IN THE SUPERIOR COURT OF GWINNETT COUNTY
STATE OF GEORGIA

JANE DOE 1, JANE DOE 2, JANE DOE 3, and JOHN DOE 1 Plaintiff, v. LANDMARK HOSPITAL OF ATHENS, LLC. Defendant.	20-A-04131-3 CIVIL ACTION FILE NO. _____ **JURY TRIAL DEMANDED**

PETITION FOR TEMPORARY RESTRAINING ORDER AND INTERLOCUTORY INJUNCTION

COMES NOW Jane Does 1-3 and John Doe ("Plaintiffs") and files this Petition for an Emergency Restraining Order and Injunctive Relief against Landmark Hospital of Athens, LLC, ("Landmark") pursuant to O.C.G.A. 9-11-65, and other applicable law for the reasons set forth herein:

INTRODUCTION

This action seeks immediate court intervention to stop Defendant Landmark Hospital from concealing and mishandling a COVID-19 outbreak in their facility, and to prevent Defendant Landmark from receiving patients into their facility or discharging or transferring patients out of their facility. Specifically, Defendant Landmark Hospital has undertaken a scheme to purposefully obtain "false negative" test results of patients who had previously tested positive for COVID-19. Defendant Landmark's medical staff including the Plaintiffs and others not bringing this action have voiced their concerns to Defendant Landmark's administration and their cries have been ignored. Defendant Landmark's acts and omissions have created a public health risk to the patients

of Defendant Landmark as well as the patient's families, staff at Defendant Landmark, their families and the staff of outside facilities that patients are transferred to for care. Governor Brian Kemp entered an executive order on April 14, 2020 ordering that employees, staff and contractors of healthcare institutions be considered auxiliary emergency management workers pursuant to O.C.G.A. 38-3-35. Pursuant to O.C.G.A. 38-3-35 (b), immunity does not extend to Defendant Landmark for willful misconduct, gross negligence or bad faith. Therefore, this Court is within its power to respond to the allegations herein.

The scheme that Defendant Landmark has used to fabricate false negative COVID-19 test results is set forth below.

1.

Plaintiffs are residents of Georgia and are currently or previously employed at Defendant Landmark Hospital.

2.

Defendant Landmark is a domestic corporation duly registered to do business in the State of Georgia and is subject to the jurisdiction of this Court. Defendant may be served by delivering a copy of the Summons and Complaint to its registered agent: Corporation Service Company, 40 Technology Pkwy South, #300, Norcross, GA 30092.

3.

Venue is proper as to the Defendant.

4.

Landmark owns and operates a hospital at 775 Sunset Drive, Athens, Clarke County Georgia. Landmark is licensed by the State of Georgia to accept up to 42 patients. See O.C.G.A. § 31-7-1; Exhibit A.

5.

Landmark is a 42-bed critical care hospital.

6.

Critical care hospitals fall under the general hospital classification. Ga. Comp. R. & Regs. r. 111-8-40-.03.

7.

Landmark does not offer "emergency room" services. Instead, other facilities refer patients to Landmark for critical care services. Patients at Landmark typically stay several weeks but sometimes for months or years. Landmark typically transfers or discharges its patients to other hospitals, nursing homes, or patients' homes.

8.

As a hospital, Landmark is subject to the rules and regulations of the Georgia Department of Community Health. O.C.G.A. § 31-7-2.1.

9.

Pursuant to regulatory requirements, Landmark must have on staff an administrator or chief executive officer who is responsible for the overall management of the hospital. Marie Saylor is employed in this role. Ga. Comp. R. & Regs. r. 111-8-40-.09.

10.

Landmark is required to have a quality management program. Kimberly Wilkinson directs this program. Ga. Comp. R. & Regs. r. 111-8-40-.13.

11.

Dr. Anthony Sagel is the Chief Medical Officer of the Hospital. He has no board certification.

12.

Dr. Mark Visitacion directs the infectious disease treatment and prevention of the Hospital. He is board certified in internal medicine.

13.

Landmark is required to have an effective infection control system to reduce the risks of hospital-acquired infections in patients, health care workers, volunteers, and visitors which shall include:

- The availability of microbiology laboratory capacity to detect and investigate outbreaks;
- A system for obtaining appropriate clinical specimens for culture;
- Access to necessary information in order to investigate infectious outbreaks; and
- Administrative, physician, and nursing support to direct hospital changes to achieve immediate control of outbreaks and for implementation of corrective actions. See Ga. Comp. R. & Regs. r. 111-8-40-.16.

14.

Plaintiffs are currently or previously employed as nurses at Landmark. Plaintiffs are referred to as Jane Doe 1, Jane Doe 2, Jane Doe 3 and John Doe in order to safeguard the Plaintiffs from intimidation and retaliation by Defendants and to preserve their medical privacy.

15.

The COVID-19 pandemic has caused unprecedented illness and death throughout the world and has been particularly devastating to patients in long term care facilities.

16.

On March 14, 2020, Governor Brian Kemp declared a Public Health State of Emergency due to the impact of COVID-19 in Georgia. This state of emergency has been renewed multiple times and was in effect at all material times.

17.

Landmark is required by law to report patients with COVID-19 to the Georgia Department of Public Health. See O.C.G.A. 31-12-2.

18.

Federal law requires Landmark to report the results of every COVID-19 test that is performed to state or local public health departments. See Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136, § 18115(a).

19.

Landmark is required to report the results of all testing within 24 hours of receiving the test results. See Exhibit B.

20.

For Covid-19 testing, Landmark is required to report the kind of COVID-19 test that was ordered and the specimen source that was obtained for the test. See Exhibit B.

21.

Landmark accepted more than $600,000.00 from the federal government through the CARES act, the receipt of which required that Landmark follow CDC guidelines related to COVID-19 testing.

TESTING METHODS

22.

The CDC has issued specific guidelines as to how COVID-19 testing is to be conducted. See Exhibits C and D.[1]

23.

These CDC guidelines specifically warn that: "Proper collection of specimens is the most important step in the laboratory diagnosis of infectious diseases. A specimen that is not collected correctly may lead to false negative test results."

24.

These CDC guidelines dictate how COVID-19 specimens should be taken from both the upper respiratory tract and the lower respiratory tract.

25.

These CDC guidelines dictate that upper respiratory tract specimens may be taken by nasopharyngeal swab ("Nasal Swab") and that Nasal Swab specimens should be taken as follows:

> d. Collecting the NP swab. Insert flexible wire shaft swab through the nares parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient indicating contact with the nasopharnyx. Gently, rub and roll the swab. Leave the swab in place for several seconds to absorb secretions before removing.

26.

CDC guidelines dictate that lower respiratory tract specimens may be taken by Tracheal Aspirate or by Sputum.

[1] These guidelines can also be retrieved at (because one set does not have DCD logo): https://www.cdc.gov/urdo/downloads/SpecCollectionGuidelines.pdf and https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

27.

These CDC guidelines dictate that Tracheal Aspirate specimens be collected as follows:

i. **BAL fluid, tracheal aspirate, pleural fluid**
Collect specimens in sterile containers. Centrifuge half of the specimen, and fix the cell pellet in formalin. Place the remaining uncentrifuged fluid into sterile vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®. Label each specimen container with the patient's name, ID number, the specimen type, and the date the specimen was collected.

LANDMARK'S COVID-19 POSITIVE PATIENTS

28.

In May, 2020, Landmark voluntarily accepted at least three patients that had tested positive for COVID-19 and then subsequently tested negative for COVID-19 prior to being transferred to Landmark.

29.

Upon information and belief, these patients were accepted by Landmark to allow Landmark to participate in an experimental medical trial aimed at treating patients who had previously been diagnosed with COVID-19.

30.

Upon information and belief, Landmark did not test any patients who had previously tested positive for COVID-19 until June 4, 2020.

31.

On June 4, 2020, Patient 1 was tested for COVID-19 prior to being sent to an outside facility for a procedure. This test resulted positive, which was Landmark's first COVID-19 positive result.

32.

Since June 4, 2020, five patients of Landmark have tested positive for COVID-19.

a) Patient 1 tested positive on June 4, 2020, and again on June 7, 2020.

b) Patient 2 tested positive on June 7, 2020.

c) Patient 3 tested positive on June 7, 2020.

d) Patient 4 tested positive on June 8, 2020.

e) Patient 5 tested positive on June 8, 2020.

33.

Patients 1 - 4 tested positive for COVID-19 using Nasal Swab specimens in the manner dictated that such tests should be performed by CDC guidelines. Patient 5 tested positive using an in-house serum antigen test.

34.

Another patient tested positive one day after leaving Landmark.

35.

After learning of the positive results, Landmark undertook a scheme to purposefully create false negative COVID-19 test results.

36.

To effectuate this scheme, Landmark banned nurses from performing COVID-19 testing and dictated that a specific Landmark administrator would be solely responsible for performing COVID-19 tests.

37.

Landmark claimed that the patients who had tested positive were false positives and began retesting these patients using a method that was contrary to CDC guidelines so as to create negative results for these patients.

38.

