August 20, 2026

Continued Access to Metrix® During the EUA Transition

Dear Metrix Customer,

The U.S. Department of Health and Human Services (HHS) has announced that the COVID-19 EUA declarations for medical devices will end on December 26, 2026.[1] Please be assured that Aptitude is prepared for this transition.

The Metrix COVID-19 Test and the Metrix COVID/Flu Test were originally authorized for use under the EUA. On August 7, 2026, the Metrix COVID Test received FDA 510(k) clearance (K253453), and the Metrix COVID/Flu Test is under active FDA review for 510(k) clearance.

In accordance with FDA's published transition guidance[2], customers are able to continue to use and purchase the Metrix EUA products during the transition. The information below answers commonly asked questions.

1. Can I continue using my existing Metrix UEA product after December 26, 2026?

Yes. Metrix EUA products may continue to be used after December 26, 2026, provided they are used before the expiration date shown on the product labeling.

2.Can I continue to purchase Metrix EUA products after December 26, 2026 ?

Yes. You may continue to purchase Metrix COVID-19 Tests in distribution after December 26, 2026, during the transition to the 510(k) cleared product. You may also continue to purchase Metrix COVID/Flu Tests after December 26, 2026, while the 510(k) submission remains under FDA review and, following 510(k) clearance, during the transition to the 510(k) cleared product.

3. Will payers continue to reimburse for testing with the Metrix EUA product in professional settings?

Yes. The end of the EUA does not end coverage for medically necessary diagnostic testing, including EUA products. Claims may continue to be submitted using the applicable billing codes. The Metrix COVID-19 Test and Metrix COVID/Flu Test may continue to be billed under CPT code 87635 and 87636 respectively. These codes apply to tests which detect COVID-19 and influenza using amplified probe technology, and are not specific to Metrix. As always, coverage, coding, and payment depend on the patient's benefit plan.

4. When will the 510(k)-cleared Metrix products be available?

The Metrix COVID Test received FDA 510(k) clearance (K253453) on August 7, 2026 and will become available following commercial release. The Metrix COVID/Flu Test is under active FDA review and will become available following FDA clearance and commercial release. Aptitude will notify customers when the 510(k) cleared products become available. In the meantime, Metrix EUA products will remain available.

Aptitude remains committed to supporting uninterrupted respiratory testing and will provide additional updates as the transition progresses. If you have any questions, please contact us at support@aptitudemedical.com.

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[1] HHS, Termination of Three Declarations Authorizing Emergency Use of Medical Devices During the COVID-19 Pandemic, 91 Fed. Reg. 40544 (July 2, 2026).

[2] FDA, Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to COVID-19 (March 27, 2023).

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