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To: All Client Facilities
From: Dr. Rita Khoury, Clinical Lab Director
Date: June 17th, 2022
Re: Update to Expiration Dates and Usage Guidelines for COVID-19 Collection Kits

Throughout the pandemic, Aculabs has worked to meet the demand for ample COVID-19 specimen collection kits. Adequate access to such supplies remains highly important for physicians in catching COVID-19 early on in vulnerable populations.

Clients who have received COVID-19 collection kits from Aculabs should continue using the kits provided, even tubes that display a past expiration date. Kits approaching their expiration date should not be discarded by the facility and are good to use.

As per guidance issued by the Centers for Disease Control and Prevention (CDC):

"To address the concern about SARS-CoV-2 testing reagents and swab supply shortages during the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) will allow laboratories and testing sites to use expired SARS-CoV-2 test kits, reagents, and swabs—unless doing so deviates from the test manufacturer's authorized instructions for use."

The CDC explains that such kits can be properly used for collection as long as quality control measures are followed:

"According to these guidelines, laboratories and testing sites may use expired supplies until non-expired supplies become available, provided that there are policies and procedures in place to ensure that reagents are performing as expected. For example, any expired supplies must pass quality control tests with each assay run."

For expired kits, Aculabs will begin performing correlation testing to confirm the validity of the kits, as per the CDC's guidance on quality control testing; however, such correlation cannot be performed for COVID-19 collection supplies until after the expiration date listed has passed.

In light of such, we performed a validation study on collection kits that expired on **April 18th**, **2022**, **April 24th**, **2022**, **April 27th**, **2022**, **May 3rd**, **2022**, **May 17th**, **2022** and **June 3rd**, **2022**. With the validation study displaying that the expired kits were performing as expected and identical to unexpired swabs, we will continue to follow the CDC's guidance and instruct clients to use collection kits regardless of expiration.

More info for the validation study can be found on our website, www.aculabs.com.

Clients should contact their customer service representative if they have further questions regarding COVID testing.

Sincerely,

Dr. Rita Khoury Clinical Lab Director