Specifically, Landmark staff collected tracheal aspirate specimens from these patients, submitted these samples as nasal swabs for purposes of obtaining false negative results for patients who had tested positive for COVID-19 only hours before.

39.

To perform reliable COVID-19 tracheal aspirate tests, Landmark would have needed equipment that they did not have, for example, a centrifuge is needed as the viscosity of tracheal aspirate specimens are thicker than nasal specimens.

40.

Landmark administrators collected the tracheal specimens from patients, swabbed this specimen using a nasal swab and then submitted it to the laboratory at Piedmont Athens for testing, under the guise that it had been taken appropriately.

41.

Landmark's Director of Nursing, Maygan Townsend, instructed respiratory therapists to suction these patients and then swab those secretions to send out for testing, knowingly giving false information to the laboratory.

42.

Landmark submitted these samples to the laboratory at Piedmont Athens Regional Hospital and the results, as planned by Landmark, came back as negative since the specimen was not tested properly.

43.

Landmark had previously attempted to submit tracheal swabs to the lab at Piedmont, and these samples had been rejected as the lab was not able to perform tests on these types of specimens.

44.

Despite knowing that Piedmont's Lab would not accept tracheal specimens for COVID-19 testing, Landmark purposefully submitted these samples with purposefully incorrect labels to orchestrate negative results for patients who had previously tested positive for COVID-19.

45.

On June 8, 2020, Maygan Townsend and Kim Wilkinson collected specimens from ten patients. Eight of these specimens were taken from Tracheal Aspirations, but the lab requisition orders all said "Nasal covid-19."

46.

Upon information and belief, Landmark fabricated negative results so as to continue to be able to discharge patients to make space for new admissions and avoid the negative publicity and oversight that would result if the positive COVID-19 results were disclosed.

47.

Landmark is required to include reports of laboratory procedures and results in a patient's medical record. Despite this requirement, Landmark removed all lab requisition orders from

patient's charts once Plaintiffs began questioning Landmark's testing procedures. These lab requisition orders show the specimen type Defendant represented the specimen to be to the lab. See Ga. Comp. R. & Regs. r. 111-8-40-.25. A sample of a lab requisition order is attached as Exhibit E.

LANDMARK'S FABRICATION OF NEGATIVE RESULTS

48.

Landmark has systematically falsified subsequent COVID-19 tests for each patient that tested positive when the test was performed using the correct method:

Patient 1:

- June 4, 2020: tested positive by Nasal Swab by a nurse;
- June 5, 2020: tested negative by Tracheal Aspiration by Marie Saylor;
- June 7, 2020: tested positive by Nasal Swab by a nurse;
- June 7, 2020: tested negative by Tracheal Aspiration by a staff respiratory therapist.

Patient 2:

- June 7, 2020: tested positive after a Nasal Swab was performed by a nurse;
- June 7, 2020: tested negative by Nasal Swab performed by a nurse;
- June 7, 2020: Nasal Swab specimen taken by nurses and test was removed by Maygan Townsend from the locked lab box and thrown away;
- June 7, 2020: tested negative after Tracheal Aspiration submitted to lab as a nasal specimen;
- June 8, 2020: tested negative after Tracheal Aspiration submitted to lab as a nasal specimen by Maygan Townsend and Kim Wilkinson;

Patient 3:

- June 7, 2020: tested positive by Nasal Swab test performed by a nurse;
- June 8, 2020: tested negative by an incorrectly performed Nasal Swab by Maygan Townsend and Kim Wilkinson.

Patient 4:

- June 8, 2020: tested positive by Nasal Swab by Maygan Townsend (patient was not intubated so Tracheal Aspiration test was not possible).
- June 9, 2020: discharged to home.

Patient 5:

- June 8, 2020: tested positive by serum antigen test, which was then thrown away and not entered into her medical records.

49.

Landmark is using intimidation to purposefully discourage providers from testing patients for COVID-19. On June 10, 2020, Kaelen Dawson, NP, entered an order for another patient to have a specimen collected for a test. Landmark CEO Marie Saylor intervened and had Dawson remove the order from the system. See Exhibit F. Plaintiffs later heard Saylor yelling at Dawson when the two were in Saylor's office.

50.

Plaintiffs and other clinical staff have repeatedly confronted Landmark's administrative staff about incorrectly collecting and falsely reporting the specimens for testing, including but not limited to confronting the administrative staff with printed copies of the CDC guidelines attached as Exhibit C and D. These employees have been intimidated and shunned by Landmark administration due to raising concerns.

51.

Nurses who have correctly performed Nasal Swab specimen tests have been intimidated and terminated.

52.

On June 10, 2020, Kim Wilkinson, Defendant Landmark's Director of Quality Management, seized control of all COVID-19 testing. Ms. Wilkinson directed nurses not to test patients even "if a doctor feels a patient should be tested immediately." Instead, the nurses were instructed to forego a doctor's order and contact her if any COVID-19 tests were ordered. See Exhibit G.

LANDMARK'S CURRENT SITUATION

53.

Landmark currently has 35 patients, including four of the patients who tested positive for COVID-19 in the last week.

54.

Patients that have tested positive have not been isolated from other patients and staff have not been given personal protective equipment or the resources to give safe treatment for these patients.

55.

Landmark does not have functioning negative pressure rooms to isolate COVID-19 patients.

56.

Even if these patients could have been properly isolated, Landmark's central air conditioning has not worked for any of the relevant time period. Air conditioning is currently provided by mobile units which blow air from the patient rooms into the halls of Landmark.

57.

The spread of COVID-19 to the patients at Landmark is most likely the result of the air conditioning system that is not working properly and the lack of equipment that has not been made available to the staff as well as the failure of Landmark to isolate COVID-19 patients.

58.

Landmark staff used the false negative results as a basis to remove Droplet Precautions from Patient 1 on June 9, 2020, only two days after her last positive Nasal Swab specimen test. See Exhibit H.

59.

At this time, the nurses do not know which patients are positive for COVID-19 and are treating patients who are both positive for COVID-19 as well as those who may not be infected yet.

60.

Other healthcare facilities require two negative tests before a patient can be discharged from Landmark. Upon information and belief, on June 12, 2020, Landmark used two false negatives to meet the requirement to discharge a patient to another facility.

61.

Healthcare facilities require two negative COVID-19 tests before a patient can be transferred to a facility for a surgical procedure. Landmark has manufactured false negatives

results from at least one patient in order to meet the requirements for a transfer to an outside facility for a procedure and will continue to do so if the Court does not intervene.

62.

On the morning of June 17, 2020, Dr. Sagel denied that Landmark had a COVID-19 outbreak to nephrologist Moti Samaki, MD, dismissing the situation as a "quick scare" and a "false alarm."

ABUSE AND NEGLECT

63.

Many of Landmark's current patients are either disabled or over 65 years of age.

64.

Rather than acknowledge the COVID-19 diagnosis, Landmark has subjected multiple patients to unnecessary painful testing and treatment to treat or diagnose other conditions unrelated to COVID-19 which has caused harm.

65.

Plaintiffs are mandatory reporters of suspected abuse and neglect of disabled adults and elderly persons. See O.C.G.A. §§ 30-5-4(a)(1)(A)(i); 19-7-5.

66.

"Abuse" means the willful infliction of physical pain, physical injury, sexual abuse, mental anguish, unreasonable confinement, or the willful deprivation of essential services to a disabled adult or elder person. O.C.G.A. § 30-5-3.

67.

"Neglect" means the absence or omission of essential services to the degree that it harms or threatens with harm the physical or emotional health of a disabled adult or elder person. O.C.G.A. § 30-5-3.

68.

Defendant's conduct, as detailed above, constitutes abuse and neglect of elderly and disabled patients in the care of Landmark, in addition to Medicare fraud, Medicaid fraud and insurance fraud.

TEMPORARY RESTRAINING ORDER AND INTERLOCUTORY INJUNCTION

69.

Plaintiffs incorporate all prior allegations.

70.

Plaintiffs request that the Court restrain and enjoin the Defendant from continuing to fabricate inaccurate COVID-19 tests results, transferring and discharging patients to outside facilities and admitting patients to Landmark.

71.

Plaintiffs will provide sealed affidavits and/or sworn testimony of specific facts evidencing the allegations set forth herein:

- Plaintiffs have reported Landmark's actions of manufacturing false negative COVID-19 tests to multiple government agencies since June 7, 2020, including the Occupational Health and Safety Administration, Georgia Department of Public Health, and the United States Department of Health and Human Services;

- To date, no government agency has intervened to stop Defendant's actions. As such, Plaintiffs have no other adequate legal remedy to safeguard themselves, their patients and the public but for the filing of this action;
- One patient has already been transferred to a nursing home based on test results that Landmark knew or should have known were false negatives;
- Patients are currently scheduled to be transferred to other facilities in the next 7 days; and
- Patients are currently scheduled to be discharged to home and will be seen by home health care workers who will be unknowingly exposed to COVID-19.

72.

Georgia's current state of emergency makes clear that a lack proper of COVID-19 testing will cause irreparable injury to the public. Falsified negative results exacerbate this risk of injury and constitutes gross negligence and bad faith on the part of Landmark.

