

March 26, 2020

COVID-19 Testing at Milwaukee Health Department Laboratory

The Milwaukee Health Department Laboratory (MHDL) continues to offer ‘*fee-exempt*’ COVID-19 testing, utilizing the CDC 2019-Novel Coronavirus (2019-nCoV) real-time RT-PCR Diagnostic Panel under a Food and Drug Administration’s (FDA) Emergency Use Authorization (EUA)¹ only. The Wisconsin State Laboratory of Hygiene (WSLH) is also offering this testing.

The test is intended for qualitative detection of nucleic acid from 2019-nCoV in respiratory specimens to help in COVID-19 diagnosis.

Testing Guidelines

- Wisconsin clinicians can order a test for COVID-19 for patients suspected to have the disease without prior approval from DHS or MHD.
- Clinicians are encouraged to use their judgment based on clinical symptoms, evolving epidemiology and testing guidance from CDC. Please refer to [Appendix 1](#) for DHS Priority levels for COVID-19 testing.

Requests for testing must include:

- [MHDL specimen requisition form](#) (See [Appendix 2](#) for required fields)
 - Please write COVID-19 in the “Other” section under “PCR” for the desired testing
 - In order to ensure rapid and accurate reporting of COVID-19 results, the “Patient Information” section of the requisition must include AT LEAST Name, DOB, Address, and Sex. Additionally, please ensure that the “Your Facility” section located at the bottom right corner of the form is filled out **as completely as possible** and reflects the correct **phone and fax numbers** for results communication. **If the report needs to be faxed to multiple locations, please note that in this section and we can honor that request.** Otherwise, the report will only be sent to the provider whose information is listed in this section.
- Wisconsin COVID-19 Patient Information Form ([Appendix 3](#)) – As of 3/26/20 specimens submitted to MHDL or WSLH must include this updated form. **The CDC Person Under Investigation (PUI) form is no longer required to be completed or submitted at the time of testing.**

Clinical Specimens

- Current CDC recommendations for upper respiratory specimens are to collect **only nasopharyngeal (NP) swabs** in viral transport media (VTM)/universal transport media (UTM). Below are ordering recommendations of acceptable collection kits:

| Transport Media | Manufacturer | Item | Catalog |
|-----------------|----------------------------|--------------------|---------|
| VTM/UTM | Remel (all 100 kits/pk) | M4 Universal Kit | R12570 |
| | | M4RT Universal Kit | R12578 |
| | | M5 Universal Kit | R12580 |
| | | M6 Universal Kit | R12582 |
| | Becton Dickinson | UVT collection kit | 220531 |

| | | | |
|-------------------------------|-------------------|---------------------------|-----------|
| | Copan Diagnostics | UTM Kit with flock swab | 305C |
| Liquid Amies-based | Copan Diagnostics | ESwab | 481C |
| | Puritan (300/cs) | Opti-swab with flock swab | 3317-H |
| Dry swab in RNase free saline | Puritan | Flock swab | 25-3317-H |
| | Copan | Minitip FloqSwab | 501CS01 |

- For clinical specimen collection information, please refer to [Appendix 4](#).

Specimen storage:

- After collection, each specimen should be placed in separate secondary leak-proof container such as a biohazardous bag or zip lock bag with an outer pocket for lab requisition/paper work.
- 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.

Packaging and Shipping to MHDL

If you have questions about how to submit specimens from approved patients for testing, contact MHDL laboratory at 414-286-3526 during normal business hours (Monday – Friday 8:00 AM – 4:45 PM).

If the specimen will be transported and received within 72 hours of collection, store specimens at 2-8° C and ship on cold packs.

- **If unable to transport the specimen for receipt within 72 hours of collection, freeze the specimen and ship on dry ice.**
- Package as a **UN3373 Biological Substance ‘Category B’**
- Monday – Friday specimens can be delivered to:
*Zeidler Municipal Building
841 N Broadway St, 2nd Floor
Milwaukee, WI 53202*
- **Please use your agency’s courier for transporting any COVID-19 specimens to the MHD lab.**
- If you *do not* have your own courier or to coordinate deliveries outside of business hours please call MHDL at 414-286-3526.

