



**Expiration Date Extension of the EUA 202686  
ADVAITE RapCov™ Rapid COVID-19 Test Kit  
Catalog No. ADV-ID-25-U**

**BACKGROUND:**

ADVAITE RapCov™ Rapid COVID-19 Test Kit Catalog No. ADV-ID-25-U was manufactured under FDA Emergency Use Authorization to meet the demand for rapid detection of IgG antibodies to SARS-CoC-2 in human fingerstick whole blood. To expedite availability of COVID-19 IgG rapid testing, the initial stability testing for expiration dating was set to allow for expedited release of the test kits. Subsequent stability studies were planned and continue to be performed to provide extended product stability. To ensure laboratories maintain diagnostic testing capabilities to detect COVID-19 IgG antibodies, the expiration dates of ADVAITE RapCov™ Rapid COVID-19 Test cassettes currently in distribution (see lot #s in table below) are being extended.

**EXPIRATION DATE EXTENSION:**

The IVD kit components are stable if maintained as directed in the product specific kit/panel Package Insert. The expiration date has been extended but the individual package labeling has not been changed. The performance of the kit will be monitored continually by Advaita during the extension period. In the event that Advaita determines that the product fails to meet manufacturing specifications prior to the new expiration date, users will be contacted and information will be provided on what actions must be taken.

PRODUCT DESCRIPTION	CATALOG NUMBER	KIT LOT NUMBER / TEST CASSETTE LOT NUMBER	ORIGINAL EXPIRATION DATE	NEW EXPIRATION DATE
ADVAITE RapCov™ Rapid COVID-19 Test Kit	ADV-ID-25-U	P1919 / 0141	October 2021	December 2023
ADVAITE RapCov™ Rapid COVID-19 Test Kit	ADV-ID-25-U	P1921 / 0151	October 2021	December 2023

Humberto Gonzalez, Quality Manager

Date

12/9/2021