Plaintiff asks the Court for the following relief:

- Landmark submit to this Court its infection control plan pursuant to Ga. Comp. R. & Regs. r. 111-8-40-.16.
- Landmark submit to this Court the lab requisition orders for all specimens submitted for testing since March 15, 2020.
- Landmark's patients be tested and quarantined due to their likely exposure to COVID-19;
- Landmark be required to report all COVID-19 positive test results to the Georgia Department of Public Health pursuant to O.C.G.A. § 31-12-2.
- Landmark be prohibited from admitting, transferring, or discharging any patients until all patients have been tested and quarantined.

- Landmark patients undergo COVID-19 testing per CDC guidelines with supervision by the Georgia Department of Health.

73.

Landmark has submitted specimens to testing laboratories, with knowledge that the specimens were not properly identified for the purpose of inducing Plaintiffs and others to rely on the results, which Plaintiffs and others should reasonably be allowed to rely on, causing Plaintiffs to suffer damages, including but not limited to the increased risk of exposure to COVID-19.

74.

Landmark has falsely represented the COVID-19 status of multiple patients, with the intention of inducing Plaintiffs and others to rely on this false information, which results Plaintiffs and others should reasonably be allowed to rely on, causing Plaintiffs to suffer damages, including but not limited to the increased risk of exposure to COVID-19.

75.

Pursuant to O.C.G.A. § 41-1-1, "A nuisance is anything that causes hurt, inconvenience, or damage to another and the fact that the act done may otherwise be lawful shall not keep it from being a nuisance. The inconvenience complained of shall not be fanciful, or such as would affect only one of fastidious taste, but it shall be such as would affect an ordinary, reasonable man."

76.

O.C.G.A. § 41-1-2 defines a public nuisance as "one which damages all persons who come within the sphere of its operation, though it may vary in its effects on individuals."

77.

By submitting and reporting false negative COVID-19 results, Defendants have knowingly and willfully destroyed, altered, or falsified medical records pursuant to O.C.G.A. § 16-10-94.1.

78.

By submitting and reporting the false results, Defendants have hidden critical data from its patients, staff, and community. This data would allow the patients, staff and community to make decisions related to quarantine and treatment.

79.

Further, Defendant has effectuated the transfer of a patient to another facility based on the false negative results and exposed staff and patients at outside facilities to harm.

80.

Unlike the general public, Plaintiffs face additional risk of injuries due to caring for patients who are COVID-19 positive and whose diagnosis is being ignored by Landmark Administration. As licensed registered nurses, Plaintiffs have a legal duty to provide care to their patients and to expose the acts and omissions of Landmark that is endangering the patients, staff and public.

81.

As a result of Landmark's acts and omissions, Plaintiffs, staff, patients of Landmark and the general public have sustained and continue to sustain damages.

82.

Landmark has intentionally submitted improper specimens to laboratories for COVID-19 testing and intimidated and/or fired nurses that objected or interfered with this scheme. As such, Plaintiffs have suffered severe emotional distress.

83.

Defendant's actions constitute willful misconduct, and were committed with malice, wantonness, and that entire want of care that would raise the presumption of conscious indifference to the consequences.

84.

As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs are entitled to judgment against the Defendant for exemplary damages to deter similar conduct in the future and to punish the Defendant, in an amount to be determined by the enlightened conscience of the finder of fact.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray and demand as follows:

1. That they receive injunctive relief as requested;
2. That they recover for special damages in an amount to be proven at trial;
3. That they recover punitive damages and attorney fees in an amount to be determined at trial;
4. That all costs of this suit be taxed against Defendant; and
5. For such other and further relief as the Court deems just and proper.

Respectfully submitted this 17th day of June, 2020.

/s/ Natalie S. Woodward____
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EXHIBIT
A

Healthcare Facility Regulation
A Division of the Georgia Department of Community Health

License Verification

To verify a licensed facility search by the name or address below. If you would like to download customizable lists of HFR licensed facilities, enter your criteria at the Facility Finder

Verify Licensure Status

landm

SEARCH

Facility Name: LANDMARK HOSPITAL OF ATHENS, LLC
Facility Type: HOSPITAL
Address: 775 SUNSET DRIVE
City: ATHENS
State: GA
Zip: 30606
Phone: 706-425-1518
Effective License Date: 07/14/2008
Date Verified: 6/14/2020

HFR Facility Finder

	Name	Facility Type	Address	City	State	Zip	County	Bed Capacity	Telephone	Effective Date of License	Administrator	Email
☐	LANDMARK HOSPITAL OF ATHENS, LLC	HOSPITAL	775 SUNSET DRIVE	ATHENS	GA	30606	CLARKE	42	7064251518	07/14/2008	Mr TIM MERRITT	

EXHIBIT B

COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115

June 4, 2020

Assuring a rapid and thorough public health response to the COVID-19 pandemic necessitates complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details, and additional information that can improve both the public health response to SARS-CoV-2 and COVID-19. These data contribute to understanding disease incidence and trends: initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities. As the country begins to reopen its doors, access to clear and accurate data is essential to communities and leadership as they use data to make decisions for a phased reopening. For individuals, access to personal test results improves feelings of safety, security, and awareness, and empowers them to take action, if necessary, to protect themselves, their families, and their communities.

Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS). In addition, the statute authorizes the Secretary to prescribe the form and manner, and timing and frequency, of such reporting. This document outlines the requirements for data submission to HHS as authorized under this law.

In an effort to receive these data in the most efficient and effective manner, the Secretary is requiring that all data be reported through existing public health data reporting methods, described below. As a guiding principle, data should be sent to state or local public health departments using existing reporting channels (in accordance with state law or policies) to ensure rapid initiation of case investigations by those departments, concurrent to laboratory results being shared with an ordering provider, or patient as applicable.

Entities Required to Report

All laboratories—including laboratories, testing locations operating as temporary overflow or remote locations for a laboratory, and other facilities or locations performing testing at point of

care or with at-home specimen collection related to SARS-CoV-2[1]—shall report data for all testing completed, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual's residence.

Methods for Submission

The required data elements related to Laboratory Data Reporting to HHS may be reported through the following avenues:

1. Submission of laboratory testing data directly to state or local public health departments, as required by state and/or local law or policy. These entities will then submit de-identified data to the CDC on a daily basis using either Health Level 7 (HL7) messaging or the CDC-provided CSV format.
2. Submission of laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories' AIMS platform) where such data will then be routed to the appropriate state and local authorities and routed to CDC after removal of elements to achieve de-identification according to applicable rules and regulations.
3. Submission of laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and to the CDC as directed by the state.

Required Data Elements

The following data elements must be collected and reported for SARS-CoV-2 laboratory tests, for the transmission of complete laboratory testing data to the CDC or the Secretary's designee. (Note: additional data elements may be requested at a future date.)

1. Test ordered – use harmonized LOINC codes provided by CDC
2. Device Identifier

[1] The CARES Act authorizes the Secretary to prescribe the laboratories which must submit the required reports. This definition of laboratories is consistent with Clinical Laboratory Improvement Amendments (CLIA), under which a laboratory is defined as a facility that performs applicable testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings. The CLIA regulations provide that "facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories." However, facilities collecting specimens may be directed by laboratories to provide the information required to be reported by the laboratories.

3. Test result – use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
4. Test Result date (date format)
5. Accession #/Specimen ID
6. Patient age
7. Patient race
8. Patient ethnicity
9. Patient sex
10. Patient residence zip code
11. Patient residence county
12. Ordering provider name and NPI (as applicable)
13. Ordering provider zip
14. Performing facility name and/or CLIA number, if known
15. Performing facility zip code
16. Specimen Source - use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes
17. Date test ordered (date format)
18. Date specimen collected (date format)

The following additional demographic data elements should also be collected and reported to state or local public health departments but these data will not be collected by CDC or the Secretary's designee. State and local privacy standards apply to the collection of these data elements. (Note: additional data elements may be requested by state, local or federal health departments at any time.)

1. Patient name (Last name, First name, Middle Initial)
2. Patient street address
3. Patient phone number with area code
4. Patient date of birth
5. Ordering provider address
6. Ordering provider phone number

In order to meet this requirement, any person or entity ordering a diagnostic or serologic test, collecting a specimen, or performing a test should make every reasonable effort to collect complete demographic information and should include such data when ordering a laboratory test to enable the entities performing the test to report these data to state and local public health departments. When information is not available, ordering health care providers (or their designees), laboratories performing SARS-CoV-2 and associated tests, and State Public Health departments should consider leveraging resources like state or regional HIEs and National Health

Information Networks (HIN) to obtain missing, required information. These exchanges and networks have significant capacity to identify missing information as they typically work with a wide range of health care provider EHR generated data, as well as a broader array of ADT (admit, discharge, transfer) feeds from local or regional stakeholders.

The following data fields are specific to SARS-CoV-2 and considered "ask on order entry" (AOE) questions for traditional Electronic Health Records or Laboratory Information Management Systems. These elements should be collected and be conformant with the HL7 Version 2.5.1 Lab Order Interface Implementation Guide and associated standards, and comprehensive of the above data fields.

