



California Department of Public Health
Viral and Rickettsial Disease Laboratory

March 2021

COVID-19 VACCINE BREAKTHROUGH TESTING GUIDANCE



Appropriate Clinical Specimens for COVID-19 Vaccine Breakthrough Testing

Testing Method	Recommended Specimens
SARS-CoV-2 WGS	Upper Respiratory Specimens (NP, nasal, or OP swabs in VTM, MTM, or saline), or
SARS-CoV-2 virus	Upper Respiratory Specimens (NP, nasal, or OP swabs in VTM only), or
SARS-CoV-2 total or	Serum

Specimen shipment to VRDL requires prior consultation with your local public health department.

Specimen Collection

Respiratory Specimens:

- Original respiratory swabs should be submitted in ≥700 uL of media. Note that viral isolation can only be performed on swabs in VTM, not MTM or saline.
- Nucleic acid extracts of positive specimens may be accepted for WGS but should be clearly indicated as such on the submittal form.

Serum:

- ≥1 mL serum collected from serum (red top) or serum separator (red/gray top) tubes

Specimen Storage

- Respiratory specimens and extracts must be stored at -70°C immediately after collection and shipped on dry ice. Serum may be stored at 4°C and shipped on cold pack or can be frozen with respiratory specimens.
- For questions about specimen collection, submittal, or shipping, please contact the CDPH/Viral and Rickettsial Disease Laboratory (VRDL) Medical and Epidemiology Liaisons (MELs) Unit at VRDL.Mail@cdph.ca.gov.

Surveillance Use Only

SARS-CoV-2 WGS, virus isolation, and neutralizing antibody tests at VRDL are not validated for clinical use. Results are to be used for public health purposes only and may not be reported to the provider or to the patient.

Shipping to the VRDL

To ship approved specimens:

- Electronically complete the [VRDL General Purpose Specimen Submittal Form](#) for EACH SPECIMEN:
 - Test(s) Requested: SARS-CoV-2 vaccine breakthrough
 - Vaccine details: date(s) of administration and manufacturer of SARS-CoV-2 vaccine
 - Laboratory data: include relevant test results and specimen information:
 - real-time RT-PCR viral target(s) Ct values for ORF1ab, N, and S targets, as applicable
 - if the specimen submitted is an original specimen or nucleic acid extract
 - for original specimens, the type of medium used
 - Clinical Findings and Symptoms: symptoms and onset date
- Include hard copy of the VRDL General Purpose Specimen Submittal Form with shipment. Handwritten forms or forms with stickers will not be accepted.
- Notify the VRDL by secure email to VRDL.Mail@cdph.ca.gov.
- Ship approved specimens to:

CDPH VRDL
Attn: Specimen Receiving
850 Marina Bay Parkway
Richmond, CA 94804
- Ship frozen specimens on dry ice for same-day or overnight arrival Monday through Thursday.