



December 10, 2020

Re: Hygiena™ Product Stability During Shipping

Dear Valued Customer:

Hygiena products are robust and have long shelf life at the recommended long-term storage temperatures. Due to potential extended shipping times related to the global pandemic, Brexit, and holidays, it is possible that Hygiena products may arrive at a customer site with ice packs that have thawed. In preparation for these delays, Hygiena has conducted stability studies to confirm that our products are resistant to temperature conditions found with potential extended shipping times. Assay performance met or exceeded our product release specifications after temperature abuse in ship/shock testing. As a result, we are issuing the following guidance:

- Hygiena “legacy” devices such as ATP devices, InSite, MicroSnap can tolerate 28 days at 21°C or 7 days at 37°C without significant loss of activity.
- Hygiena Innovate products tolerate 7 days at 25°C without significant loss of activity.
- Hygiena BAX® System kits (tablets & lysis reagents) tolerate 28 days at 25°C without significant loss of activity.

When Hygiena products are shipped insulated and with “blue ice”, the core function of that packaging is to protect the products from excessive temperatures during shipping.

Additional temperature studies are on-going that shows even better stability and robustness for some products that will allow great flexibility for shipping and dispatch dates. Hygiena will provide further information and advice in due course.

We value your business and your trust in our products. If you have any questions regarding this guidance, please contact [TechService@hygiena.com](mailto:TechService@hygiena.com).

Sincerely,

A handwritten signature in black ink that reads "Martin Easter". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Dr Martin Easter  
( Chief Scientific Officer)