1. First test (Y/N/U)
2. Employed in healthcare? Y/N/U
3. Symptomatic as defined by CDC? Y/N/U; if yes, then Date of Symptom Onset mm/dd/yy
4. Hospitalized? Y/N/U
5. ICU? Y/N/U
6. Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other setting): (Y/N/U)
7. Pregnant? Y/N/U

Data Reporting and Transmission Requirements

Recognizing that the data elements requested go above and beyond what has been historically requested, this information should be made available in all reporting (including through methods using existing technical infrastructure such as an HIE) to state and local public health departments and subsequently the CDC as soon as possible, but no later than August 1, 2020.

When possible, all information should be collected using health information technology certified to the ONC 2015 Edition certification criteria, and all information should be structured in accordance with the US Core Data for Interoperability (USCDI) when available or when possible. All data transmission should occur electronically using Health Level 7 (HL7) electronic laboratory reporting (ELR) implementation guides when possible but a predefined flat file format may also be acceptable. In addition, clinical/point of care testing facilities using electronic health records (EHRs) are encouraged to use electronic case reporting (eCR) standards to report laboratory testing data, at the receiver's discretion, provided the above data elements and timeliness requirements can be met.

For home-based collection of samples that are sent to a laboratory for testing, the laboratory must be able to collect the required information for reporting, so the process for sample collection should include submission of the data elements above (along with the specimen) to the lab performing the test, which will then report to the state and/or local public health department and

subsequently HHS or entity designated by the Secretary. For point of care testing, the laboratory (including a facility or setting with a certificate of waiver) must ensure the test is set up and operational to deliver timely and complete electronic results (with identifiers) as per the methods of submission.

Tests that are performed entirely in the home with test results delivered on the testing device within the home are being developed and may be authorized in the future. Developers of such tests are encouraged to consider ways in which the data elements and information described above could be collected and reported given its critical importance to public health efforts. This might be accomplished through applications on a personal smartphone or tablet, a patient portal, direct transmission from the test platform itself, or other innovative technologies.

Links to the relevant applicable standards are available here:

- https://loinc.org/sars-coronavirus-2/
- https://confluence.ihtsdotools.org/display/snomed/SNOMED%2BCT%2BCOVID-19%2BRelated%2BContent
- https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html
  https://phinvads.cdc.gov/vads/SearchVocab.action
- https://www.healthit.gov/test-method/transmission-public-health-agencies-reportable-laboratory-tests-and-valueresults#ccg
- http://www.hl7.org/implement/standards/product_brief.cfm?product_id=98
- https://hl7v2-elr-testing.nist.gov/mu-elr/#
- https://www.healthit.gov/isa/covid-19

Additional Resources provided by CDC and FDA:

Test developers with questions about coding can send questions to:
SHIELD-LabCodes@fda.hhs.gov.
Test users (e.g., laboratories/healthcare providers) can send questions to: dlsinquiries@cdc.gov.

Laboratory Data Reporting and Electronic Health Records

Laboratory data serves not only as important information to support decision making related to the public health emergency, but also as a critical piece to better understanding the performance of tests in real-world conditions, the effectiveness of clinical interventions, and patient outcomes and interventions. Better understanding the characteristics and performance of tests can help ensure that healthcare providers are equipped with the maximum information necessary to make clinical decisions, develop recommendations, and provide the most appropriate care for their patients. Additionally, with widespread use of electronic health records (EHR), incorporating information related to laboratory testing can ensure completeness for future clinical research on

treatments, outcomes, quality and performance of diagnostic tests, and our clinical understanding of COVID-19.

To ensure that data can be captured in the electronic health record (EHR), HHS also recommends, but does not require, that the transmission of laboratory results back to the ordering provider (whenever possible) include the following information.

1. Test result – use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
2. Test result date (date format)
3. Unique patient identifier
4. Test ordered – use appropriate LOINC codes
5. Device Identifier
6. Accession #/Specimen ID

These data fields represent the minimum information and any data transmission should be in accordance with the HL7 Lab Results Interface (LRI) implementation guide and standard. To ensure that patients receive timely and critical information regarding their own health condition and status, HHS also recommends, but does not require, the transmission of laboratory results be sent directly to the patient (or parent/guardian), either by mail (in writing), email (electronically), and/or via a patient portal or secure standard-based application programming interface (electronically), using commonly available standards such as FHIR (for instance, the Argonaut Data Query Implementation Guide.)

LOINC and SNOMED-CT codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC, should be used when possible to help ensure normalization and harmonization of data elements related to laboratory test and results.

Laboratories that meet the definition of a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations are permitted to disclose this protected health information (*i.e.,* laboratory results and other data elements described above) as provided in this guidance under the HIPAA Privacy Rule. A laboratory's business associate also is permitted to disclose this protected health information if their business associate agreement allows the disclosure, or if the disclosure is pursuant to OCR's Notification of Enforcement Discretion for Business Associates. Nothing in this guidance changes the existing requirements for HIPAA covered entities and business associates to comply with the applicable HIPAA Privacy, Security, and Breach Notification Rules.

EXHIBIT
C

SPECIMEN COLLECTION GUIDELINES

Purpose of this document

The purpose of this document is to provide general specimen collection guidelines for healthcare providers and public health staff during a respiratory disease outbreak when the pathogen is unknown. The specimens listed in this document are those that may need to be collected to detect the etiologic agent during a respiratory disease outbreak. When a specific pathogen is known or very strongly suspected, specimen collection should be tailored to the pathogen (Appendix A).

Note: Consult your local or state health department about the potential respiratory outbreak as soon as possible.

Reference Testing

Testing may be conducted by clinical laboratories, reference laboratories or city, county or state public health laboratories. Only State Health Departments and other Federal Agencies may submit specimens for reference testing to CDC. All specimen submissions to CDC require first approval by the individual State Health Department and CDC prior to shipment.

Private citizens, health practitioners and hospitals must contact their local (city or county) health department about how and when to submit specimens. If the local health department is unable to make a determination, they will forward the specimen to their State Health Department.

A list of State and Local Health Departments can be found at http://www.cdc.gov/mmwr/international/relres.html.

The State list of the Association of State and Territorial Public Health Officials can be found at http://www.astho.org/index.php?template=regional_links.php.

Special arrangements will be made for specimens collected for studies/projects by collaborators of CDC investigators. Contact the Principle Investigator for specific instructions.

General principles

1. **Integrated approach**. These guidelines are designed for use in an outbreak setting where the etiologic agent is unknown. Sensitive assays should allow for an efficient and coordinated approach to specimen collection and diagnostic testing to evaluate multiple potential viral and bacterial etiologies.

   Each respiratory pathogen requires a unique set of specimen types, collection methods and handling conditions to optimize diagnostic yield. Because these guidelines are designed for detection of multiple pathogens, the sensitivity of detection of any one agent may be compromised. If a particular agent is strongly suspected, please refer to

pathogen-specific materials. To rule out other pathogens, multiple specimens may be necessary.

2. **Recommended specimens.** Please refer to Appendix A.
3. **Timing of specimen collection**. Respiratory tract specimens should be collected as soon as possible in the course of the illness and before antimicrobic therapy begin, if possible. The likelihood of recovering most viruses and many bacteria diminishes markedly >72 hours after symptom onset and after the initiation of appropriate antimicrobial therapy. If possible, respiratory specimens should be collected within 72 hours of symptom onset and no later than 7 days after onset.
4. **Interpretation of results**. The interpretation of laboratory test results should take into account whether proper specimen collection and handling occurred prior to receiving the specimen in the laboratory and pathogen specific test sensitivities and concurrent treatment. Also, some pathogens colonize the upper respiratory tract (***e.g. S. pneumoniae*** and Hib), or can cause asymptomatic or symptomatic infection (***e.g.*** rhinovirus or coronavirus). Therefore, each laboratory result needs to be interpreted individually for each pathogen. Combining results from selected cases may significantly improve the overall specificity for identifying the predominant cause or causes of an outbreak.

Collection of Upper Respiratory Tract Specimens

1. **Oropharyngeal (OP) and nasopharyngeal (NP) swabs**

    a. Optimal timing. Specimens should be collected within 3 days of symptom onset and no later than 7 days from all patients meeting the case definition identified during the outbreak, ideally prior to the initiation of antimicrobial chemoprophylaxis or therapy.

    b. Swab types. Use only sterile dacron or rayon swabs with plastic shafts or if available, flocked swabs. DO NOT use calcium alginate swabs or swabs with wooden sticks, as they may contain substances that inactivate some viruses and inhibit some molecular assays.

    c. Collecting the OP swab. Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

    d. Collecting the NP swab. Insert flexible wire shaft swab through the nares parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient indicating contact with the nasopharnyx. Gently, rub and roll the swab. Leave the swab in place for several seconds to absorb secretions before removing.

    e. Specimen handling. Place NP and OP swabs immediately into a sterile vial containing 2 ml of viral transport media **without** antibiotics. Both swabs can be

placed in the same vial, if desired. Aseptically, cut or break applicator sticks off near the tip to permit tightening of the cap. Label the vial with the patient's name, ID number, specimen type, and date collected. If specimens will be examined within 48 hours after collection, keep specimen at 4ºC and ship on wet ice or refrigerant gel-packs, otherwise store frozen at ≤-70ºC and ship on dry ice. Avoid freezing and thawing specimens. Viability of some pathogens from specimens that were frozen and then thawed is greatly diminished and may result in false-negative test results.

