



Molecular Diagnostics Laboratory WICHITA STATE UNIVERSITY

Saliva Specimen Collection Instructions

Included in this kit: Pre-labeled sterile tube for saliva collection and biohazard bag with absorbent material.

NOTE: DO NOT eat, drink, smoke, brush teeth, or chew gum at least 30 minutes prior to collection. Saliva collection is intended to be self-administered in a contact-free collection method observed by a trained witness. PPE can be minimized to mask and gloves while maintaining at least 6 feet of separation. Additional PPE as defined by CDC may be worn.

1. Observer provides consent form to patient and confirms consent verbally.
2. Patient provides Observer with 4-digit PIN# needed to access test results.
3. Observer registers specimen using bar code on pre-labeled tube at: mdl.wichita.edu.



4. Patient cleans hands prior to collection with alcohol-based sanitizer or soap and water.
5. Patient should begin to pool saliva in their mouth-use a gentle sucking motion to help move saliva to the middle of the mouth (this should be normal saliva (spit) that collects in the mouth. DO NOT cough or sniffle to collect deep saliva/sputum).

6. Patient removes the lid of the sterile collection container and gently expels (spit) the collected saliva into the tube until the liquid reaches the 1ml mark on the tube (DO NOT include bubbles in the measurement). It is okay if the saliva is above the 1 mark.
7. Patient replaces the lid securely on the collection tube. Failure to properly secure lid may result in specimen rejection or delayed testing.
8. Patient places sample in biohazard bag and securely seals.
9. Patient cleans hands with alcohol-based sanitizer or soap and water. If observer had contact with the patient, then observer cleans hands and changes gloves.
10. Transfer the sample at room temperature to the laboratory for sample processing within 12 hours of collection. If the transport will be delayed more than 12 hours, please refrigerate the sample.



DO NOT use kit if specimen collection tube is damaged or broken.

11/05/2020

NOTICE AND AUTHORIZATION FOR COVID-19 TESTING AND RELEASE OF INFORMATION

In response to the COVID-19 worldwide pandemic and national emergency, the Wichita State University Molecular Diagnostic Laboratory ("MDL") has implemented policies and procedures based on current recommendations from the Centers for Disease Control and Prevention ("CDC") and other state and local public health authorities to ensure the safety of the community. As part of these measures, we ask that you consent and authorize MDL to process a COVID-19 diagnostic test as set forth below.

What are the possible risks and benefits of the test? As with any test, there is a potential for a false positive or false negative result. As such, the test result should not be interpreted as a clinical diagnosis of COVID-19 infection. MDL is not acting as your healthcare provider to provide medical services. A diagnosis can only be made by your healthcare provider after all clinical and laboratory findings are evaluated.

What will you do with my test results? MDL is asking you to authorize the handling of your test results as follows:

- If you agree to it, this authorization will remain in effect until the earlier of: (a) a declaration that the COVID-19 worldwide pandemic and national emergency is over; or (b) twelve (12) months from the date of specimen collection.
- While this authorization is in effect, MDL may access, disclose and use your COVID-19 test result to your healthcare provider, your employer, school, or any other third party requesting that you take this COVID-19 test, and, to the extent required by law, applicable federal, state, or local governmental entities in order to monitor for COVID-19 and promote the health and safety of the community. Please note that any redisclosure of your COVID-19 test result may no longer be protected by federal and state privacy laws.

How will my test results be reported? If you've agreed to the terms and conditions, your test results will be sent to you through **SoftGenePortal from SCC Soft Computer®**. Otherwise, your results will be reported to you by your healthcare provider that ordered the COVID-19 test.

What should I do if I am injured? Due to the coronavirus emergency, the federal government issued an order that may limit your right to sue if you are injured or harmed while participating in testing. If the order applies, it limits your right to sue researchers, healthcare providers, any manufacturer, distributor, including Wichita State University. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program," please visit <https://www.hrsa.gov/cicp>.

- **You agree to allow Wichita State University to process your COVID-19 test.**
- **You have been provided this informed consent to read.**
- **You have verbally consented to the terms in this informed consent and agree to allow your healthcare provider or another person overseeing the sample collection to record your acknowledgement of this informed consent.**
- **You acknowledge that you have been informed about the testing process and its possible risks and benefits.**
- **You also acknowledge that you have been given the opportunity to ask questions before testing and have had them answered to your satisfaction.**

If you agree to the above, please turn to your healthcare provider and verbally say "I agree to the Consent." Your healthcare provider will record your answer in the appropriate health record system for our records.