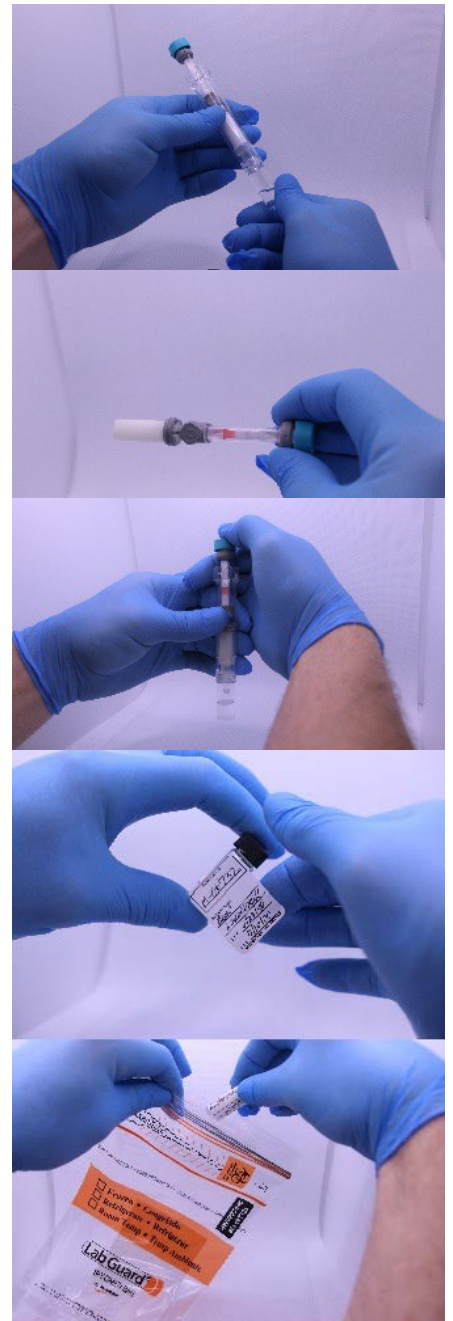


**mLife True™ Oral Fluid/Viral Collection Kit  
Instructions for Use**



**IMPORTANT: Watch Instructional Video before administering the test. Patient should not place anything (including food, drink, gum or tobacco products) in their mouth for at least 15 minutes prior to the procedure. DO NOT BITE, SUCK, OR CHEW ON SWAB. Refrain from talking while collection swab are in mouth.**

1. **Know your kit!** It includes an oral swab, a compression tube, a capped vial with viral deactivation buffer, 2 labels, a specimen bag w/absorbent pad, bubble wrap, a pre-paid shipping label, and corrugated return box. Ensure the kit is not expired.
2. Uncap the vial containing the viral deactivation buffer and screw onto the bottom of the compression tube. Do not spill buffer. **If the buffer contacts any part of the body, flush immediately and completely with water.**
3. Remove swab from compression tube and have patient insert swab into mouth and scrub all surfaces inside mouth (around 30 seconds). Then, have patient put swab in a comfortable position and generate saliva until swab is thoroughly saturated (think of making the swab as wet as possible) and a solid red rectangle indicator bar appears on the swab stem near the swab material. Instruct the patient not to bite, or otherwise squeeze saliva from the swab material.
4. Once the patient has collected a sufficient saliva specimen, the swab should be handed to the HCP. Firmly grip the tube in one hand and insert the swab perpendicularly into the tube with the other hand so the swab enters the funnel gasket (do not let swab hang on the gasket ledge). Using the heel of the hand or thumb(s) steadily push the swab into the tube as far as possible to compress swab and release saliva (observe saliva being released into the vial).
5. Remove the vial from the compression tube and securely tighten cap on the deactivation buffer containing the collected saliva. Shake capped vial for 5 seconds.
6. Fill in label with Specimen I.D. (obtained from Express Gene online portal or paper requisition form), Patient Name, Date of Birth, Date of Collection, and Time of Collection. Apply label with lettering along the length of the vial. Properly discard tube and swab as biohazard waste.
7. Place the labeled vial into the biohazard bag with the absorbent pad and press firmly across the closure to securely zip closed. Collected samples can remain at room temperature prior to shipping.
8. Follow the included shipping instructions to send specimen to Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory for processing. Hand washing IS required by the shipping instructions.



**See Reverse for Instructional Video and Shipping Instructions.**

This product has not been FDA cleared or approved, but been authorized for emergency use by FDA under an EUA for use by authorized laboratories

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.



**mLife True™ Oral Fluid/Viral Collection Kit**

To Access the Instructional Video  
Scan the QR Code:



To Access the Shipping Instructions  
Scan the QR Code:



Or Visit the Link Below:  
[www.mlifedx.com/truevideo](http://www.mlifedx.com/truevideo)

Or Visit the Link Below:  
[www.mlifedx.com/trueinsert](http://www.mlifedx.com/trueinsert)

**Place Barcode Label or Write Specimen ID in this Box:**

**Patient Information**

**(Please Print)**

<b>First Name:</b>	<b>Last Name:</b>
<b>Date of Birth:</b>	<b>Phone Number:</b>

**Email:**

mLife Diagnostics, LLC  
511 N. Washington Avenue  
Marshall, Texas 75670

[info@mlifedx.com](mailto:info@mlifedx.com) [www.mlifedx.com](http://www.mlifedx.com)

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