2. **Nasopharyngeal wash/aspirate.** This specimen is commonly collected in children <5 years old.
    a. Optimal timing. Specimens should be collected within 3 days of symptom onset and not later than 7 days from all patients meeting the case definition identified during the outbreak, ideally prior to the initiation of antimicrobial chemoprophylaxis or therapy.

    b. Specimen collection. Have the patient sit with head tilted slightly backward. Instill 1 ml-1.5 ml of nonbacteriostatic saline (pH 7.0) into one nostril. Flush a plastic catheter or tubing with 2 ml-3 ml of saline. Insert the tubing into the nostril parallel to the palate (not upwards). Aspirate nasopharyngeal secretions. If permitted, repeat this procedure for the other nostril.

    c. Specimen handling. Collect the specimens in sterile vials. Label each specimen container with the patients name, ID number, specimen type, and the date collected. If specimens will be examined within 48 hours after collection, keep specimen at 4ºC and ship on wet ice or refrigerant gel-packs, otherwise store frozen at ≤-70ºC and ship on dry ice. Avoid freezing and thawing specimens. Viability of some pathogens (*e.g.* respiratory syncytial virus) from specimens that are frozen and then thawed is greatly diminished and may result in false-negative test results.

Collection of Lower Respiratory Tract Specimens

1. **Sputum, tracheal aspirate, broncheoalveolar lavage (BAL) fluid, pleural fluid.** Due to the increased technical skill and equipment needs, collection of specimens other than sputum from the lower respiratory tract may be limited to patients presenting with more severe disease, including persons admitted to the hospital and/or fatal cases.

    a. Optimal timing. These specimens may be obtained at any time during the clinical course, but ideally prior to initiation of antimicrobial therapy.

    b. Specimen types. Acceptable lower respiratory tract specimens include sputum, tracheal aspirate, BAL fluid, pleural fluid, or lung biopsy. Specimens with less chance for upper airway contamination (i.e., BAL fluid, pleural fluid, lung biopsy) are preferred.

c. Specimen collection.

i. **BAL fluid, tracheal aspirate, pleural fluid**
Collect specimens in sterile containers. Centrifuge half of the specimen, and fix the cell pellet in formalin. Place the remaining uncentrifuged fluid into sterile vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®. Label each specimen container with the patient's name, ID number, the specimen type, and the date the specimen was collected.

ii. **Sputum**
Educate the patient about the difference between sputum and oral secretions. Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile screw-cap collection cup or sterile dry container.

d. Specimen handling. Label the vial or container with the patient's name, ID number, specimen type, and date collected. Store fixed cells at room temperature. If unfixed specimens will be examined within 48 hours after collection, keep specimen at 4ºC and ship on wet ice or refrigerant gel-packs, otherwise store frozen at ≤-70ºC and ship on dry ice. Avoid freezing and thawing specimens. Viability of some pathogens from specimens that were frozen and then thawed is greatly diminished and may result in false-negative test results.

Collection of Blood Components

1. **Acute and convalescent serum specimens.** If possible, acute **and** convalescent sera should be obtained from all patients identified during the outbreak. For most respiratory pathogens, both acute and convalescent sera must be collected to permit a definitive diagnosis. Antibody titers against suspected bacteria or viruses may be measured in sera and provide an important adjunct to or confirmation of PCR and culture results. However, these results are not timely enough to guide clinical care.

a. Optimal timing.

i. Acute. Acute serum specimens should be collected within one week of symptom onset and submitted as soon as possible.

ii. Convalescent. Convalescent specimens should be collected and submitted at 3-6 weeks after the acute specimen was collected.

b. Collecting the sera. For each serum specimen, collect 5 ml of whole blood into a serum separator tube (marble or tiger top SST). A minimum of 1 ml of whole blood is needed for testing of pediatric patients.

c. Specimen handling. Allow whole blood to clot at room temperature for a

minimum of 30 minutes and centrifuge. Label the tube with the patient's name, ID number, specimen type, and date collected. Store refrigerated at 4ºC or frozen, and ship on refrigerant gel packs or dry ice.

d. Aliquoting sera. If aliquoting is performed, divide the sera into 0.5 ml aliquots in sterile containers. Label each vial with the patient's name, ID number, specimen type, and date collected. Store refrigerated at 4ºC or frozen, and ship on refrigerant gel packs or dry ice.

2. **Whole blood for Culture.** This specimen may be limited to patients with more severe disease including persons admitted to the hospital.

   a. Optimal timing. Whole blood should be collected as soon as possible after illness onset and ideally before initiation of antimicrobial chemoprophylaxis or therapy. For fatal cases, postmortem whole blood should always be obtained at autopsy.

   b. Collection. Collect whole blood in bottles according to clinical laboratory guidelines.

   c. Specimen handling. Label the bottle with the patient's name, ID number, specimen type, and date collected. Store and ship specimens with cold packs to keep the specimen at 4ºC.

3. **Whole blood plasma for PCR.** For selected situations, whole blood may be obtained for PCR.

   a. Optimal timing. Whole blood should be collected as soon as possible after illness onset and ideally before initiation of antimicrobial chemoprophylaxis or therapy. For fatal cases, postmortem whole blood should always be obtained at autopsy.

   b. Collection. Collect 5-10 ml of whole blood in an EDTA (purple-top) tube.

   c. Specimen handling. Label the tube with the patient's name, ID number, specimen type, and date collected. Store and ship specimens with cold packs to keep the specimen at 4ºC.

Collection of Tissue Specimens

1. **Fixed tissues**

   a. Target population. A complete autopsy should be performed on all fatal cases associated with a respiratory disease outbreak. Lung tissue should also be received from any non-fatal case where a biopsy is performed.

   b. Specimen types. On all fatal cases, tissues should be collected from all major organs and fixed in formalin or embedded in paraffin. The following tissues are

particularly important:

1. Central (hilar) lung with segmented bronchi

2. Right and left proximal and distal bronchi, upper airways (*e.g.* epiglottis, larynx, trachea)

3. Representative pulmonary parenchyma from right and left lung

Representative tissues from all major organs should also be submitted for evaluation. In particular, for patients with suspected myocarditis, encephalitis, or rhabdomyolysis, specimens should include heart (right ventricle, septum, and left ventricle), CNS (cerebral cortex, thalamus, basal ganglia, midbrain, pons, medulla, cerebellum, and spinal cord), and skeletal muscle. Specimens should be included from any other organ showing significant gross or microscopic pathology.

c. Specimen handling. **Since prolonged fixation may interfere with certain immunohistochemical or molecular diagnostic assays, the original paraffin blocks (tissues prepared for initial pathologic evaluation prior to fixation in formalin) are preferred for analysis if the fixed tissues have been stored in formalin > 2 weeks.** Fixed tissues from various organs may be stored and shipped in one or separate containers. Label the container(s) with the patient's name, ID number, specimen type(s), and date collected. Store and ship at room temperature. Paraffin blocks are usually shipped at room temperature; they should not be frozen. However, if the weather is extremely hot, shipping with a cold pack might prevent incidental melting of the paraffin. **DO NOT FREEZE FIXED TISSUES.** For fatal cases, a preliminary autopsy report should be provided with the tissues.

2. **Non-fixed tissues from lung and upper airway (*e.g.* trachea, bronchus)**

a. Target population. A complete autopsy should be performed on all fatal cases associated with a respiratory disease outbreak. Lung tissue should also be received from any non-fatal case where a biopsy is performed.

b. Specimen types. On all fatal cases, tissues should be collected from lung and upper airways (*e.g*. epiglottis, trachea, bronchi), and any other primarily affected organs.

c. Specimen collection. On all fatal cases specimens should be collected aseptically as soon as possible after death since technique and time will impact risk of post-mortem contamination. Use a separate sterile instrument for each collection site. Place each specimen in separate sterile containers containing small amounts of saline.

d. Specimen handling. Label each container with the patient's name, ID number,

specimen type(s), and date collected. If specimens will be examined within 48 hours after collection, keep specimen at 4ºC and ship on wet ice or refrigerant gel-packs, otherwise store frozen at -70ºC and ship on dry ice. **On all fatal cases, a preliminary autopsy report should be provided with the tissues**.

Collection of Other Specimens

1. **Urine**

    a. Optimal timing. Urine may be collected within 7 days of symptom onset from every patient identified during a respiratory disease outbreak for antigen detection.

    b. Specimen collection. Collect 10-20 ml of urine in a sterile container.

    c. Specimen handling. Label the container(s) with the patient's name, ID number, specimen type(s), and date collected. Store refrigerated at 4ºC and ship on wet ice or refrigerant gel packs.

