



MOLECULAR DIAGNOSTICS

1 ACCOUNT INFORMATION

The ordering physician must sign his/her name and indicate the date the test is ordered. The signature constitutes as a certification, that with respect to tests reimbursed by Medicare, Medicaid, or other third party payers that the testing is medically necessary and the results will be used in the management of the patient.

X
Physician Signature _____ Date _____

2 PATIENT INFORMATION

| | | | |
|------------------|--|--|-----|
| Last Name | | First Name | |
| D.O.B (MM/DD/YY) | | Sex <input type="checkbox"/> M <input type="checkbox"/> F | |
| Phone (Day) | | (Evening) | |
| Address | | | |
| City | | State | Zip |

THIS SECTION IS TO BE COMPLETED BY A CLINICIAN

VALIDATED RISK ASSESSMENT LOW MODERATE HIGH The clinician must always document clear medical reason and necessity in progress notes.

REASON FOR TEST Respiratory Failure Cough Chills Hypoxia Joint Pain Muscle Pain No sense of taste or smell
 Fever Nasal Discharge (Rhinorrhea) Chest Pain Sore Throat Fatigue Shortness of Breath Body Ache

3 INSURANCE INFORMATION

Client Bill See Attached Insurance Forms

Insured's Name (if different from Patient) _____ Policy ID # _____

Primary Insurance Name & Plan / Workers Comp. Carrier _____ Group/Plan/Book # _____

Address (Insurance) _____

Cash Check Received by: _____

SPECIMEN INFORMATION

Specimen Source: Nasopharyngeal Swab
 Throat Swab (Only for 4020(SARS-COV-2))

Date Collected: ____ / ____ / ____

Time: ____ : ____ AM PM

Collector: _____

4 DIAGNOSIS CODES

- | | | |
|--|--|--|
| <input type="checkbox"/> R07.0 Pain in throat | <input type="checkbox"/> J11.1 Influenza due to unidentified influenza virus with other respiratory manifestations | <input type="checkbox"/> J15.7 Pneumonia due to Mycoplasma pneumoniae |
| <input type="checkbox"/> J02.9 Acute pharyngitis, unspecified | <input type="checkbox"/> J21.1 Acute bronchiolitis due to human metapneumovirus | <input type="checkbox"/> J12.2 Parainfluenza virus pneumonia |
| <input type="checkbox"/> J20.8 Acute bronchitis due to other specified organisms | <input type="checkbox"/> B97.0 Adenovirus as the cause of diseases classified elsewhere | <input type="checkbox"/> B97.4 Respiratory syncytial virus as the cause of diseases classified elsewhere |
| <input type="checkbox"/> J18.9 Pneumonia, unspecified organism | <input type="checkbox"/> J18.8 Other pneumonia, unspecified organism | <input type="checkbox"/> B34.8 Other viral infections of unspecified site |
| <input type="checkbox"/> J16.0 Chlamydial pneumonia Adenovirus infection, unspecified | <input type="checkbox"/> B34.2 Coronavirus infection, unspecified | <input type="checkbox"/> R06.02 Shortness of breath |
| <input type="checkbox"/> B34.0 infection, unspecified | <input type="checkbox"/> B97.81 Human metapneumovirus as the cause of diseases classified elsewhere | <input type="checkbox"/> R50.9 Fever, unspecified |
| <input type="checkbox"/> B97.4 Respiratory syncytial virus as the cause of diseases classified elsewhere | | <input type="checkbox"/> R05 Cough |
| | | <input type="checkbox"/> R53.83 Other fatigue |
| | | <input type="checkbox"/> Z20.828 Contact with and (suspected) exposure to other viral communicable diseases |
| | | <input type="checkbox"/> Z03.818 Encounter for observation for suspected exposure to other biological agents ruled out |

ICD 10 CODES Please enter diagnosis code(s) in the box
_____, _____, _____, _____

PLEASE NOTE: This resource is provided for informational purposes only and does not guarantee that billing codes will be appropriate or that coverage and reimbursement will result. Providers should consult with their payers for all relevant coverage coding and reimbursement requirements. It is the sole responsibility of the provider to select proper codes. This resource is not intended as legal advice or a substitute for a provider's independent professional judgement. Clarity Laboratories, LLC, assumes no liability for the results or consequences associated with the use of this quick reference guide and makes no representation, warranty, or guarantee as to the accuracy or validity of any of the information contained herein. For comprehensive coding guidance see complete ICD-10-CM code set and Official Coding Guidelines, 2017 edition.

