ZUCKERBERG
SAN FRANCISCO GENERAL
Hospital and Trauma Center

COVID-19 Testing at ZSFG Clinical Lab

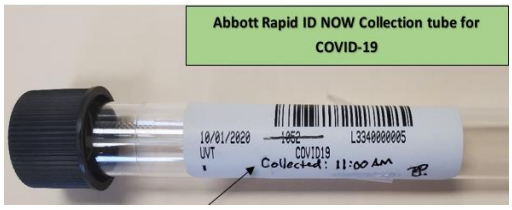
COLLECTION INSTRUCTIONS

DO NOT SEND SPECIMEN USING PNEUMATIC TUBE for ZSFG Bldg. 25 and 5.

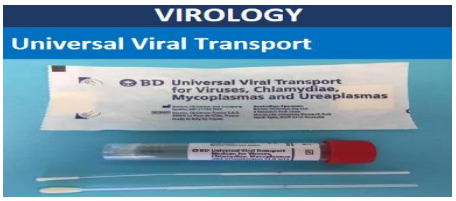
Send specimen directly to Microbiology Lab via messenger or courier service (see exceptions below).

1. **Collection Kit for <u>Abbott Rapid Testing ONLY</u>** (Send to the lab immediately after collection).

   - **Nasopharyngeal**: Insert swab into nostril parallel to the palate, leave swab in place for a few seconds to absorb secretions. Swab both nares with the same swab, if possible. Place swab inside the sterile black top container and secure cap tightly. Place patient label on black top container and write collection time. Immediately deliver the specimen in the Biohazard bag. **Specimens that exceed the 1 hour stability from collection to testing will be rejected and must be recollected. Deliver specimen to Lab STAT window.**



2. **Swabs with UVT (pink solution) for Upper Respiratory Tract collection (**Refrigerate at 2-8°C if transport will be delayed more than 2 hours.) *For ED- deliver specimen to Lab STAT window*.



OR

OR

This collection kit can be tested on the following testing platforms;

- Rapid GeneXpert (~ 1 hour analytical time)
- Abbott M2000 (~8 hours of analytical time, batch testing)
- Quant PCR (~7 hours of analytical time, batch testing)
- Hologic Panther (~5 hours of analytical time)

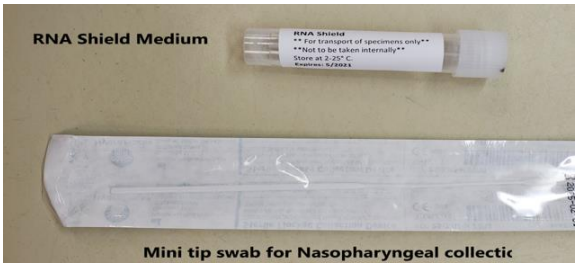
- **Nasopharyngeal**: The NP swab is a mandatory collection. Insert swab into nostril parallel to the palate, leave swab in place for a few seconds to absorb secretions. Swab both nares with

the same swab, if possible.

- **Oropharyngeal:** The OP swab is optional. Swab the posterior pharynx, avoiding the tongue.
- **Place one or both swabs into one UVT tube. Secure cap tightly.**

3. **NP Flock Swab with RNA shield media (clear solution) for Nasopharyngeal collection** (stable at room temperature)

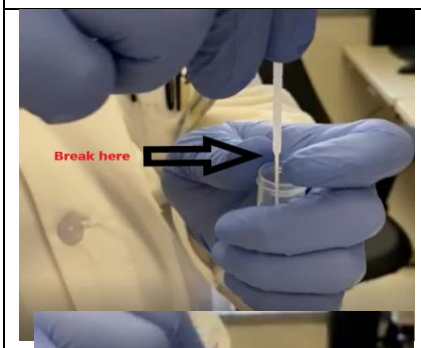
- **Nasopharyngeal:** Insert swab into nostril parallel to the palate, leave swab in place for a few seconds to absorb secretions. Swab both nares with the same swab. Place the swab in the RNA shield tube (clear solution), secure cap tightly and send to the lab.

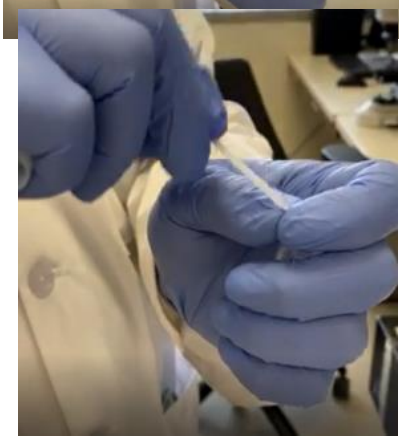


OR

This collection kit can be tested on the following testing platforms;

- Rapid GeneXpert (~ 1 hour analytical time)
- Abbott M2000 (~8 hours of analytical time, batch testing)
- Quant PCR (~7 hours of analytical time, batch testing)





1) After collecting the swab from the patient, partially insert the swab inside the tube, exposing the point where the plastic shaft narrows.

2) Use your thumb and pointer finger to grasp the shaft at the narrow point and bend the swab handle back and forth until it breaks. The swab should break easily after several swivels.