Specimen Rejection Criteria

- Dry swabs and/or those not submitted in VTM, UTM, VCM transport media or equivalent
- Specimens received at room temperature and *not* submitted on cold packs or dry ice
- Unfrozen specimens received at the MHDL >72 hrs. after collection

Test Results

Test results will be available within 1-2 days of receipt of specimens by MHDL. Depending on when we receive specimens or for significantly higher volume of test requests, TAT could be longer. All results will be reported to the submitter electronically. Submitter and WI DHS will be notified by phone with any positive results. **Please ensure that correct phone and fax numbers are provided on the MHDL requisition form.**

Test results will be reported as one of the following:

- **Positive** - Positive results do not rule out bacterial infection or co-infection with other viruses. Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms. (Note that this is an actionable result)
- **Negative** – Negative results do not preclude 2019-nCoV infection and should not be used as the sole

basis for treatment or other patient management decisions.

- **Inconclusive** – This test result is inconclusive. It did not meet the full criteria established by the CDC for the presence of 2019-nCoV. This specimen will be sent to the CDC for additional testing.
- **Invalid** – This specimen exhibited inhibition in the PCR assay or the specimen contained an inadequate amount of clinical material. If clinically warranted, repeat testing is suggested.

¹The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Letter of Authorization (FDA EUA) Fact Sheet for Healthcare Providers, and Fact Sheet for Patients can be found at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

²Check CDC website routinely for current [2019-nCoV testing criteria](#)

Appendix 1. DHS Priority levels for COVID-19 testing. Rev: 3/26/20

| |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tier One: |
| <ul style="list-style-type: none"> • Patient is critically ill and receiving ICU level care with unexplained viral pneumonia or respiratory failure |
| -OR- |
| <ul style="list-style-type: none"> • Patient resides in a long-term care facility or other high consequence congregate setting (e.g. prisons or jails), with unexplained fever OR signs/symptoms of acute respiratory illness |
| -OR- |
| <ul style="list-style-type: none"> • Post-mortem testing for people who died of unknown causes, if COVID-19 testing would influence infection control interventions or inform a public health response |
| Tier Two: |
| <ul style="list-style-type: none"> • Hospitalized (non-ICU) patients with unexplained fever AND signs/symptoms of acute respiratory illness |
| -OR- |
| <ul style="list-style-type: none"> • Health care workers or first responders with unexplained fever AND signs/symptoms of acute respiratory illness, regardless of hospitalization |
| -OR- |
| <ul style="list-style-type: none"> • Essential staff in high consequence congregate settings (e.g. correctional officers) with unexplained fever AND signs/symptoms of acute respiratory illness, regardless of hospitalization |
| Tier Three: Testing of tier three specimens will not be performed at WSLH or MHDL |
| <ul style="list-style-type: none"> • Patient is in an outpatient setting and meets criteria for influenza testing. This includes individuals with co-morbid conditions including diabetes, COPD, congestive heart failure, age >50, immunocompromised hosts among others |
| -OR- |
| <ul style="list-style-type: none"> • Health care workers with acute respiratory symptoms (rhinorrhea, congestion, sore throat, cough) without fever |
| Tier Four: Testing of tier four specimens will not be performed at WSLH or MHDL |
| <ul style="list-style-type: none"> • Other patients, as directed by public health or infection control authorities (e.g. community surveillance or public health investigations) |
| Do NOT Test |
| Patients without symptoms |
| Patients with mild upper respiratory symptoms only who are not health care workers |

Microbiology Requisition H-445

City of Milwaukee Health Department Laboratory

841 N. Broadway, Rm. 205, Milwaukee, WI 53202-3653

Phone: (414) 286-3526 FAX: (414) 286-5098

email: mhdlab@milwaukee.gov web: www.milwaukee.gov/healthlab

Only one specimen per form.

Please refer to Test Reference Manual and Fee Schedule for more information:

<https://city.milwaukee.gov/health/testing-fees>

PATIENT INFORMATION (required)

Last Name: _____

First Name: _____ MI: _____

Date of Birth (mm/dd/yyyy): ____/____/____

Social Security Number: _____-_____-_____

Street Address: _____

City/State/Zip: _____

Phone: _____

Gender: M F M→F F→M Other

Race: White Black Native Hawaiian/Pacific Islander
 Native American/Native Alaskan Asian Unknown

Ethnicity: Hispanic/Latino Not Hispanic/Latino Unknown

SPECIMEN TYPE

Check appropriate specimen and fill in requested information.