2. **Stool**

    a. Optimal timing. Stool may be collected within 14 days of symptom onset from patients hospitalized as part of a respiratory disease outbreak (*e.g.* from SARS CoV suspect cases for RT-PCR).

    b. Specimen collection. Collect 10-20 ml stool in a clean, dry, leak-proof container.

    c. Specimen handling. Label the container(s) with the patient's name, ID number, specimen type(s), and date collected. If specimens will be examined within 48 hours after collection, they can be refrigerated at 4ºC; otherwise store frozen at -70ºC and ship on dry ice.

Appendix A

LISTS OF RECOMMENDED CLINICAL SPECIMENS TO COLLECT FROM OUTPATIENTS, INPATIENTS, AND FATAL CASES IN THE SETTING OF AN UNEXPLAINED RESPIRATORY DISEASE

The specimens are listed in order of priority; those listed first are those most useful for testing for the greatest number of different pathogens with a single clinical specimen.

OUTPATIENTS

Upper Respiratory
- Nasopharyngeal (NP) and oropharyngeal (OP)
- Nasopharyngeal wash/aspirate

Lower Respiratory
- Sputum

Blood
- Serum: Acute (at onset) and convalescent (3-6 weeks post onset)
- Blood (plasma)

Urine

Stool

INPATIENTS

Lower Respiratory
- Bronchoalveolar lavage, tracheal aspirate, pleural fluid
- Sputum

Upper Respiratory
- Nasopharyngeal (NP) and oropharyngeal (OP) swabs
- Nasopharyngeal wash/aspirate

Blood
- Serum: Acute (at onset) and convalescent (3-6 weeks post onset)
- Whole blood (plasma)

Tissue (e.g., lung)

Urine

Stool

FATAL CASES

All available premortem specimens

Tissue
- Fixed tissue from all major organs (e.g., lung, heart, spleen, liver, brain, kidney, adrenals)
- Non-fixed tissue from lung and upper airways (e.g., trachea, bronchus)

Lower Respiratory
- Bronchoalveolar lavage, tracheal aspirate, pleural fluid
- Sputum

Blood
- Serum
- Blood (plasma)

Deep lung swab for bacterial culture

EXHIBIT D

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)

Updated May 22, 2020

Summary of Recent Changes

Revisions were made on May 22, 2020 to reflect the following:

- Change in specimen shipping address.

Revisions were made on May 5, 2020 to reflect the following:

- Add guidance on properly handling bulk-packaged sterile swabs for specimen collection.

Revisions were made on April 29, 2020 to reflect the following:

- Update guidance on viral transport medium (VTM) to note that some point-of-care tests advise against its use.
- Remove preference for NP swabs.
- Update guidance for use of personal protective equipment while obtaining specimens.

Revisions were made on April 14, 2020 to reflect the following:

- Clarify specimen collection procedures for all swab types and align with other respiratory disease specimen collection guidelines.

Healthcare providers* considering testing people with possible COVID-19 should work with their local and state health departments to coordinate testing through public health laboratories, or work with commercial or clinical laboratories using viral tests granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration. CDC has guidance for who should be tested, but decisions about who should be tested are at the discretion of state and local health departments and/or healthcare providers. Testing for other pathogens by the provider should be done as part of the initial evaluation, as indicated, but should not delay testing for SARS-CoV-2, the virus that causes COVID-19.

Positive SARS-CoV-2 results should be reported. Read CDC's Data and Reporting FAQ for Laboratories.

Clinical laboratories should NOT attempt viral isolation from specimens collected from people suspected to have COVID-19 unless this is performed in a BSL-3 laboratory.

*Pharmacists are considered healthcare providers in this guidance.

Specimen Type and Priority

All testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider. Specimens should be collected as soon as possible once a decision has been made to pursue testing, regardless of the time of symptom onset. The guidance below addresses options for collection of specimens.

For initial diagnostic testing for SARS-CoV-2, CDC recommends collecting and testing an upper respiratory specimen. The following are acceptable specimens:

- A nasopharyngeal (NP) specimen collected by a healthcare provider; or
- An oropharyngeal (OP) specimen collected by a healthcare provider; or
- A nasal mid-turbinate swab collected by a healthcare provider or by a supervised onsite self-collection (using a flocked tapered swab); or
- An anterior nares (nasal swab) specimen collected by a healthcare provider or by onsite or home self-collection (using a flocked or spun polyester swab); or
- Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by a healthcare provider.

Swabs should be placed immediately into a sterile transport tube containing 2-3mL of either viral transport medium (VTM), Amies transport medium, or sterile saline, unless using a test designed to analyze a specimen directly, (i.e., without placement in VTM), such as some point-of-care tests. If VTM is not available, see the standard operating procedure for public health labs to create viral transport medium in accordance with CDC's protocol.

The NW specimen and the non-bacteriostatic saline used to collect the specimen should be placed immediately into a sterile transport tube.

Testing lower respiratory tract specimens is also an option. For patients who develop a productive cough, sputum should be collected and tested for SARS-CoV-2. The induction of sputum is not recommended. When under certain clinical circumstances (e.g., those receiving invasive mechanical ventilation), a lower respiratory tract aspirate or bronchoalveolar lavage sample should be collected and tested as a lower respiratory tract specimen.

Collecting and Handling Specimens Safely

For providers collecting specimens or within 6 feet of patients suspected to be infected with SARS-CoV-2, maintain proper infection control and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

For providers who are handling specimens, but are not directly involved in collection (e.g. self-collection) and not working within 6 feet of the patient, follow Standard Precautions; gloves are recommended. Healthcare personnel are recommended to wear a form of source control (facemask or cloth face covering) at all times while in the healthcare facility.

PPE use can be minimized through patient self-collection while the healthcare provider maintains at least 6 feet of separation.

Handling Bulk-Packaged Sterile Swabs Properly for Upper Respiratory Sample Collection

Sterile swabs for upper respiratory specimen collection may be packaged in one of two ways:

- Individually wrapped (preferred when possible)
- Bulk packaged

Bulk-packaged swabs may be used for sample collection; however, care must be exercised to avoid SARS-CoV-2 contamination of any of the swabs in the bulk-packaged container.

- Before engaging with patients and while wearing a clean set of protective gloves, distribute individual swabs from the bulk container into individual disposable plastic bags.
- If bulk-packaged swabs cannot be individually packaged:
  - Use only fresh, clean gloves to retrieve a single new swab from the bulk container.
  - Close the bulk swab container after each swab removal and leave it closed when not in use to avoid inadvertent contamination.
  - Store opened packages in a closed, airtight container to minimize contamination.
  - Keep all used swabs away from the bulk swab container to avoid contamination.
- As with all swabs, only grasp the swab by the distal end of the handle, using gloved hands only.
- When patients are self-collecting their swabs under clinical supervision:
  - Hand a swab to the patient only while wearing a clean set of protective gloves.
  - The patient can then self-swab and place the swab in transport media or sterile transport device and seal.
  - If the patient needs assistance, you can help the patient place the swab into transport media or a transport device and seal it.

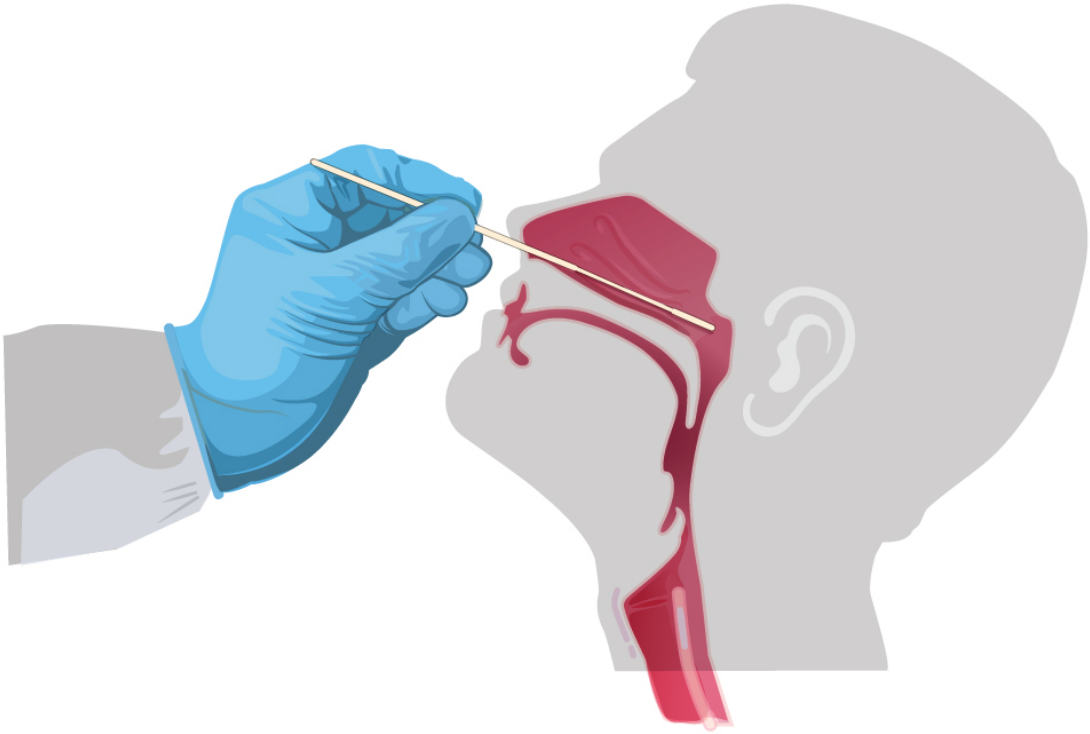
General Guidelines

Proper collection of specimens is the most important step in the laboratory diagnosis of infectious diseases. A specimen that is not collected correctly may lead to false negative test results. The following specimen collection guidelines follow standard recommended procedures. For more information, including illustrations and step-by-step guidance, see the CDC Influenza Specimen Collection instructions. Note that these instructions are applicable for respiratory viruses in general, and not specific for only influenza virus.

