ClarityLabs
Testing for Better Health

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CLIA # 31D2140149

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 repsect 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 ☐ M ☐ F

Phone (Day) (Evening)

Address

City State Zip

THIS SECTION IS BE TO 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 ☐ Fever ☐ Cough ☐ Nasal Discharge (Rhinorrhea) ☐ Chills ☐ Chest Pain ☐ Hypoxia ☐ Sore Throat ☐ Joint Pain ☐ Fatigue ☐ Muscle Pain ☐ Shortness of Breath ☐ No sense of taste or smell ☐ 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

☐ R07.0	Pain in throat	☐ J11.1	Influenza due to unidentified influenza virus with other respiratory manifestations	☐ J15.7	Pneumonia due to Mycoplasma pneumoniae
☐ J02.9	Acute pharyngitis, unspecified			☐ J12.2	Parainfluenza virus pneumonia
☐ J20.8	Acute bronchitis due to other specified organisms	☐ J21.1	Acute bronchiolitis due to human metapneumovirus	☐ B97.4	Respiratory syncytail virus as the cause of diseases classified elsewhere
☐ J18.9	Pneumonia, unspecified organism	☐ B97.0	Adenovirus as the cause of diseases classified elsewhere	☐ B34.8	Other viral infections of unspecified site
☐ J16.0	Chlamydial pneumoniaAdenovirus			☐ R06.02	Shortness of breath
☐ B34.0	infection, unspecified	☐ J18.8	Other pneumonia, unspecified organism	☐ R50.9	Fever, unspecified
☐ B97.4	Respiratory syncytial virus as the cause of diseases classified elsewhere	☐ B34.2	Coronavirus infection, unspecified	☐ R05	Cough
		☐ B97.81	Human metapneumovirus as the cause of diseases classified elsewhere	☐ R53.83	Other fatigue
				☐ Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
				☐ 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 quide 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)**

☐ **4020(SARS-CoV-2)** (Novel Coronavirus for COVID-19)** ☐ **RPP3 (RPP1* w/ reflex to 4020(SARS-CoV-2))****

☐ **4050 (SARS-CoV-2**w/ reflex to RPP1*)** ☐ **4051 (SARS-CoV-2 IgG AntiBody) [SST]**

☐ **RPP5 (Inf A, Inf B, RSV, SARS-CoV-2)**

RESPIRATORY BACTERIA TESTS

☐ **RPPM** Mycoplasma Pneumoniae

☐ **RPPB** Bordetella Pertussis

☐ **RPPC** Chlamydophila Pneumoniae

VIRUSES: Adenovirus, Coronavirus 229E, CoronavirusHKU1, 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, Chlamydophila 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 providingmedical 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 responsiblefor 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 thisfrom. 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 BENIFICIARY NOTICE (ABN)

Your physician may sometimes order laboratory testing that he or she believes to be necessary for your care, but which does not quality 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

SPECIMEN SOURCE
Nasal, Throat

COLLECTION MEDIA
Nasopharyngeal Swab (UTM Swab)
Oropharyngeal Swab (Eswab)
Serum Seperation Tube (SST)

SPECIMEN PREPARATION
Place the swab in Universal Transport Media (UTM) or ESwabs. Place each specimen in an individually sealed bag

UNACCEPTABLE CONDITIONS
Specimens not in Universal Transport Media (UTM) or ESwabs
Broken Sample Collection Tubes

TURN AROUND TIME
24 hours

TEST PERFORMED
7 days

Nasopharyngeal specimen's storage condition is listed below:
- 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

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.

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

SPECIMEN SOURCE
Blood

COLLECTION MEDIA
Serum Seperation Tube (SST)

UNACCEPTABLE CONDITIONS
Broken Sample Collection Tubes

TURN AROUND TIME
24 - 48 hours

TEST PERFORMED
7 days

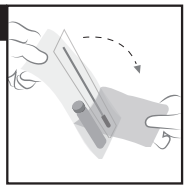
SST specimen's storage condition:
- Frozen sample up to 30 days at -15 to -25 C
- Room temperature up to 4 hours (15-25 C)
- Refrigerated up to 3 days at 2-8 C

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.

Nasopharyngeal and Oropharyngeal **Swab**
SPECIMEN COLLECTION PROCEDURE

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

1

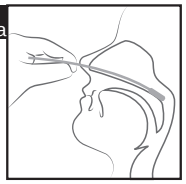


Open the sterile, flexible minitipped swab package and remove the swab.

2

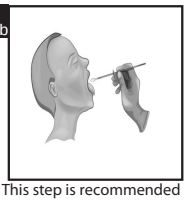
Tilt the patient´s head back (head should be inclined from vertical)

3a



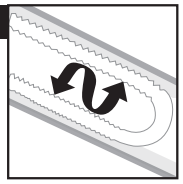
Gently insert the sterile swab along the nasal septum just above the floor of the passage to the nasopharynx until resistance is met.

3b



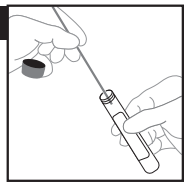
This step is recommended onlyfor4020(SARS-COV-2) in addition to step 3a. Sticking out the patient's tongue, use a sterile swab to swab the posterior nasopharynx and tonsillar arches. (Proceed to step-5)

4



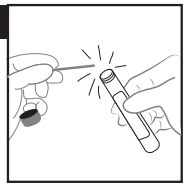
Rotate the swab gently against the nasopharyngeal mucosa for 10-15 seconds and gently remove the swab.

5



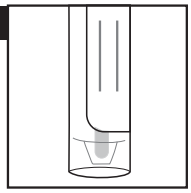
Insert the swab into the UTM tube pushing it all the way to the bottom of the tube.

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

8

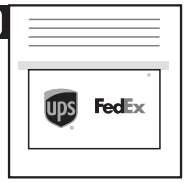
Transport the specimen to the lab after collection. If specimen delivery will be delayed the specimen may be stored at 2 - 8°C using cold packs, wet or other refrigerant coolants for up to 7 days. If longer storage is required, the specimen should be frozen at -70°C.

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.

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.

10



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