

June 6, 2022

To whom it may concern,

Pursuant to FDA's January 31, 2022 Letter Granting EUA Revision(s),

The Fastep COVID-19 IgG/IgM Rapid Test Device and Ecotest COVID-19 IgG/IgM Rapid Test Device have been granted an extension to the shelf life expiration date based on real-time stability data.

Attachment A lists the lot numbers of Fastep COVID-19 IgG/IgM Rapid Test Device and Ecotest COVID-19 IgG/IgM Rapid Test Device labeled with nine months shelf life. These products' shelf life has now been extended to a total of eighteen months.

Best Regards,



Frank Luo

Director
Azure Biotech Inc.

Attachment A

Fastep		
Lot Number	Printed shelf life (9 months)	Extended shelf life (18 months)
I2104116	1/1/2022	10/1/2022
I2104097	1/15/2022	10/15/2022
I2108081	5/11/2022	2/11/2023
I2108151	5/18/2022	2/18/2023
I2108187	5/25/2022	2/25/2023
I2109153	6/25/2022	3/25/2023
I2112135	9/6/2022	6/6/2023
I2112311	9/20/2022	6/20/2023
I2112437	9/28/2022	6/28/2023
I2201499, I2201290	10/4/2022	7/4/2023

Ecotest		
Lot number	Printed shelf life (9 months)	Extended shelf life (18 months)
I2104117	1/1/2022	10/1/2022
I2108082	5/11/2022	2/11/2023
I2108171	5/24/2022	2/24/2023
I2109042	6/5/2022	3/5/2023
I2109154	6/25/2022	3/25/2023
I2112259	9/3/2022	6/3/2023
I2112194	9/8/2022	6/8/2023
I2112312	9/20/2022	6/20/2023
I2201291	10/4/2022	7/4/2023