



**Abbott**

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06.08.2021

**Change Notification**

**Panbio™ COVID-19 Ag Rapid Test Device - Shelf Life Change**

To Whom it May Concern,

We, Abbott Rapid Diagnostics Jena GmbH, the legal manufacturer of the Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal) and Panbio™ COVID-19 Ag Rapid Test Device (Nasal), hereby notify that the shelf life of the aforementioned products has been changed from 12 months to 24 months. This update is the result of newly available data from an accelerated stability study.

The accelerated stability study was conducted for a total of 38 weeks at 45°C in order to support product shelf life for 24 months when stored at the recommended storage temperature of 2~30°C. The Panbio™ COVID-19 Ag Rapid Test Device met the performance acceptance criteria under the stability conditions of 45°C for the planned 38 weeks, which is equivalent to 25 months of storage at 30°C.

Based on these stability results, it can be predicted that the Panbio™ COVID-19 Ag Rapid Test Device is stable for 24 months at 2-30°C. Consequently, the shelf life of the product is extended from 12 months to 24 months.

Signed on behalf of Abbott Rapid Diagnostics Jena GmbH,

Claudia Christner-Albrecht

Head of Regulatory Affairs



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