Nasal Self-Swab Concept of Implementation

Overview of Adjusted Operations Using Less Invasive Nasal Self-Swab Testing Method

April 16, 2020

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Agenda

1. What is Different
2. Screening Criterion
3. Concept of Operations
4. Reduction in PPE Requirements
5. Instructional Video
6. Updated Informed Consent

What is Different from the Nasopharyngeal Concept of Operations

- No longer a requirement to take a temperature on site; with onsite registration, you just need to ask screening criteria questions.
- Extremely limited contact with the individual in the car; when the car window is down, the personnel on the site will always be greater than 6 feet away.
- With staff remaining greater than 6 feet away, their only PPE could be gloves. However, for the staff to protect each other from respiratory secretions, and based on CDC guidance, the recommendation is that the staff does wear surgical masks as well.
- Gloves may either be latex or nitrile; most sites will be using nitrile gloves.
- Formerly, an extensive informed verbal consent was required due to the invasive nature of the nasopharyngeal swab. Recommendation for the new nasal swab is to either 1) include an informed consent as part of the online registration or 2) include the consent in Step 1 on site. [Example on last page of this implementation guide.]

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Screening Criterion

- The Screening Criterion are based on HHS and CDC Guidance, dated 23 March 2020. This is subject to change with the progression of COVID-19.
- Priority 1 and Priority 2 are the focus of the Community Based Testing Site program.

Priority 1 Ensure optimal care options for all hospitalized patients, lesson the risk of healthcare-associated infections, and maintain the integrity of the U.S. healthcare system.	Priority 2 Ensure those at highest risk of complication of infection are rapidly identified and appropriately triaged.	Priority 3 As resources allow, test individuals in the surrounding community of rapidly increasing hospital cases to decrease community spread, and ensure health of essential workers.	Non-Priority
▪ Hospitalized patients ▪ Healthcare facility workers with symptoms	▪ Patients in long-term care facilities with symptoms ▪ Patients over age 65 years with symptoms ▪ Patients with underlying conditions with symptoms ▪ First responders with symptoms	▪ Critical infrastructure workers with symptoms ▪ Individuals who do not meet any of the above categories with symptoms ▪ Healthcare facility workers and first responders ▪ Individuals with mild symptoms in communities experiencing high numbers of COVID-19 hospitalizations	▪ Individuals without symptoms

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Concept of Operations

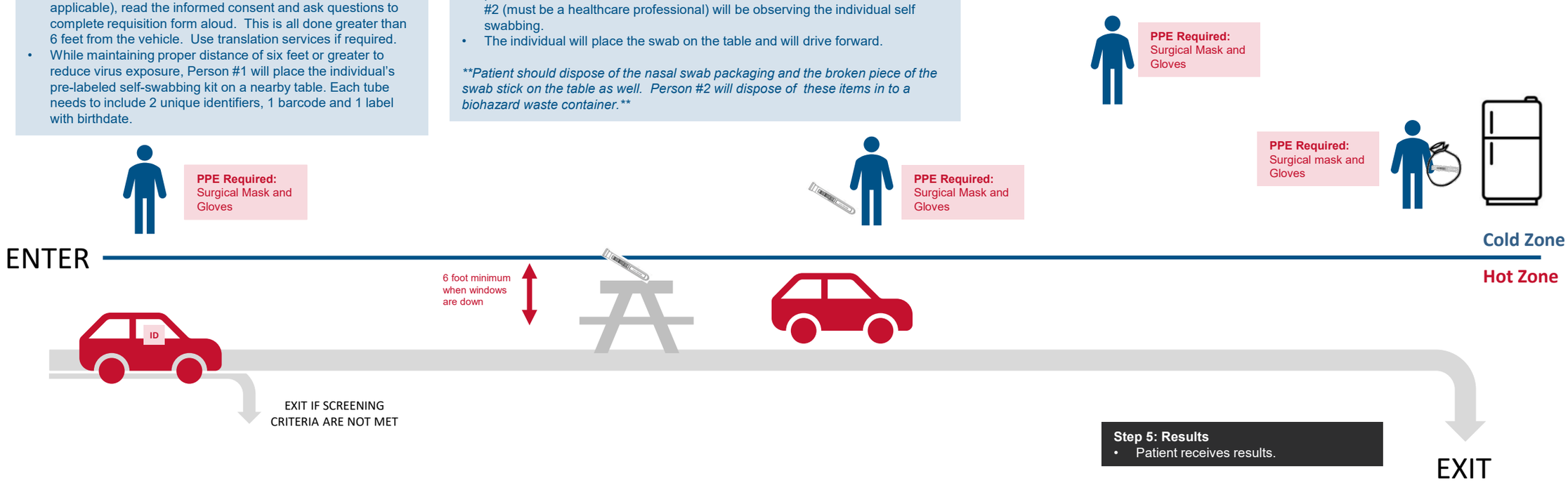
Step 1: Registration
- For sites with online registration, screening and informed consent, all the tubes are already prepared with patients unique identifiers, Person #1 can look at the photo ID through the window to validate identity in order to identify proper prepared tube or ask a person's name and DOB greater than 6 feet away from vehicle.
- For sites requiring onsite registration and informed consent, Person #1 will ask screening criteria questions (individual should be prepared to show healthcare/first responder ID if applicable), read the informed consent and ask questions to complete requisition form aloud. This is all done greater than 6 feet from the vehicle. Use translation services if required.
- While maintaining proper distance of six feet or greater to reduce virus exposure, Person #1 will place the individual's pre-labeled self-swabbing kit on a nearby table. Each tube needs to include 2 unique identifiers, 1 barcode and 1 label with birthdate.