NOTE: Avoid breaking the swab at the scored point of the shaft. Doing so will create a swab that is too long to fit into the collection tube. Do not try and force a swab to fit into the tube, as it may inadvertently fly out during capping or re-opening of the tube.

Click on the link below for a video demonstration:

http://sfghdean.ucsf.edu/ClinLab/NP_and_RNA_shield_instruction.mp4

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4. SELF SWAB Collection Kit for Employee Testing ONLY (Follow instructions on the kit).

OR

This collection kit can be tested on the following platforms;

- Rapid GeneXpert (~ 1 hour analytical time)
- Abbott M2000 (~8 hours of analytical time, batch testing)
- Quant PCR (~7 hours of analytical time, batch testing)

COVID TEST RESULTS

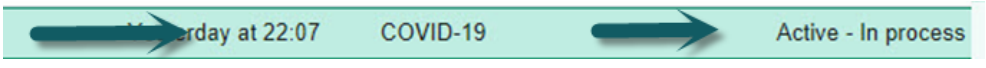
The Clinical Laboratory at Zuckerberg San Francisco General Hospital provides testing with a turnaround time of less than 24 hours for routine tests and less than 1.5 hours for rapid tests. The COVID-19 result will be available in Epic as soon as testing has been completed.

Reference Range: Not Detected or Negative

Test Interpretation: Negative (Not Detected) results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

Note: Refer to RAPID ABBOTT ID NOW Test Limitations in the Technical Brief below

To determine status of testing in Epic, refer to **COVID-19** order status in the table below.

Example: 

Active – Collected (Date + Time)	√ Specimen has been **collected** X Specimen has **not been** received in the lab (in transport or waiting for transport)
Active – In process	√ Specimen has been **collected** √ Specimen has been **received** in the lab X Testing is **in progress** AND is **not** complete

Completed – Final result	√ Specimen has been **collected** √ Specimen has been **received** in the lab √ Testing has been **completed**; result is **final**
Completed – Edited Result – FINAL	√ Specimen has been **collected** √ Specimen has been **received** in the lab √ Testing has been **completed**; result was **edited.**

TURN AROUND TIME

(from time of specimen receipt to result time)

1. ***ZSFG Clinical Laboratory***:
   a. ***Abbott Rapid testing –*** less than 1 hour (average of 30 minutes)
   b. ***GeneXpert Rapid testing –*** less than 1.5 hours (average of 1 hour)
   c. ***Hologic Panther Rapid Testing –*** average of 5 hours
   d. ***COVID Routine testing (Abbott M2000 and Quant Studio) –*** less than 24 hours
2. ***SFDPH Laboratory***: 1 – 3 days. For results, check EPIC or to inquire about status of testing, call 415-554-2800**.**
3. ***UCSF Clinical Laboratory***: 1-3 days

Technical Brief - September 2020
ID NOW COVID-19 Labeling Updates

Over the past several months, Abbott has been working closely with the FDA on post-authorization clinical studies for our on-market ID NOW COVID-19 product. As these interim results have been reviewed, data indicates that molecular testing using ID NOW performs best when used within 7 days of symptom onset, affirming the critical role played by rapid tests in helping to slow the spread of COVID-19 in early detection of the SARS CoV-2 virus.

Given Abbott's intention for ID NOW to be used at the point of care, our sample collection guidance on our product insert has been modified to one hour at room temperature and guides customers to test immediately or store in a clean unused tube for best performance.

The following Product Insert change will be effective immediately. We anticipate this change to be implemented in **ID NOW COVID-19 (PN: 190-000)** labeling the week of September 28th with the following four areas updated and detailed below.

1. **The ID NOW™ COVID-19 Intended Use will be updated to state the following:**
   ID NOW COVID-19 assay performed on the ID NOW Instrument is a rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19 by their healthcare provider **within the first seven days of the onset of symptoms.** Testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests. The ID NOW COVID-19 assay is also authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

2. **The ID NOW COVID-19 Specimen Storage and Transport will be updated to state the following:**
   For best performance, direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, **and to maintain best performance, it is highly recommended the nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30°C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing.**

   If the swab is to be returned to its package for transport, carefully return to allow the swab head to only come into contact with the lower portion of the packaging. Avoid touching the outside of the wrapper with the swab.

3. The ID NOW COVID-19 Conditions of Authorization language was updated to reflect recent EUAs with no change to the conditions.

4. The ID NOW COVID-19 Analytical Studies now includes the results of an ID NOW evaluation of FDA SARS-CoV-2 Reference Panel. All 58 EUA manufacturers were asked by the FDA to participate in this evaluation and results are now publicly available as of September 16, 2020 on the FDA website.

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The results are summarized in the table below.

Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Nasopharyngeal Swab	$3.0x10^5$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL
N/A: Not applicable
ND: Not detected

After completion of our post-authorization clinical study, we will update the ID NOW COVID-19 Product Insert with final clinical study results and will provide additional customer communications at that time.

We appreciate your continued interest and support of Abbott ID NOW products to help fight the COVID-19 pandemic.