PBM Princeton BioMeditech Corporation
Makers of Advanced Rapid Diagnostic Products

Dear Valued Customer,

We are pleased to inform you that the *Status*™ COVID-19/Flu A&B test (Item No.33225) has received U.S. Food and Drug Administration (FDA) 510(k) clearance and CLIA-waived categorization. This achievement advances the test beyond Emergency Use Authorization (EUA) to full commercial IVD status.

Please note that there are no changes to the device design, chemistry, or test performance between the EUA and 510(k) cleared versions. Updates in the 510(k) cleared labeling reflect:

- Inclusion of additional analytical performance data
- Inclusion of clinical performance study data from the 2023–2024 season
- Terminology update from "capsule" to "vial"

Customers may continue using existing EUA inventory without interruption. Packaging will be transitioned from EUA to 510(k) cleared labeling during 2026.

In addition, based on ongoing real-time stability testing, **the product expiration dating has been extended** as described in the separate expiration dating notification. We recommend retaining the notification with your product records for compliance purposes.

If you have questions or require further information regarding this transition, please contact Technical Support at technical@lifesignmed.com, or phone at 1-800-526-2125.

Thank you for your continued trust in our products.

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