

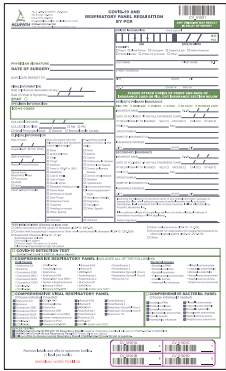
COVID-19 (SARS-CoV-2) Nasopharyngeal Specimen Collection

Please read all instructions before starting COVID-19 Collection

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results.

The kit is provided for the detection and/or diagnosis of COVID-19 and is performed under the FDA Emergency Use Authorization (EUA), under Section 564 (b)(1) of the Act 21, U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Specimen Collection Kit Contents:



Requisition



Nasopharyngeal swab with synthetic flocked fiber tip



Sterile specimen transport container with 3 mL Viral Universal Transport Medium (UTM)



Biohazard bag for returning specimen

For Out of State Clients:



UPS label



Frozen ice pack

Directions:



1. Insert swab into one nostril until tip reaches posterior nasopharynx (half way between nostrils and outer opening of ear)

2. Rotate swab over surface of posterior nasopharynx



3. Withdraw swab from collection site

4. Place swab immediately into UTM transport tube and close



5. Hand write the required information on the transport media tube. (The label must contain at a minimum last and first name of the patient/employee.)

6. Immediately transport specimen to the laboratory

If transport is delayed by 24hrs place specimen on ice or in refrigerator

To learn more or order kits please contact us:
COVID19@acupath.com (516) 775-8103 WWW.ACUPATH.COM



COVID-19 (SARS-CoV-2) Nasopharyngeal Specimen Collection Instructions

IMPORTANT INFORMATION PRIOR TO SENDING COVID-19 SAMPLES TO ACUPATH LABORATORIES, INC.

Fill out the requisition form.

On the right side of the form, the following information is mandatory for reporting results to the local health departments.

- Date of Birth
- Patient Gender
- Ethnicity
- Patient name
- Patient Address
- Patient Phone Number
- Insurance
- Date of collection
- Check COVID-19 testing
- Provide a face sheet with insurance information for the patient/employee
- Place the transport media into the specimen bag
- Place the requisition in the pouch of the specimen bag.

COVID-19 AND PATHOLOGY PANEL REQUISITION BY PCR

CV_01001

ANY OMISSION MAY RESULT IN DELAY OF REPORT

PATIENT INFORMATION

SS# _____ DATE OF BIRTH _____ M F

ETHNICITY
 Asian Black/African Caucasian Hispanic/Latin Native American
 Pacific Islander Prefer not to Answer Other: _____

LAST NAME _____ FIRST NAME _____ M.I. _____

STREET ADDRESS _____

CITY _____ STATE _____ ZIP _____

TEL. # _____ CHART # _____ PATH # _____

PLEASE ATTACH COPIES OF FRONT AND BACK OF INSURANCE CARD OR FILL OUT INSURANCE SECTION BELOW

PATIENT'S PRIMARY INSURANCE
BILL TO: MEDICARE PATIENT OTHER NO FAULT WORKERS COMP
INSURED'S NAME _____ D.O.B. ____/____/____
DATE OF ACCIDENT (IF NO FAULT/WORKERS COMP) ____/____/____
PT RELATIONSHIP TO INSURED: SELF SPOUSE CHILD OTHER
POLICY # _____ SS# _____
GROUP NAME# _____
NAME OF INSURANCE CO. _____
INSURANCE ADDRESS _____
CITY _____ STATE _____ ZIP _____

SECONDARY INSURANCE
INSURED'S NAME _____ D.O.B. ____/____/____
DATE OF ACCIDENT (IF NO FAULT/WORKERS COMP) ____/____/____
PT RELATIONSHIP TO INSURED: SELF SPOUSE CHILD OTHER
POLICY # _____ SS# _____
GROUP NAME# _____
NAME OF INSURANCE CO. _____
INSURANCE ADDRESS _____
CITY _____ STATE _____ ZIP _____

I authorize the release to my insurance carrier of any medical information necessary to process this claim, and I authorize payment of medical benefits directly to Acupath Laboratories, Inc. I understand that if I do not have insurance, I will be billed directly by Acupath Laboratories, Inc.