- Blood
- Body Fluid Specify: _____
- Bronchial wash
- Lesion
- Wound Specify: _____
- Sputum
- Stool
- Swab (Genital) Specify: _____
- Swab (Non-Genital) Specify: _____
- Tissue Specify: _____
- Urine
- Other Specify: _____

Date Collected: ____/____/____ Time: _____
mm dd yyyy

Specimen ID# _____

TEST(S) REQUESTED Check all that apply.

Bacteriology (Culture)

- Campylobacter
- Chlamydia trachomatis
- Escherichia coli O157:H7
- Legionella pneumophila
- Mycobacterium
- Mycoplasma hominis
- Mycoplasma pneumoniae
- Neisseria gonorrhoeae
- Salmonella
- Shigella
- Ureaplasma urealyticum
- Yersinia enterocolitica

Parasitology

- Acanthamoeba
- Cryptosporidium & Giardia
- Cyclospora
- Cystoisospora (Isospora)
- Microsporidia
- Ova & Parasite Exam
Suspect agent: _____

Clinical/Referred Isolate for ID

- Bacterial Fungal
- Viral Mold

Suspect agent: _____

Previous test performed (if any): _____

Serology EIA

- HIV 1/2
- Measles IgG
- Mumps IgG
- Rubella IgG
- Shiga Toxin
- Syphilis w/reflex RPR, TPPA
 RPR (titer) TPPA (only)

Molecular Testing

- Chlamydia/Gonorrhea Combo NAAT
- Mycoplasma genitalium NAAT
- Trichomonas vaginalis NAAT
- Gastrointestinal Pathogen Panel
- Respiratory Pathogen Panel

PCR

- Bordetella pertussis/parapertussis
- Clostridium difficile
- Enterovirus
- Herpes Simplex Virus 1/2
- Influenza A/B
- Legionella pneumophila
- Measles
- Mumps
- Mycobacterium tuberculosis/RIF
- Mycoplasma pneumoniae
- Norovirus (GI & GII)
- Rubella
- Varicella Zoster Virus
- Other: **COVID-19**

DNA Sequencing: Bacterial ID
 Fungal ID

DNA Probe: Blastomyces dermatitidis
 Coccidioides immitis
 Histoplasma capsulatum

** Please contact the lab for Select Agent rule-out confirmation.**

PATIENT HISTORY/CLINICAL INFO

Clinical Diagnosis: _____

Date of onset: ____/____/____
mm dd yyyy

Surveillance Disease Determination

Date of death: ____/____/____
mm dd yyyy

OTHER SIGNIFICANT FACTORS

- Animal contact Test of cure
- Arthropod contact Travel
- Foodborne risk Waterborne risk
- Immunocompromised Other outbreak-related
- Occupational risk

YOUR FACILITY Enter your facility address. Results are returned to this address.

Facility Name: _____

Physician: _____

Address: _____

City/State/Zip: _____

Phone: _____ Fax: _____

For internal use only

WISCONSIN 2019 NOVEL CORONAVIRUS (COVID-19)