5 TEST SELECTION

- RPP1 (RESPIRATORY PATHOGEN PANEL)* RPPV (RESPIRATORY VIRUS PANEL) RPP2 (RPP1* with (SARS-COV-2)) **RESPIRATORY BACTERIA TESTS**
- 4020 (SARS-CoV-2)** (Novel Coronavirus for COVID-19) RPP3 (RPP1* w/ reflex to 4020(SARS-CoV-2))** RPPM Mycoplasma Pneumoniae
- 4050 (SARS-CoV-2** w/ reflex to RPP1*) 4051 (SARS-CoV-2 IgG AntiBody) [SST] RPPB Bordetella Pertussis
- RPP5 (Inf A, Inf B, RSV, SARS-CoV-2) RPPC Chlamydomphila Pneumoniae

VIRUSES: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus A/B, Influenza A subtype H1, Influenza A subtype H1N1/2009/pdm09, Influenza A subtype H3, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial Virus A/B, Rhinovirus/Enterovirus.

BACTERIAS: Bordetella pertussis, Chlamydomphila pneumoniae, Mycoplasma pneumoniae

6 PATIENT CONSENT

PATIENT CONSENT REIMBURSEMENT: Clarity Labs (CL) will make every reasonable effort to obtain reimbursement for the ordered tests above. I hereby authorize CL to release to Medicare and/or any insurance carrier providing medical benefits to me and any health plan to which I am a member any and all medical or other information necessary for claims purposes. I hereby authorize payment of medical insurance benefits to the party who bills for these claims and accepts assignments. I understand that if my insurance company pays me directly for the services provided by CL that I am responsible for forwarding such payment to CL. I understand that I am responsible for any outstanding balances, deductible/co-payments as required by my plan. By signing this I have read all of the above and understand it. Medicare Advance Beneficiary Notice: I have read the ABN on the bottom of this form. If Medicare denies payment, I agree to pay for the identified test(s). I understand that CL may use my specimen and any testing performed on that specimen, for research, development, and potential publication purposes, so long as the information has been properly de-identified pursuant to law.

X
PATIENT NAME (please print) _____ PATIENT SIGNATURE _____ DATE _____

IMPORTANT MEDICARE INFORMATION TO THE BENEFICIARY: ADVANCED BENEFICIARY NOTICE (ABN)
Your physician may sometimes order laboratory testing that he or she believes to be necessary for your care, but which does not qualify for coverage under your Insurance Provider's and Medicare's standards. Insurance Providers and Medicare will only pay for services that it determines to be "reasonable and necessary" based upon the diagnosis information furnished to Clarity Laboratory by your physician. If, under your Insurance Provider's and Medicare's standards, your diagnosis does not support the testing ordered, your Insurance Providers and Medicare will deny coverage. In those cases where your Insurance Providers and Medicare denies coverage, the billing will be forwarded to you, and you will be responsible for the cost of the laboratory tests.

FOR LAB USE ONLY
Date: ____ / ____ / ____
Received by: _____ Time: ____ : ____ AM PM

FOR LAB USE ONLY

SPECIMEN REQUIREMENTS

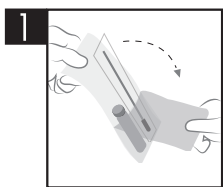
| | | |
|--|---|---|
| <p>SPECIMEN SOURCE Nasal, Throat</p> <p>COLLECTION MEDIA Nasopharyngeal Swab (UTM Swab) Oropharyngeal Swab (Eswab) Serum Separation Tube (SST)</p> <p>SPECIMEN PREPARATION Place the swab in Universal Transport Media (UTM) or ESwabs. Place each specimen in an individually sealed bag</p> | <p>UNACCEPTABLE CONDITIONS Specimens not in Universal Transport Media (UTM) or ESwabs Broken Sample Collection Tubes</p> <p>TURN AROUND TIME 24 hours</p> <p>TEST PERFORMED 7 days</p> | <p>Nasopharyngeal specimen's storage condition is listed below:</p> <ul style="list-style-type: none"> • Room temperature up to 4 hours (15-25 C) • Refrigerated up to 3 days at 2-8 C • Frozen sample up to 30 days at -15 to -25 C <p>Clarity labs recommends all samples collected must be stored in a refrigerator prior to courier handling. When storing samples in the specimen box or shipping out by Fed-Ex or UPS, the UTM SWAB must be stored with cold pack.</p> |
|--|---|---|

