



## **mLife True™ Oral Collection Kit Product Insert**

### **INTENDED USE AND PRINCIPLES**

The mLife True™ Oral Collection Kit provides for easy-to-use collection of oral samples for laboratory testing. During collection, a swab initially is rubbed vigorously over all surfaces in the oral cavity and material and fluid are collected by the swab. When the swab is sufficiently saturated with oral fluid, the specimen donor will sense the saturation of the swab and also will observe a red indicator stripe appear on the swab stem. The stripe on the swab stem turning from white to red is an indicator of adequate fluid collection, but the donor also should ensure that, after scrubbing the inside surfaces of the mouth, the swab is completely saturated and is not squeezed or compressed prior to removal of swab from the mouth. There may be a tendency for donors to squeeze or suck prior to removal of the swab from the mouth to avoid dripping, but best results are obtained by a fully saturated swab that subsequently is inserted into the collection tube as instructed below. The specimen is deposited in a glass vial with a liquid viral deactivation/RNA preservation buffer (“Buffer”), and the vial is then sealed with a cap and sent to a laboratory for testing.

The Buffer in the mLife True collection kit is designed for ambient storage and transport of total nucleic acids (DNA and RNA) from samples collected using the mLife swab. The Buffer prevents the growth of Gram-negative and Gram-positive bacteria and fungi, and also inactivates viruses allowing the resulting non-infectious samples to be handled and shipped safely. In addition, the Buffer eliminates the need to immediately process or freeze samples and allows the samples to be shipped to centralized testing facilities at ambient temperatures. The components of the Buffer allow DNA samples to be stored at room temperature for over 2 years and RNA samples to be stored at room temperature for over 2 months. Samples collected with the mLife True collection kit and preserved using the Buffer are compatible with most commercially available DNA and RNA isolation methods.

#### **Buffered Sample Specifications**

<b>Kit Specifications</b>	
Stability of DNA at Room Temperature	2 years
Stability of RNA at Room Temperature	2 months

#### **Advantages**

- No need to immediately process samples
- Total DNA, including viral DNA, preserved at room temperature over 2 years
- Total RNA, including viral RNA, preserved at room temperature over 2 months
- Inactivate microorganisms including bacteria, fungi, yeast and viruses
- Ship swab samples at room temperature safely
- Compatible with most DNA and RNA isolation methods

#### **mLife True Collection Kit Materials**

- Orab swab and collection tube; collection tube – polycarbonate (PC); swab – PC + GLS thermoplastic elastomer; cap – HIPS; gasket – LDPE; sponge – CDC approved HRM (PP/PE)
- Glass vial and cap containing a liquid viral deactivation/RNA preservation buffer
- Product Insert
- Instruction Sheet and (optionally) laboratory requisition form and donor consent
- Sealable specimen bag
- Vial label
- Optionally: shipping label, container and instructions

## COLLECTION PROCEDURE

1. Bring collection kit to room temperature (15-30°C/60-86°F) before use. Avoid placing anything (including food, drink, gum and tobacco products) in your mouth for at least 15 minutes prior to specimen collection. Read the Instruction Sheet completely and follow all instructions fully.
2. Unscrew the cap on the vial containing the Buffer. Screw the vial onto the bottom of the collection tube. Ensure not to cross thread the threads of the vial/collection tube and ensure that the vial is properly screwed onto the collection tube. Stand collection tube with vial vertically so as to not spill the Buffer.
3. Force a cough three times into your elbow to move any material in the back of the throat forward in the mouth without expelling this material. Vigorously scrub and sweep/rub the oral swab over all inside surfaces of the oral cavity (cheek, gums, tongue, inside of the lips), including any material moved forward with the coughs. This should be done just long enough to rub over all surfaces in the mouth and be completed within around thirty (30) seconds or so. Thereafter, rest the swab in the mouth in a comfortable position so that you may generate saliva that will be absorbed by the swab. Do not bite, suck, or chew on the sponge or otherwise squeeze or compress the swab, which will release the oral fluid. When the swab is sensed to be sufficiently saturated, look for a red indicator stripe to appear on the swab stem. The stripe on the swab stem turning from white to red is an indicator of adequate fluid collection, but also ensure that it is completely saturated and is not squeezed or compressed prior to removal of the swab from the mouth. Avoid any tendency to squeeze or suck prior to removal of the swab from the mouth to avoid dripping. Best results are obtained with a fully saturated swab, so take whatever time is needed for this to occur.
4. Remove the swab from mouth and insert the swab into the collection tube. In a steady manner push the swab down into the collection tube as far as you can. Note that this should be a slow, steady and firm push – this allows air to vent from the vial while the specimen is being collected and before being sealed by the funnel-shaped gasket. Also note that the top cap just has to be close to even with the swab tube in the final position; this is to ensure that the sponge is squeezed to move the saliva into the vial.
5. Remove the vial from the collection tube and firmly screw the top cap onto the vial. The used tube with the swab may be discarded.

## HANDLING AND SHIPPING

Apply the label to the vial using the alignment marks on the label as a guide to position the label on the vial. The vial label is to be attached to the vial in the instructed manner to ensure that the donor information is visible. Put the capped and labeled vial into the specimen bag and securely close the zip lock on the specimen bag. If there is a laboratory services requisition form (or similar document) provided, please complete it fully and accurately. Results may be delayed if any such form or document is not filled out completely and accurately. Follow instructions for getting your specimen to the lab. Follow the separate instructions for receiving your test result.

## LIMITATIONS

Follow all instructions including with your mLife True™ Oral Collection Kit, including supplemental instructions or safety data included therewith. Do not ingest or spill the Buffer. If the Buffer contacts any part of the body, flush immediately and completely with water. If accidentally ingested, reference the Safety Data Sheet on our website and contact your local poison center. If you have any questions or if you need further information, please contact us as indicated below.



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