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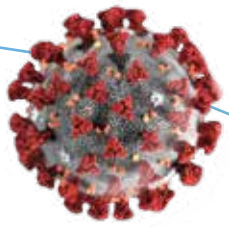
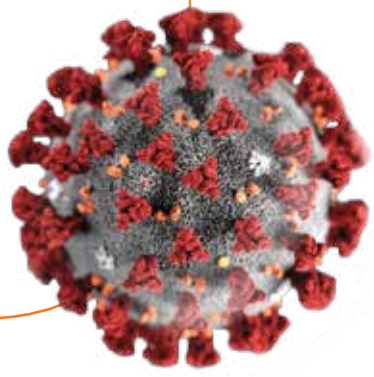
Mylab
Discovery solutions
Translating Discovery to Delivery



DIAGNOSE DETECT DEFEAT

PathoDetect™

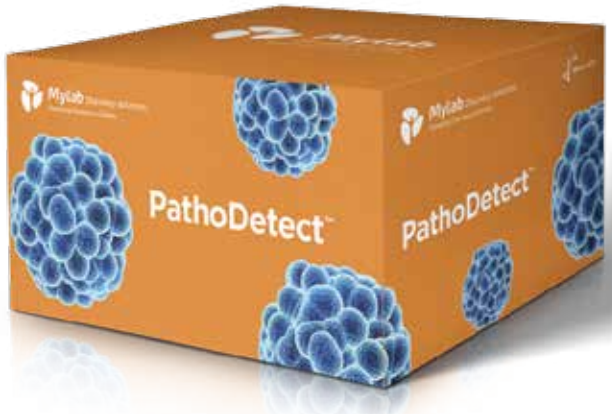
FIGHT CORONA VIRUS



Guidelines for working with

Potentially Infectious Materials

(COVID-19)



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PathoDetect™ OncoScreen™ DiscoverSeries™

Laboratory Requirements:

- Certified Class II Biological Safety Cabinet (BSC*).
- Sealed cold centrifuge 4^0C 12000 RPM to prevent aerosol spread
- Real time PCR with FAM/VIC dye.
- PCR Work Station [UV lamp; Laminar flow (Class 100 HEPA filtered)]
- Vortex mixer
- Microcentrifuge
- Micropipettes (2 or 10 µl, 200 µl and 1000 µl)
- Multichannel micropipettes (5-50 µl)
- 2 x 96-well cold blocks
- -20°C (non-frost-free) freezers; 4°C refrigerator
- Mylab's PathoDetect

* Recommended adequately ventilated room at a minimum natural ventilation with at least 160l/s/patient air flow, or negative pressure rooms with at least 12 air changes per hour and controlled direction of air flow when using mechanical ventilation

Guideline for the Laboratory Staff:

1) Limit the number of persons present in the room to the minimum required

2) Use the adequate PPE: (PPE, personal protective equipment.)

- Respirators (NIOSH-certified N95, EU FFP2 or equivalent, or higher level of protection).

  Note: (When putting on a disposable particulate respirator, always check the seal/fitness. Be aware that the presence of facial hair (e.g. beard) may prevent a proper respirator fit for the wearer.)
- Eye protection (i.e. goggles or a face shield).
- Clean, long-sleeved disposable fluid resistant gown.(If gowns are not fluid resistant, a waterproof apron should be used for procedures where it is expected that fluid might penetrate the gown
- Gloves
- Caps
- Shoe covers

3) Perform hand hygiene before and after contact with the patient and his or her surroundings and after PPE removal.

4) Procedure for: Donning PPE (Putting on PPE)

- Perform hand hygiene
- Put on shoe covers
- Put on cap
- Put on gown
- Put on mask/respirator
- Put on eye protection
- Put on gloves

5) **Procedure for: Doffing PPE(Removing PPE)**

- Remove shoe covers
- Remove cap
- Remove gown and gloves together*
- Perform hand hygiene
- Remove eye protection
- Remove mask/respirator
- Perform hand hygiene

Note: * The preferred method for doffing a disposable gown and gloves is, to break the ties at the neck by pulling on the upper front portion of the gown with the hands still gloved, balling or rolling in the contaminated surfaces, and pulling the gloves off inside-out as the hands are withdrawn from the gown's sleeves. The gown and gloves can then be placed in a disposal receptacle together.

