping and storage conditions for our products. The testing has been designed to simulate shipment from Cepheid to domestic and international customers and includes conditioning product in the final packaging configurations for 24 hours at +43°C followed by 5 days at +50°C (75% relative humidity) for the "Summer Excursion Profile". For the "Winter Excursion Profile" cartridges are stored at -24°C for 24 hours followed by 5 days at -18°C. It is then assumed that product received by a customer would be returned to a storage temperature range between +2°C and +28°C or +2°C to +8°C (please refer to product labeling for required storage conditions). Under our functional stability testing, the performance of all products have been exposed to these conditions and continues to meet all release specifications until the labeled expiration date.

Shipping and prolonged storage (>6 days) of these products at temperatures below 2°C or exceeding 30°C has not been specifically assessed but we believe these storage conditions will reduce product performance and should be avoided.

If you have further questions, please contact Cepheid Technical Support.

Telephone: 1.888.838.3222

EMAIL: TechSupport@cepheid.com

Sincerely,

Keith Everiss, Ph.D.

Vice President, Global Manufacturing Quality

Cepheid

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