

APPENDIX

Accessioning SOP for saliva samples collected by the SalivaDirect At-Home Collection Kit

For designated labs to be processed with the SalivaDirect test

For Rx Use Only

For In Vitro Diagnostic Use Only

For Use Under Emergency Use Authorization Only

For individuals 18 years or older

Saliva specimen receipt and accessioning:

1. Collection tubes containing saliva specimens are shipped overnight to the designated SalivaDirect laboratory listed on the activation card in the SalivaDirect At-Home Collection Kit.
2. Upon receipt at the lab, samples are inspected for acceptability (e.g. tube intact and not leaking; shipped according to packaging instructions).
 - Date and time of shipment received must be less than or equal to 56 hours from the date of sample collection.
 - Unacceptable specimens will undergo next steps depending on the issue identified:
 - i. Tubes that are open or damaged with leaked sample, and empty tubes are rejected.
 - ii. Tubes with missing or damaged identifiers are rejected.
 - iii. Non-SalivaDirect At-Home collection tubes are rejected.
3. Specimen information (e.g. date and time of receipt) and verified patient information are logged into the laboratory system for tracking.
4. Specimens are accessioned and tracked with unique sample and patient identifiers. Identifiers are verified on all test orders.
5. Acceptable specimens proceed to testing with the SalivaDirect test after secondary peer review confirming all sample information is correct and matched to the appropriate clinical order.

Warnings

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA;
- This product is authorized only for the collection and maintenance of saliva specimens as an aid in the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;
- 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 medical devices 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.