I. Respiratory Specimens

A. Upper respiratory tract

Nasopharyngeal swab/Oropharyngeal (Throat) swab



Use only synthetic fiber swabs with plastic or wire shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. CDC is now recommending collecting only the NP swab, although OP swabs remain an acceptable specimen type. If both NP and OP swabs are collected, they should be combined in a single tube to maximize test sensitivity and limit use of testing resources.

NP swab: Insert minitip swab with a flexible shaft (wire or plastic) through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the minitip is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

OP swab: Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

Nasal mid-turbinate (NMT) swab, also called Deep Nasal Swab

Use a flocked tapered swab. Tilt patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at turbinates). Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.

Anterior nares specimen

Using a flocked or spun polyester swab, insert the swab at least 1 cm (0.5 inch) inside the nostril (naris) and firmly sample the nasal membrane by rotating the swab and leaving in place for 10 to 15 seconds. Sample both nostrils with same swab.

Nasopharyngeal wash/aspirate or nasal wash/aspirate

Attach catheter to suction apparatus. Have the patient sit with head tilted slightly backward. Instill 1 mL-1.5 mL of non-bacteriostatic saline (pH 7.0) into one nostril. Insert the tubing into the nostril parallel to the palate (not upwards). Catheter should reach depth equal to distance from nostrils to outer opening of ear. Begin gentle suction/aspiration and remove catheter while rotating it gently. Place specimen in a sterile viral transport media tube.

B. Lower respiratory tract

Bronchoalveolar lavage, tracheal aspirate, pleural fluid, lung biopsy

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

Due to the increased technical skill and equipment needs, collection of specimens other than sputum from the lower respiratory tract may be limited to patients presenting with more severe disease, including people admitted to the hospital and/or fatal cases.

Sputum

Educate the patient about the difference between sputum and oral secretions (saliva). Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap collection cup or sterile dry container.

II. Storage

Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.

III. Shipping

Samples may be shipped to CDC if repeated testing results remain inconclusive or if other unusual results are obtained. Please contact CDC at respvirus@cdc.gov prior to submitting samples.

If shipping samples to CDC: If specimens will ship without delay, store specimens at 2-8°C, and ship overnight to CDC on ice pack. If a delay in shipping will result in receipt at CDC more than 72 hours after collection, store specimens at -70°C or below and ship overnight to CDC on dry ice. Additional useful and detailed information on packing, shipping, and transporting specimens can be found at Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).

Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations external icon .

Label each specimen container with the patient's ID number (e.g., medical record number), unique CDC or state-generated nCov specimen ID (e.g., laboratory requisition number), specimen type (e.g., serum) and the date the sample was collected. Complete a CDC Form 50.34 for each specimen submitted. In the upper left box of the form, 1) for *test requested* select "Respiratory virus molecular detection (non-influenza) CDC-10401" and 2) for *At CDC, bring to the attention of* enter "Unit 84 (Non-flu Resp Virus)".

Please refer to our instruction guidance for submitting CDC Form 50.34 found here: Guidelines For Submitting Specimens to CDC .

For additional information, consultation, or the CDC shipping address, contact the CDC Emergency Operations Center (EOC) at 770-488-7100.

Additional Resources

- Nasal (Anterior Nasal) Specimen Collection for SARS-CoV-2 Diagnostic Testing [1 page]
- Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19) [2 pages]

Page last reviewed: May 22, 2020
Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

EXHIBIT
E

2 FORMS ... SPECIMEN REQUIRED

121075P (Rev. 12/19) White – Laborato... ...low – Office Copy

07613

Piedmont ATHENS REGIONAL

LAB OUTREACH

P: 706-475-6881 F: 706-475-2170

T: 866-475-6881 F: 866-869-0973

COLLECTOR: [illegible] ☐ Standing Order

PRIORITY	COLLECTION DATE			ACCOUNT NAME AND ADDRESS
☒ Stat	10.8.20			Ors 4
☐ Routine	TIME	FASTING		
☐ Call	15:00	Y	N	

☐ BILL PATIENT ☐ BILL INS. ☑ BILL ACCOUNT

Ordering Physician's Signature LHOS

PATIENT NAME LAST	FIRST	MI	DOB 62	Sex M/F M	SSN - -	Tele. No. ( ) -

PATIENT ADDRESS _____ Street _____ Apt# _____ City _____ State _____ Zip _____

INS. CO. NAME _____ POLICY # _____ GROUP # _____ PLAN # _____

NOTICE

Medicare requires that the physician document the need for all tests ordered by providing an ICD-10 code consistent with the patient's current condition/medical record for **each** test. The Office of the Inspector General has requested that we inform you that when ordering tests for which Medicare reimbursement is sought, physicians should only order tests that are **medically necessary for diagnosis or treatment of the patient, not for screening purposes.**

TEST	CPT	✓	COLL
Hepatitis Panel, Acute	80074		R
Basic Metabolic Panel	80048		G
Comp Metabolic Panel	80053		G
Electrolyte	80051		G
Hepatic Function Panel	80076		G
Lipid Panel	80061		G
Obstetric Panel	80055		*
Obstetric Panel c HIV	80081		*
Renal Function Panel	80069		G
GENERAL TESTS:			
ANTIBODY SCREEN	86850		L
ABO / RH	86900/86901		L
ALPHA-FETOPROTEIN QUAD SCREEN	*82105, 84702, 82677, 86366		R
ALBUMIN	82040		G
ALT (SGPT)	84460		G
AMYLASE	82150		G
ANA Screen, IFA w/rflx	86038		R
ASO	86063/86060		R
AST (SGOT)	84450		G
BILIRUB - DIRECT	82248		G
BILIRUB - TOTAL	82247		G
BNP	83880		L
BUN	84520		G
C3	86160		R
C4	86160		R
CA 125	86304		R
CALCIUM	82310		G
CBC w/Diff	85025		P
CBC No Diff/Hemogram	85027		P
CEA	82378		R
CHOLESTEROL	82465		G
	82550		G
CORTISOL	82533		R
CREATININE	82565		G
	86140		G
CYCLOSPORIN	80162		G
DILANTIN	80185		G
DIOXIDIOL	82670		R
DILANTIN	82728		G
EDTA, RBC (protect from light)	82747		P

TEST	CPT	✓	COLL
FOLIC ACID (Folate)	82746		G
FSH	83001		G
GAMMA GT (GGT)	82977		G
GLUCOSE	82947		GR
GLUCOSE 2 HR TOLERANCE	82951		GR
GLUCOSE 3 HR TOLERANCE	82951/82952		*
GLUCOSE 2 HR PP	82947		GR
GLUCOSE, 50 G	82950		*
HCG-QUAL (PREG SERUM)	84703		R
HCG-QUANT SERUM	84702		G
HCT	85014		P
HEPARIN ASSAY (UNFRACTION)	85520		B
HEPARIN ASSAY (LMWH)	85520		B
HEPATITIS A IGM AB	86709		R
HEPATITIS B CORE IGM AB	86705		R
HEP B SURF AB	86706		R
HEP B SURF AG	87340		R
HEPATITIS C ANTIBODY	86803		R
HEP C AB W Reflex Conf	86803/86804		R
HGB	85018		P
HGB A1C/GLY HGB	83036		P
HEMOGLOBIN EVALUATION	83021		P
HIV AG/AB 4TH GEN w/rflx	87389		R
HOMOCYSTEINE	83090		R
H. PYLORI BREATH TEST	83013		
IMMUNOFIXATION ELECT SRM	86334		R
IRON	83540		G
IRON / TIBC	83550/83550		G
LEAD, WHOLE BLD	83655		RB
LDL, CHOL Direct	83721		G
LH	83002		G
LIPASE	83690		G
MAGNESIUM	83735		G
MONO	86308		R
MPO/PR-3 (ANCA Screen)	86021		R
PHOSPHOROUS	84100		G
POTASSIUM	84132		G
PRE ALBUMIN	84134		G

ICD-10

SPECIMEN ID LABEL

To:ARMC – Lab (Unregistered)