Sample Type:

Specimen	Collection	Storage & Transport
Broncheoalveolar lavage, tracheal aspirate, pleural fluid	Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.	Specimens can be stored at 4°C for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -20°C or lower.
Sputum	Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.	
Nasopharyngeal swab AND oropharyngeal swab (NP/OP swab)	Use only synthetic fiber swabs with plastic 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. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media.	
Tissue from biopsy or autopsy including from lung	Sterile container with saline	≤24 hours: 4°C >24 hours: -70°C
Serum (2 samples acute and convalescent possibly 2-4 weeks after acute phase)	Serum separator tubes (adults: collect 3-5 ml whole blood)	≤5 days: 4°C >5 days: -70°C
Urine	Urine collection container	

Waste Management and Decontamination Procedures:

6) **Ensure that all materials used is disposed appropriately.**

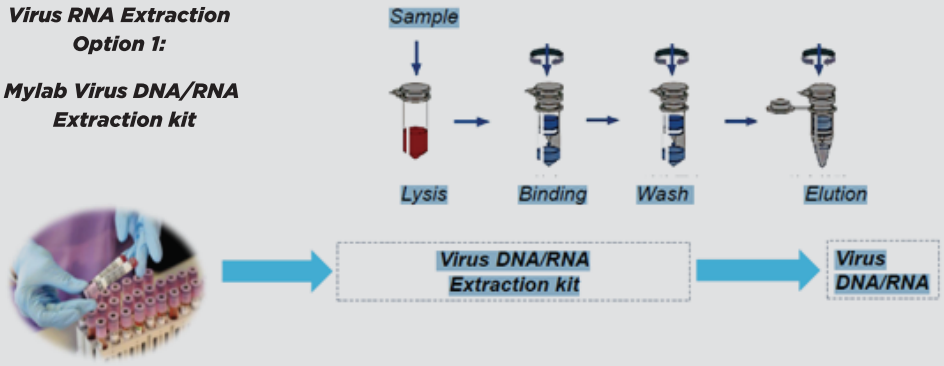
7) **Disinfection of work areas and decontamination of possible spills of blood or infectious body fluids should follow validated procedures, usually with chlorine-based solutions**

8) **Specifics for transport of samples to laboratory:**

- Ensure that personnel who transport specimens are trained in safe handling practices and spill decontamination procedures. •
- Follow the requirements in the national or international regulations for the transport of dangerous goods (infectious substances) as applicable
- Deliver all specimens by hand whenever possible. Do not use pneumatic-tube systems to transport specimens.
- State the full name, date of birth of the suspected case clearly on the accompanying request form. Notify the laboratory as soon as possible that the specimen is being transported.
- Packaging and shipment to another laboratory Transport of specimens within national borders should comply with applicable national regulations.

Nucleic acid extraction amplification

- Laboratory workers should wear appropriate personal protective equipment (PPE) which includes disposable gloves, mask, disposable laboratory gown and eye protection when handling potentially infectious specimens.
- The following activities involving manipulation of potentially infected specimens should be, performed in a certified Class II BSC in a BSL-2 facility.
- All procedure with the potential to generate aerosols or droplets e.g., vortexing centrifugation should be performed in a certified Class II Biological Safety Cabinet (BSC). Use sealed rotors for centrifugation to prevent aerosols spread. Load and unload rotors in a BSC.
- Aliquoting and/or diluting specimens, Nucleic acid extraction procedures involving potentially infected specimens should be done inside BSC.
- Viral RNA extraction:



Real Time PCR

Contact Mylab for recommended RTPCR's

Use of any real-time RT PCR (rRT-PCR) assays with FAM/VIC dye for the in vitro qualitative detection of 2019-Novel Coronavirus (2019-nCoV) in respiratory specimens and sera.

Dispose of infectious materials

Use Acceptable surface decontaminants. Clean and decontaminate all work surfaces, pipets, centrifuges and other equipment prior to use by using following reagents. Put on, use, take off and dispose of personal protective equipment properly.