Step 2: Self-Swabbing
- The individual has pulled up in their car, rolls down the window and secures tube with his/her personal unique identifiers.
- The tests are easily self-administered. Within the cold zone, Person #2 will provide a brief demonstration of the test and answer any questions.
- The individual will open the self swab, will insert the swab in the right mid-nostril, and rotate it twice and hold it in place for 15 seconds; the individual will then insert the swab in the left mid-nostril, and rotate it twice and hold it in place for 15 seconds. The individual will then open the transport media vial and will place the swab in the vial and break it off, and will then close the vial. Person #2 (must be a healthcare professional) will be observing the individual self swabbing.
- The individual will place the swab on the table and will drive forward.

Patient should dispose of the nasal swab packaging and the broken piece of the swab stick on the table as well. Person #2 will dispose of these items in to a biohazard waste container.

Step 3: Specimen Handling
- Person #2 will drop the specimen off in a specimen bag that will be sealed and secured by Person #3.
- Person #2 will decontaminate the surface of the table with a hypochlorite solution and will doff his/her gloves and don new gloves.

Step 4: Specimen Storage & Shipment
- Person #3 places bagged specimen in refrigeration at 2-8°C (35.6-46.4°F).
- When shipped, sample must remain at 2-8°C (35.6-46.4°F).
- Sample will be picked up for shipment to designated laboratories.



Personal Protective Equipment Adjustments

Weekly Re-supply	Per Kit	Unit of Measure
Nasal Foam Swab [NOT NASOPHARYNGEAL SWABS]	2,500	Each
Transport Media (Viral Transport Media, Universal Transport Media, or Normal Saline)	2,500	Each
Matched standard code-128 barcodes with unique numbers	2,500	Pairs
Gloves (Nitrile) (S, M, L)	20,000	Each
Surgical Masks	150	Each
Biohazard Bags	50	Boxes
Specimen Transport Bag with requisition pouch. 6 x 9″ polyethylene specimen bags case of 100	25	Case
Insulated Foam Shipping Kit - 30 1⁄4 x 14 1⁄2 x 16"	25	Each
Single-Use Cold Packs - 12 oz (24 pack x2)	10	Pack
UN3373 Biological Substance, Category B Air labels (roll of 500)	8	Pack
Tamper-Evident Tape, 3" x 110 yds	12	Pack
Telatemp Heat Indicator •6 windows in 10°F increments.(pack of 25)	5	Carton
Cavicide wipes	50	Containers
Care Touch Sterile Alcohol Prep Pads (2 Ply) - Alcohol Wipes 600 (weekly)	5	Boxes
Bleach	100	Containers
4.5" x 9" x 2.5 mil 18 oz. Whirl-Pak Sampling Bags case of 500	5	Case

One time purchase items (no weekly re-supply)	Per Initial Kit
Sharps containers 2 gallon or larger	10
Red Uline Garbage Cans 32 gallons	10

Instructional Video

Covid-19 Drive up Testing

(Youtube)

- This video is based on the concept that registration, screening and informed consent have all occurred online prior to arriving on site.

https://www.youtube.com/watch?v=vsQVxsQY3jc

Adjusted Informed Consent

PRIVACY ACT STATEMENT
Collection of this information is authorized by the Public Readiness and Emergency Preparedness Act (PREP Act), Pub. L. No. 109-148, and the President's Proclamation of a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak. Your information will be used to notify you of your test results and to seek reimbursement from your health insurance provider, if applicable. Providing this information is voluntary, however failure to do so will make it impossible for us to notify you of your results. We will share this information with a diagnostics lab that will test your sample, with a call center that will notify you of your results, and with your health insurance provider.

You have agreed, by coming to this test site, to participate in testing designed to identify whether you have been infected by the novel coronavirus and have developed COVID-19, the disease caused by the novel coronavirus. Your participation in this process is voluntary. Should you decide not to participate, you will not suffer any penalty or loss of benefits to which you are otherwise entitled. In addition, you should be aware of the following: This test involves the administration of a nasal swab that will capture mucus and secretions from your nose. Self-administering the swab is a low risk procedure and participation in this process and any records developed as a result of your participation that could be used to identify you are confidential and will be maintained in confidence.

Notes to Consider

1. Online Versions
   - Have individuals click to acknowledge the informed consent as part of the registration process.

2. On Site Versions
   - Have this printed on large foam board so those individuals who are hard of hearing can still read and acknowledge the consent.
   - Have translation services available so those individuals whose first language is not English are fully supported.

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