



<b>SOP Name</b>	Salivary Sample Collection
<b>SOP Identifier</b>	KI001 Salivary Sample Collection
<b>Edition</b>	Version 1
<b>Effective Date</b>	July 11, 2024
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## 1. SCOPE

Collection of salivary samples for VACCELERATE clinical trials

## 2. PURPOSE

To ensure standardized salivary sample collection procedures within the VACCELERATE clinical trial network

## 3. POLICY

VACCELERATE works within the guidelines and regulations of the EU CT Directive 2001/20/EC, GCP Commission Directive 2005/28/EC, ICH/GCP and with all other local and international applicable regulatory requirements.

## 4. ROLES AND RESPONSIBILITIES

It is the responsibility of all staff involved in salivary sample collection from VACCELERATE participants to follow standard procedures, and of the relevant Principal Investigators to ensure that all staff are properly trained.

## 5. DEFINITIONS

N/A

## 6. RELATED DOCUMENTS

- Persisting Salivary IgG Against SARS-CoV-2 at 9 Months After Mild COVID-19: A Complementary Approach to Population Surveys, Alkharaan et al. *J. Infect Dis.* 2021, 224(3):407-414. PMID: 33978762. DOI: [10.1093/infdis/jiab256](https://doi.org/10.1093/infdis/jiab256)
- Salivary IgG to SARS-CoV-2 indicates seroconversion and correlates to serum neutralization in mRNA-vaccinated immunocompromised individuals. Healy et al. *Med*, 2022, 3(2):137-153.e3. PMID: 35075450. DOI: [10.1016/j.medj.2022.01.001](https://doi.org/10.1016/j.medj.2022.01.001)

## 7. PROCEDURES

All saliva samples were processed by a standardized protocol as previously described in the manuscripts listed above in section 5: Related Documents.

- 1) Unstimulated whole saliva was self-collected by fasted study participants as described earlier using standardized picture instructions.
- 2) Participants were instructed to passively drool into a clean cup for five minutes after which the saliva was aliquoted in sterile tubes using a transfer pipette provided by the project.
- 3) Samples are either submitted at the study site or mailed in by overnight post. All samples are immediately placed at 4°C upon arrival thereafter stored at -80°C on the same day.
- 4) Sample relevant info (sample ID, collection date, receiving date etc.) is registered same day in project database/logbook for subsequent linkage to research data.

## 8. REVIEW AND REVISION

Version 1 prepared July 11, 2024.

## 9. DOCUMENT HISTORY

Version Number	Effective Date:	Summary of changes from previous version:	Edited by: (name and role)
01	July 11, 2024		William Martin Matti Sällberg Margaret Sällberg-Chen

## 10. APPENDICES

\*See manuscripts listed above in Section 6: Related Documents.