



29 November 2021

This memo is to notify you regarding the extension of the shelf-life expiration date of the INDICAID COVID-19 Rapid Antigen Test. As a part of the EUA conditions of authorization, PHASE Scientific submits updated real-time product stability data to the U.S. Food and Drug Administration (FDA) on an on-going basis.

Pursuant to FDA's Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), Guidance for Developers and Food and Drug Administration Staff (November 15, 2021 revision), we have updated the shelf-life expiration to nine (9) months at 2-30°C from the date of manufacture while the submitted real-time stability data is under review by FDA.

The shelf-life for all current lots of the INDICAID may be extended by three (3) months from the expiration dating provided on the product packaging.

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