For instruments and pipettes

Contact Mylab for availability and supply

- DNAZapTM (Life Technologies)

  It is a nucleic acid decontamination solution completely degrades contaminating DNA and RNA at the level of PCR sensitivity

- DNA AwayTM (Fisher Scientific)

  It degrades DNA more quickly and effectively than autoclaving, eliminating unwanted DNA and DNase from glassware and plastic ware

- RNAse AwayTM (Fisher Scientific)

  Solution use for eliminating RNase contamination from labware

For Lab surfaces and work benches:

- Bleach (1:10 dilution of commercial 5.25-6.0% sodium hypochlorite)

REF

Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV)

https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Flab-biosafety-guidelines.html

https://www.who.int/docs/default-source/coronaviruse/who-rights-roles-respon-hw-covid-19.pdf?sfvrsn=bcabd401_0

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

https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-detection-instructions.html

Biosafety in Microbiological and Biomedical Laboratories 5th edition available at http://www.cdc.gov/biosafety/publications/.

according to WHO recommendations available at: https://www.who.int/csr/disease/coronavirus_infections/Biosafety_InterimRecommendations_NovelCoronavirus20 12_31Oct12.pdf?ua=1 Information on biosafety for SARS, a Betacoronavirus that can cause severe respiratory disease can be consulted at https://www.who.int/csr/sars/biosafety2003_04_25/en/. and other guidance.

Coronavirus disease (COVID-19) Qualitative PCR Kit in humans

Intended use:

PathoDetect 2019-nCoV Detection Kit offers an in vitro diagnostic real time PCR assay for qualitative detection of 2019- novel Coronavirus RNA in respiratory specimens and sera. The kit offers the universal detection of SARS-like coronaviruses and specific detection of 2019-nCoV.

Note: please read disclaimer

PathoDetect 2019-nCoV Detection Kit:

Mylab Discovery solutions 2019-nCoV Detection Kit provides ready to use solution for detection of coronavirus using real time PCR technology. Detection is based on the amplification of a specific conserved RNA sequences of coronavirus and detection by Taqman probe based chemistry. An Internal control is detected along with the coronavirus target controlling the extraction efficacy and possible PCR inhibition. The test is designed to use across wide range of PCR platforms. The recommended CDC protocol for coronavirus detection ensures that the kit leads to highly-specific and ultrasensitive results in short time.

Kit content:

- Reagents for Nucleic acid extraction from respiratory/sera specimens
- Reagents for Real time PCR
- Inclusion of synthetic positive and negative controls

Key features:

- Design of the kit as per CDC recommended protocol
- Highly Sensitive real time PCR test for novel coronavirus 2019 detection
- Includes all reagent required to perform Sample to Result analysis no additional reagents needed.
- Synthetic Positive controls provided for validity of the test
- Inclusion of internal control for quality check throughout the procedure
- Low contamination risk – no post-PCR product handling
- High-throughput – can screen up to 24 samples in a single run
- Fast – sample to results within two hours

Ordering Information:

Coronavirus disease (COVID-19) Qualitative PCR Kit in humans

Product	Cat. No.	Reaction size / kit	Price Per kit
PathoDetectTM COVID-19 Qualitative PCR kit	PCOVS25	25	37500
PathoDetectTM COVID-19 Qualitative PCR kit	PCOVS50	50	67500
PathoDetectTM COVID-19 Qualitative PCR kit	PCOVS100	100	120000
As a National Emergency Mylab will be offerring 50% Discount to the Kits			

Disclaimer:

Mylab Discovery Solutions follows Centers for Disease Control and Prevention (CDC) guidelines while offering PathoDetect 2019-nCoV Detection Kit. Currently functionality of the test is checked against synthetic positive controls. Mylab hasn't established any regulatory clearance for the test yet, which is obvious scenario in pandemic. Though Public health centers or hospitals that use this test need to validate the test performance in house, Mylab is trying to collect sufficient clinical data for kits utility and reliability and also keeping an eye on any mutations or changes to existing novel coronavirus strain for further validity of the test

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Mylab Discovery solutions Translating Discovery to Delivery