



SOP Name	Saliva SARS-CoV-2 Antibody Analysis
SOP Identifier	KI002 Salivary Analysis
Edition	Version 1
Effective Date	July 11, 2024
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1. SCOPE

Analysis of salivary samples for VACCELERATE clinical trials

2. PURPOSE

To ensure standardized salivary sample analysis 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

- 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)
- Comparison of SARS-CoV-2 spike-specific IgA and IgG in nasal secretions, saliva and serum. Bladh et al. *Front. Immunol.*, 2024, PMID: 38558811. DOI: [10.3389/fimmu.2024.1346749](https://doi.org/10.3389/fimmu.2024.1346749)

7. PROCEDURES

1. Prior to antibody analysis, saliva samples are thawed at 4°C and centrifuged at 400xg for one minute at 4°C to separate any debris.
2. The supernatant is then transferred to 96-well PCR plates (100 µL/well) and sealed using qPCR foil seals and frozen at - 20°C until antibody analysis.
3. The ability of the thawed saliva to bind SARS-CoV-2 Spike protein (wild-type or mutant variants) or block Spike-protein binding to ACE2, a measure of viral neutralization capacity, is measured using the V-PLEX SARS-CoV-2 Panel 25 or higher (IgG, IgA or ACE2 kits) purchased from Meso Scale Diagnostics (Rockville Maryland, USA). Assays were performed according to manufacturer's instructions.

Total salivary immunoglobulin concentration may be included in a separate measurement for internal standardizations (optional).

8. REVIEW AND REVISION

Version 1 prepared July 11, 2024.

9. DOCUMENT HISTORY

Version Number	Effective Date:	Changes from previous version:	Edited by:
01	July 11, 2024	N/A	William Martin Matti Sällberg Margaret Sällberg- Chen

10. APPENDICES

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