SPECIMEN REQUIREMENTS for 4051(SARS-CoV-2 IgG Antibody)

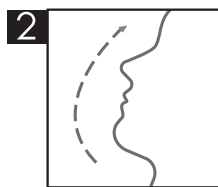
| | | |
|---|---|---|
| <p>SPECIMEN SOURCE Blood</p> <p>COLLECTION MEDIA Serum Separation Tube (SST)</p> <p>UNACCEPTABLE CONDITIONS Broken Sample Collection Tubes</p> | <p>TURN AROUND TIME 24 - 48 hours</p> <p>TEST PERFORMED 7 days</p> <p>SST specimen's storage condition:</p> <ul style="list-style-type: none"> • Frozen sample up to 30 days at -15 to -25 C | <ul style="list-style-type: none"> • Room temperature up to 4 hours (15-25 C) • Refrigerated up to 3 days at 2-8 C <p>Clarity labs recommends all samples collected must be stored in a refrigerator prior to courier handling. When storing samples in the specimen box or shipping out by Fed-Ex or UPS, the SST must be stored with cold pack.</p> |
|---|---|---|

Nasopharyngeal and Oropharyngeal Swab SPECIMEN COLLECTION PROCEDURE

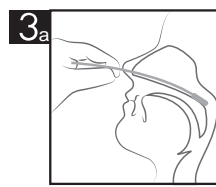
Proper collection and handling of patient specimens are of utmost importance in respiratory virus detection.



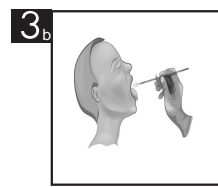
1 Open the sterile, flexible minitipped swab package and remove the swab.



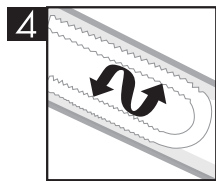
2 Tilt the patient's head back (head should be inclined from vertical)



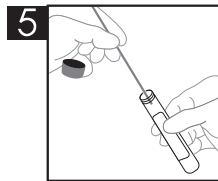
3a Gently insert the sterile swab along the nasal septum just above the floor of the passage to the nasopharynx until resistance is met.



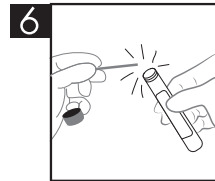
3b This step is recommended only for 4020(SARS-COV-2) in addition to step 3a. Sticking out the patient's tongue, use a sterile swab to swab the posterior nasopharynx and tonsillar arches. (Proceed to step-5)



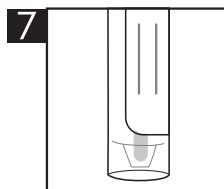
4 Rotate the swab gently against the nasopharyngeal mucosa for 10-15 seconds and gently remove the swab.



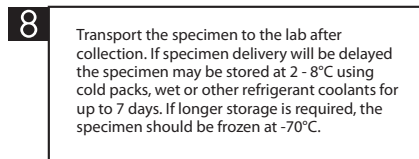
5 Insert the swab into the UTM tube pushing it all the way to the bottom of the tube.



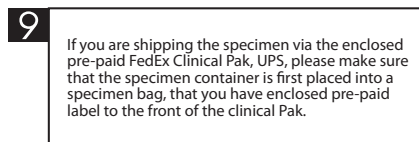
6 Holding the swab shaft close to the rim of the tube and point the tube away, break the swab shaft along the prescored breakpoint indentation.



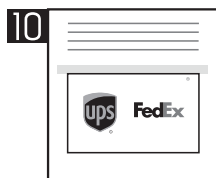
7 Label specimen appropriately including two patient identifiers, (e.g. patient name, and date of birth), specimen source and date and time of collection.



8 Transport the specimen to the lab after collection. If specimen delivery will be delayed the specimen may be stored at 2 - 8°C using cold packs, wet or other refrigerant coolants for up to 7 days. If longer storage is required, the specimen should be frozen at -70°C.



9 If you are shipping the specimen via the enclosed pre-paid FedEx Clinical Pak, UPS, please make sure that the specimen container is first placed into a specimen bag, that you have enclosed pre-paid label to the front of the clinical Pak.



10 UPS, FedEx or Call Clarity Labs for pick-up service.

NOTE: When using the Clarity Labs courier, please ensure that specimen is in the specimen box with a refrigerated cold pack. Courier pickup is available seven days a week.