

LabCorp is providing information related to questions received about the updated “FAQs on Diagnostic Testing for SARS-CoV-2” posted by the FDA on March 26, 2020, on the following webpage: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>.

LabCorp will not accept all transport media listed in the guidance, as not all transport media have been validated on our assays. Validation of transport media is necessary to maintain the integrity and high-quality of our testing.

## Update as of May 29, 2020

Specifically, LabCorp has **not** validated the following transport media listed by the FDA and will **not currently** accept swabs collected in this media:

Medium containing guanidinium thiocyanate (GITC) or other guanidine compounds, including:

- PrimeStore MTM by LongHorn Vaccines and Diagnostics
- Ruhof Inactivate, Product code 354CVTK

Additionally, LabCorp does **not accept**:

- Dry swab without media
- Swabs in “Molecular media” (Marketed to inactivate pathogens and preserve RNA/DNA)
- Aptima swabs
- Amies gel swabs, Anaerobic media, charcoal media
- Specimens submitted in glass tubes/containers
- 3D printed swabs

LabCorp does not recommend aliquoting UTM/VTM as this may result in a volume submitted that does not allow repeat analysis on certain platforms. We cannot recommend lab prepared media as we cannot validate preparation. LabCorp will accept expired UTM/VTM (if expired within the last 18 months) for SARS-CoV-2 testing only.\* LabCorp does not recommend Hanks Balanced Salt Solution media.

\*The rapid spread of COVID-19 has made it difficult to obtain certain testing supplies due to supply chain disruption, and the immediate delivery and fulfillment of these supplies is necessary to broaden the availability of testing for the safety and health of the public. To meet the medical necessity of continued COVID-19 testing, the Company's scientific leadership team is authorizing on an emergency basis the use of expired transport media, but not greater than 18 months past expiry, as this exception for medical necessity will not affect the performance of the COVID-19 test.



[www.LabCorp.com](http://www.LabCorp.com)

## Transport media

LabCorp can receive specimens in the following transport media:

**Viral Transport Media:** LabCorp can receive specimens in viral transport media that is suitable for influenza specimens (1 mL or 3 mL volumes) and which is not marketed as “molecular media.” These include known appropriate media such as Copan viral transport media (VTM); Becton Dickinson universal transport media (UTM); Puritan UniTranz media; Thermofisher M4, M5 and M6; Hardy Diagnostics Healthlink UTM; Starplex Scientific Multitrans; and Ruhof VTM 345TK-2. Foam and flocked swabs are acceptable.

**ESwabs™:** LabCorp can receive ESwab™ specimens, such as those from Copan and BD for COVID-19 testing only (it cannot be used for our other respiratory virus testing).

### Swabs submitted with viral transport media or ESwabs™:

LabCorp will accept any sterile swab of appropriate size and configuration with a synthetic tip. This includes Dacron swabs, polyester tip swabs, flocked synthetic swabs, and foam swabs. LabCorp **does not accept** any swabs with calcium alginate tips, swabs with preservatives, and swabs with wooden shafts. We do not recommend cotton tip swabs in UTM/VTM at this time.

Collection should be conducted with a sterile swab. If the applicator handle requires additional trimming, the trimming should be performed with a sterile pair of scissors to prevent contamination of the sample.

**Sterile Saline:** LabCorp can receive OP or NP swabs in 1 mL to 3 mL of sterile normal saline (0.85 to 0.9%) in a sterile screw cap container (it cannot be used for our other respiratory virus testing). Please use the LabCorp-provided materials. Do not use vacutainer or “pop-top” tubes.

**Swabs submitted with sterile saline:** LabCorp will accept any sterile swab of appropriate size and configuration with a plastic handle and a synthetic tip or a cotton tip. This includes Dacron swabs, polyester-tip swabs, flocked synthetic swabs and foam swabs. LabCorp does **not accept** swabs with calcium alginate tips, swabs with preservatives, and swabs with wooden shafts.

Collection should be conducted with a sterile swab. If the applicator handle requires additional trimming, the trimming should be performed with a sterile pair of scissors to prevent contamination of the sample.

**See the online Test Menu at [www.LabCorp.com](http://www.LabCorp.com) for more information, including collection, storage instructions, and causes for rejection.**