PATIENT INFORMATION FORM

PATIENT DEMOGRAPHICS

FIRST NAME: _____ LAST NAME: _____ DATE OF BIRTH: ____/____/____

GENDER: M F OTHER UNKNOWN

ADDRESS: _____ CITY: _____

STATE: _____ ZIP: _____ COUNTY: _____

PHONE 1 : _____ PHONE 2: _____ EMAIL: _____

REPORTING FACILITY

NAME: _____ PERSON REPORTING: _____ PHONE: _____

SPECIMEN AND CLINICAL INFORMATION

ONSET DATE: _____ SYMPTOMS: _____

COLLECTION DATE: _____ SPECIMEN TYPE: NP OP NP/OP SPUTUM BAL FLUID

PLEASE SELECT ALL THAT APPLY BELOW TO DETERMINE TEST PRIORITY

| |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| TIER ONE: |
| <input type="checkbox"/> Patients who are critically ill and receiving ICU level care with unexplained viral pneumonia or respiratory failure |
| -OR- |
| <input type="checkbox"/> Patients who are residents of long-term care facilities or other high consequence congregate settings (e.g. prisons or jails), with unexplained fever OR signs/symptoms of acute respiratory illness. |
| -OR- |
| <input type="checkbox"/> Post-mortem testing for people who died of unknown causes, if COVID-19 testing would influence infection control interventions or inform a public health response |
| TIER TWO: |
| <input type="checkbox"/> Hospitalized (non-ICU) patients with unexplained fever AND signs/symptoms of acute respiratory illness |
| -OR- |
| <input type="checkbox"/> Health care workers or first responders with unexplained fever AND signs/symptoms of acute respiratory illness, regardless of hospitalization |
| -OR- |
| <input type="checkbox"/> Essential staff in high consequence congregate settings (e.g. correctional officers) with unexplained fever AND signs/symptoms of acute respiratory illness, regardless of hospitalization |
| TIER THREE: TESTING OF TIER THREE SPECIMENS WILL <u>NOT BE PERFORMED</u> AT WSLH OR MHDL |
| <input type="checkbox"/> Patient is in an outpatient setting and meets criteria for influenza testing . This includes individuals with co-morbid conditions including diabetes, COPD, congestive heart failure, age >50, immunocompromised hosts among others |
| -OR- |
| <input type="checkbox"/> Health care workers with acute respiratory symptoms (e.g. rhinorrhea, congestion, sore throat, cough) without fever |
| TIER FOUR: TESTING OF TIER FOUR SPECIMENS WILL <u>NOT BE PERFORMED</u> AT WSLH OR MHDL |
| <input type="checkbox"/> Other patients, as directed by public health or infection control authorities (e.g. community surveillance or public health investigations) |
| DO NOT TEST |
| Patients without symptoms |
| Patients with mild upper respiratory symptoms only who are not health care workers |

WHEN SUBMITTING SPECIMENS TO THE WSLH AND MHDL, THIS PATIENT INFORMATION FORM **MUST BE ACCOMPANIED BY THE APPROPRIATE REQUISITION FORM:**

Milwaukee Health Department Laboratory: [Microbiology Requisition H-455](#)
Wisconsin State Laboratory of Hygiene: [CDD Requisition Form A \(#4105\)](#)

Appendix 4. Clinical Sample Collection

Infection control precautions for Collection of Nasopharyngeal swabs for COVID-19 and Influenza:

1. Primary care provider should wear all PPE including an N95 mask, eye protection/face shield and follow the CDC Infection prevention and control guidelines, including the donning and doffing of PPE
2. Collection should be done in a designated room with the door closed and with only the member and PCP present
3. If possible after the specimen for COVID-19 is collected, obtain a Rapid Influenza test to rule out Influenza

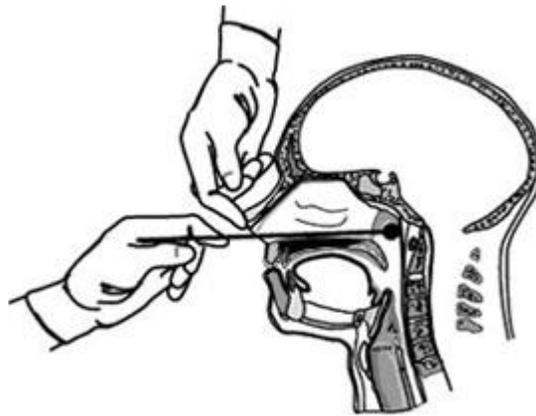
Collection Instructions:

See the current CDC guidelines for upper and lower respiratory specimen collection and appropriate biosafety precautions for healthcare workers found at:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html>

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/caring-for-patients.html>

1. Label tube of UTM legibly with the patient's name **and** date of birth, or medical record number (specimen tube **must** have two unique patient identifiers on it, or it will not be tested).
2. **Nasopharyngeal specimen (NP):**
 - a. Use the flexible shaft NP swab provided to collect the specimen.
 - b. Have the patient blow their nose and then check for obstructions.
 - c. Tilt the patient's head back 70 degrees & insert the swab into nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from nostrils to outer opening of patient's ear indicating contact with nasopharynx. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab while rotating it.



- d. Insert the swab into the tube of UTM, making certain that the swab tip is covered by the liquid in the tube. The swab is to remain in the tube for transport
- e. Plastic shaft NP swab: The swab shaft extends past the top of the tube. Snap it off at the break line on the shaft, allowing the end with the swab tip to remain in the liquid. The tip of the swab must be immersed in the liquid.