8031153811389597

From:Landmark Hospitals

TEST	CPT	✓	COLL
PROGESTERONE	84144		*
PROLACTIN	84146		GR
PROTEIN ELECTROPHORESIS	84155		*
PSA	84153		R
PSA, TOTAL & FREE	84154/84153		G
PSA, TOTAL MCR SCREENING	G0103		P
PTH INTACT W/CA	83970/82310		B
PROTIME-INR (PT)	85610		B
PTT (APTT)	85730		B
RHEUMATOID FACTOR	86431		R
RETIC	85045		R
SYPHILLIS SCREEN	86780		R
RUBELLA IGG	86762		R
SED RATE	85652		P
TSPOT	86481		P
QUANTIFERON TB GOLD PLUS (ONE TUBE)	86480		*
T3 FREE	84481		*
T3 TOTAL	84480		G
T4 (FREE)	84439		G
T4 TOTAL	84436		G
TESTOSTERONE TOTAL IMMUNOASSAY	84403		R
TESTOSTERONE FREE TOTAL	84403/84270		R
TRIGLYCERIDES	84478		G
TSH	84443		G
URIC ACID	84550		G
VALPROIC ACID	80164		G

TEST	CPT	✓	COLL
VITAMIN B12	82607		G
VITAMIN D 25	82306		G
RANDOM URINE:			
CREATININE, RANDOM U	82570		U
DRUG SCREEN, URINE	80307		U
IMMUNOFIXATION RANDOM URINE	86335		U
MICROALBUMIN (INCLUDES CREATININE)	82570/82043		U
PROTEIN, RANDOM UR	84156		U
PROTEIN/CREATININE RATIO	82570/84156		U
URINALYSIS NO RFLX TO CULT	81003		U
URINALYSIS W/ RFLX TO CULT	81003/87086		U
24 HOUR URINES (INCLUDES TOTAL VOLUME CPT 81050):			
CALCIUM 24 HR	82340		
CREATININE 24 HR	82570		
CREATININE CLEARANCE	82575		
PHOSPHOROUS 24 HR	84105		
PROTEIN, TOTAL 24 HR	84156		
SODIUM 24 HR	84300		
IMMUNOFIXATION 24 HR	86335		
URIC ACID 24 HR	84560		

SPECIMEN TYPE / NUMBER OF TUBES

Lav____Red/Gold____Grn____Blue____Other____

☐ URINE ☐ Urine Transport

☐ 24 Hour Urine ☐ Stool

☐ Swab ☐ BD Affirm

ADDITIONAL TEST(S)

nasal covid 19

MICROBIOLOGY / PARASITOLOGY

TEST	CPT	✓
...N SOURCE:		
...AFB/Smear	87206/87015/87116	
Anaerobic	87075	
Blood	87040	
...Compre. Viral	87252x5/87253x2/87254x2	
CSF/Smear	87070	
Eye/Ear/Smear	87205/87070	
Fungus/Smear	87206/7102	

TEST	CPT	✓
CULTURE, Genital/Smear	87205/87070	
CULTURE, Grp B Strep	87070	
CULTURE, Herpes	87255	
CULTURE, Mycoplasma	87109	
CULTURE, Respiratory (Sputum)	87205/87070	
CULTURE, Body Fluid/Smear	87070/87205/87075	
CULTURE, Throat	87070	
CULTURE, Full Throat	87070	
CULTURE, Urine	87086	

TEST	CPT	✓
CULTURE, Wound/Smear	87205/87070	
GC&CHLAMYDIA, AMP PROBE, SWAB	87491/87591	
GC&CHLAMYDIA, AMP PROBE, URINE	87491/87591	
STD PANEL (GC/CHL/TRIC)	87491/87591/87661	
INFLUENZA A&B (FLU ONLY)	87400	
INFLUENZA A/B AND RSV	87631	
MYCOPLASMA, IGM	86738	
STREP A (Rapid Strep Screen)	87880	

TEST	CPT	✓
STOOL STUDIES:		
C-DIFF BY PCR	87493	
CULTURE, Stool	87427	
GIARDIA CRYTOSPORDIUM	87328/87329	
H. PYLORI STOOL	87338	
OCCULT BLOOD	82270	
OVA & PARASITE (O&P)	87177/87209	
ROTAVIRUS	87425	
WBC, FECES	89055	

PHYSICIANS ORDERS X-RAY REPORTS

EXHIBIT
F

Physician Order

Nursing Order for

DOB/Sex: 1954 M **Visit/MRN:** 300000694/5492 **Admit Date:** 05/23/2020

Landmark Hospital of Athens
775 Sunset Dr.
Athens, GA 30606 (EST)

COVID-19 TEST (REJECTED)

Order	Covid-19 test	Ordering Method	Provider Entry
Priority	Scheduled / Routine	Order Number	#1166569
Start Date/Time	06/10/2020 16:45	Order Status	Rejected
Additional Directions			

Charting Date/Time	Action	User	Provider	Signature Status	Notes
06/10/2020 16:45	**Requested**	Dawson, Kaelan (DNP)	Dawson, Kaelan (DNP)	ELECTRONICALLY SIGNED 06/10/2020 16:45	
06/10/2020 17:41	**Rejected**	Dawson, Kaelan (DNP)	Dawson, Kaelan (DNP)	ELECTRONICALLY SIGNED 06/10/2020 17:41	

EXHIBIT G

Gmail Brian Cathey <cathey@sjwtriallaw.com>

FW: Info

@landmarkhospitals.com> Fri, Jun 12, 2020 at 7:10 AM
To: @landmarkhospitals.com>,
@landmarkhospitals.com>,
"cathey@sjwtriallaw.com" <cathey@sjwtriallaw.com>

From: Kim Wilkinson
Sent: Thursday, June 11, 2020 6:17 PM
To:
Subject: Info

Hey! Hope your day was well!

Sorry that it took so long to get this information to you. I wanted to make sure that I did thorough research. Here are a few things that I learned this week from the DPH. I have talked to a few people from there, including their epidemiologist. I was also directed to the American Society for Microbiology for information.

The issue that some of the doctors have with nasal swabs are the detection of the viral genetic material (RNA) and its shedding. The length of viral shedding has ranged anywhere from 6-47 days. And if the RNA is detected, it suggests that the virus may be present. However, this doesn't necessarily mean that the patient is still contagious. The PCR does not distinguish between the presence of live virus and non-infectious viral debris. I think this is where the term "false positive" comes in to play. So, I do agree that this is not the BEST term to use. The test has definitely detected something. The question would be if it is active or just the shedding.

I know that you specifically mentioned the tracheal testing vs regular nasal testing. Based off of my conversation with Dr. Jenkins, the thoughts are that a simple suction does not need a centrifuge because it is considered a sputum specimen. It's not deep enough to be a BAL. He prefers this method because the specimen is more sensitive. From the American Society for Microbiology, they state that "We are learning something new every day about the best specimen types, collection methods and testing platforms for detection. Nasopharyngeal (NP) swabs are the preferred specimen type of the CDC, but this topic is rapidly evolving. CDC guidance has been revised in the past few weeks

to allow for lower respiratory tract testing, oropharyngeal (OP) swab testing, self-collected swabs and nasal turbinate swabs. How well these specimens perform against each other is difficult to guess, as we have limited data on this topic."

After speaking with the DPH about everything going on here, she did assure me that the negative/positive/negative results have been very common in ALL facilities and no one has a true answer for why this happens. After asking Dr. V about it, he said that the only thing that makes sense to him is that the cilia in our noses hold on to some of the virus, like I mentioned above, and it detects it. He said it we do several tests, it may have all gotten swabbed out, or the nose became raw and the cilia was no longer there to offer the virus. Either way, there is still a huge mystery on a lot concerning COVID.

The best advice I could get was to treat all of our patients as they are positive, and wear N-95 masks with shields or goggles, which is what we are currently doing. Hope this helps! Please feel free to forward to anyone else who may have had concerns. And again, thanks for bringing it to my attention!

Kimberly Wilkinson

Director of Quality Management

Respiratory Therapy and Lab

knwilkinson@landmarkhospitals.com

706-425-1519 (o)

706-206-8630 (c)

EXHIBIT H

Physician Order

Nursing Order for

DOB/Sex: /1941 F **Visit/MRN:** 300000669/5307 **Admit Date:** 05/04/2020

Landmark Hospital of Athens
775 Sunset Dr.
Athens, GA 30606 (EST)

DC DROPLET PRECUATIONS (ACCEPTED)

Order	DC droplet precuations	Ordering Method	Verbal
Priority	Scheduled / Routine	Order Number	#1165640
Start Date/Time	06/09/2020 14:32	Order Status	Accepted
Additional Directions			

Charting Date/Time	Action	User	Provider	Signature Status	Notes
06/09/2020 14:33	**Requested** (Verbal)		Sagel, Anthony (MD)	ELECTRONICALLY SIGNED 06/10/2020 16:56	
06/09/2020 14:41	**Accepted**				
06/09/2020 16:12	**Verification**				
06/10/2020 12:23	**Note**				This RN will not D/C droplet isolation on pt with t wo positive COVID swabs in past week.