I also authorize release of my pathology results to my doctor utilizing all methods of transmission according to HIPAA regulations.

Patient Signature _____

Call Acupath For a Pickup 516-775-8103

- Place all specimen bags in a large transport bag provided by Acupath
- Keep specimens refrigerated until it is time for a pick up
- Then place in specimen box

If You Are an Out of State Customer Follow the Additional Instructions Below

- Place specimens in a cooler with a frozen ice pack that Acupath provided
- Seal the cooler with tape
- Place the cooler in the box provided by Acupath and seal the box with tape
- Place the UPS label provided by Acupath on the box, and affix with tape
- EMAIL pickup@acupath.com or CALL UPS OR ACUPATH 1(888) 228-7284 FOR A PICK UP
DO NOT DROP IN A UPS COLLECTION BOX

Results are generally reported within 24-48 hours of receiving the samples at Acupath Laboratories, Inc.



COVID-19 (SARS-CoV-2) Nasopharyngeal Specimen Collection Instructions

Guidelines for Collection, Handling, Storage and Shipping of COVID-19 Specimens

Collecting the Specimen

Training in specimen collection is highly recommended due to the importance of specimen quality

Swab Specifications

Follow specimen collection device manufacturer instructions for proper collection methods

Acupath only uses COPAN FLOQSwabs® in their kits. A FLOQSwab® is a flocked swab that consists of a molded plastic applicator stick with a variable size and shape tip. The tip of the applicator is coated with short Nylon® fibers that are arranged in a perpendicular fashion. (Add image of swab from kit)

Transport System and Transport Media

- The supplied sterile specimen transport container is a polypropylene screw-cap filled with 3 mL of phosphate buffered saline as the virus transport media
- 1 mL of Viral transport media may result in a QNS

Storing Specimens

- Specimens can be stored at 2-8°C for up to 72 hours after collection
- If a delay in extraction is expected, store specimens at -70°C or lower
- Extracted nucleic acid should be stored at -70°C or lower

When Sending COVID-19 Specimens

- Specimens must be packaged, shipped, and transported according to IATA Dangerous Goods Regulation
- Follow regulations for UN 3373 Biological Substance, Category B
- Store specimens at 2-8°C and ship overnight to Acupath on ice pack
- If a specimen is frozen at -70°C or lower, ship overnight to Acupath Laboratory on dry ice

Reasons For Rejecting A Specimen On Receipt At Acupath

- Requisition not labeled according to the NYS/FDA guidelines
- Glass tubes/containers
- Improperly labeled, grossly contaminated, broken or leaking transport device
- Tube is not labeled
- No swab is present
- Cotton-tip swabs in UTM/VTM
- Swabs with calcium alginate
- Swabs with wooden shafts
- Collection with substances inhibitory to PCR including heparin, hemoglobin, ethanol, EDTA contamination >0.01M
- Refrigerated samples greater than 72 hours old
- Room temperature swabs greater than 24 hours old

For additional information on Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods CLSI MM13-A may be referenced as an appropriate resource. [https://clsi.org/standards/products/molecular-diagnostics/documents/mm13/Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation \(PUIs\) for 2019 Novel Coronavirus \(2019-nCoV\)](https://clsi.org/standards/products/molecular-diagnostics/documents/mm13/Interim%20Guidelines%20for%20Collecting,%20Handling,%20and%20Testing%20Clinical%20Specimens%20from%20Patients%20Under%20Investigation%20(PUIs)%20for%202019%20Novel%20Coronavirus%20(2019-nCoV))<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.htm>

Acupath Laboratories, Inc
Acupath COVID-19 Real-Time (RT-PCR) Assay
Acupath Laboratories is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.
The following information is available to healthcare providers and patients on the Acupath website:
•Fact Sheet for Healthcare Providers: Molecular Laboratory Developed Test (LDT) COVID-19 Authorized Tests
•Fact Sheet for Patients: Molecular Laboratory Developed Test (LDT) COVID-19 Authorized Tests
<https://www.acupath.com/covid-19-testing/>

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