COVID-19 Tests

- **Nucleic Acid**
  - Directly probe for the RNA of the virus
  - Nucleic Acid Amplification
    - RT-PCR (CDC; Thermofisher; Roche; others)
    - Isothermal (Panther; Abbott; others)
  - Specimen is from the throat or nasal passage

- **Serology Test**
  - Antibodies to the virus
  - Patient’s serum
Specimen Type for Viral Tests

- A nasopharyngeal (NP) specimen collected by a HCP

- An oropharyngeal (OP) specimen collected by a HCP

- A nasal mid-turbinate swab collected by HCP or by a supervised onsite self-collection – or possibly by “tele-observation”

- An anterior nares (nasal swab) specimen collected by a HCP or by onsite or home self-collection

- Saliva (pending FDA approval; currently problematic for high throughput screening)
COVID-19 Tests at YNHHS

- Cepheid (GeneXpert)
  - Cartridge
  - Limited supply
  - 2 hour TAT

- CDC
  - RT-PCR
  - 6 hour TAT

- ThermoFisher
  - RT-PCR
  - Next Day TAT
  - High Volume

- Reference Lab
  - U of W, Mayo, Quest
  - 48 hour + TAT

- Hologic - Panther
  - TMA
  - 6 hour TAT
  - High Volume
### Table 1. Agreement between ACOV and IDNCOV (95% confidence interval)

<table>
<thead>
<tr>
<th>Site</th>
<th>Total Samples Tested</th>
<th>ACOV+/INDCO+</th>
<th>ACOV+/INDCO-</th>
<th>ACOV-/INDCO+</th>
<th>ACOV-/INDCO-</th>
<th>Positivity</th>
<th>Positive Agreement</th>
<th>Negative Agreement</th>
<th>Performance Agreement (Kappa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMCC A</td>
<td>208</td>
<td>33</td>
<td>13</td>
<td>1</td>
<td>161</td>
<td>22%</td>
<td>71.74 (56.32, 83.54)</td>
<td>99.38 (96.09, 99.97)</td>
<td>.783 (.779, .788)</td>
</tr>
<tr>
<td>IMCC B</td>
<td>125</td>
<td>39</td>
<td>17</td>
<td>0</td>
<td>69</td>
<td>44%</td>
<td>69.64 (55.74, 80.84)</td>
<td>100.0 (93.43, 100.0)</td>
<td>.711 (.706, .717)</td>
</tr>
<tr>
<td>ED 1</td>
<td>105</td>
<td>26</td>
<td>11</td>
<td>0</td>
<td>68</td>
<td>35%</td>
<td>70.27 (52.83, 83.56)</td>
<td>100.0 (93.33, 100.0)</td>
<td>.751 (.744, .757)</td>
</tr>
<tr>
<td>ED 2</td>
<td>31</td>
<td>12</td>
<td>3</td>
<td>0</td>
<td>16</td>
<td>50%</td>
<td>80.0 (51.37, 94.69)</td>
<td>100 (75.92, 100.0)</td>
<td>.803 (.792, .814)</td>
</tr>
<tr>
<td>ED 3</td>
<td>55</td>
<td>29</td>
<td>3</td>
<td>1</td>
<td>22</td>
<td>60%</td>
<td>90.63 (73.83, 97.55)</td>
<td>95.65 (76.03, 99.77)</td>
<td>.852 (.844, .861)</td>
</tr>
<tr>
<td>Overall</td>
<td>524</td>
<td>139</td>
<td>47</td>
<td>2</td>
<td>336</td>
<td>35%</td>
<td>74.73 (67.74, 80.67)</td>
<td>99.41 (97.64, 99.89)</td>
<td></td>
</tr>
</tbody>
</table>
# COVID Testing-Ramp Up Numbers

<table>
<thead>
<tr>
<th>Instruments</th>
<th>5-May</th>
<th>11-May</th>
<th>1-Jun</th>
<th>1-Jul</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC / LDT</td>
<td>300</td>
<td>300</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Thermo PCR</td>
<td>500</td>
<td>3,000</td>
<td>9,000</td>
<td></td>
</tr>
<tr>
<td>Cepheid (All YH)</td>
<td>165</td>
<td>165</td>
<td>165</td>
<td>165</td>
</tr>
<tr>
<td>BD Max / Diasonin</td>
<td>40</td>
<td>60</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Panther - Micro</td>
<td>-</td>
<td>750</td>
<td>750</td>
<td>750</td>
</tr>
<tr>
<td>Panther Fusion - Viro</td>
<td>-</td>
<td>-</td>
<td>850</td>
<td>850</td>
</tr>
<tr>
<td>Panther Plus - SRC</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>850</td>
</tr>
<tr>
<td>Roche 6800</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1140</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>505</strong></td>
<td><strong>1,875</strong></td>
<td><strong>4,875</strong></td>
<td><strong>12,865</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Current Testing</th>
<th>Instruments and tests on hand now</th>
<th>Instruments ordered with scheduled deliveries</th>
<th>Instruments ordered but no scheduled deliveries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staffing</td>
<td>Current Staffing Adequate</td>
<td>Current Staffing Adequate#</td>
<td>Current Staffing Inadequate#</td>
<td>Current Staffing Inadequate</td>
</tr>
<tr>
<td>Staffing Needs*</td>
<td>N/A</td>
<td>N/A</td>
<td>26 FTE (Pending Approval)</td>
<td>Additional 20 to 26 FTE (Not Submitted)</td>
</tr>
</tbody>
</table>

# Some current testing staff can be pulled from other laboratories and roles due to reduced volume / demand. Reopening of clinical work will require re-distribution of staff back to original labs and roles.

- NB: 30 Open Positions in Lab Med including virology and microbiology pre-COVID.
- Total= total capacity, includes capacity needed for YNHHS/YM testing.
CDC Guidelines (updated 4/27/2020)

PRIORITIES FOR COVID-19 TESTING
(Nucleic Acid or Antigen)

High Priority

• Hospitalized patients
• Healthcare facility workers, workers in congregate living settings, and first responders with symptoms
• Residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms
• Persons identified through public health cluster and selected contact investigations

Priority

• Persons with symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea and/or sore throat
• Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.
1. All patients will be **screened** for COVID-19 symptoms, including fever checks, the day of admission/visit and no more than two calendar days prior to visit whenever possible.

2. All inpatient admissions will be **tested** for COVID-19.

3. All outpatient Aerosol Generating Procedure (AGP) visits, as outlined below, will be **screened** via phone and **tested** no more than two calendar days prior to their planned procedure and if presented negative test, will be **screened** again for symptoms upon arrival the day of their procedure:
   a. Aerosol generating Interventions
   b. Cases where general anesthesia is planned
   c. Cases in Hybrid suites in OR
   d. ASA 3 or 4 Cases
   e. Cases requiring admission after interventions

4. Testing should be administered for asymptomatic individuals being admitted before immunosuppressive procedures.

5. Test all patients coming from high-risk facilities, such as assisted living facilities, correctional facilities, etc.

6. All other planned outpatient visits (clinic visits and non-AGP visits) shall receive a screening call no more than two calendar days prior to their visit and will be screened again for new onset of symptoms upon arrival the day of their visit.

*This policy applies to both inpatient and outpatient care for adult and pediatric patients. This policy should be applied to required accompanied designated caregivers.*
**PATIENT POPULATION:** This patient testing process would be applicable to patients who are not currently COVID-19 positive and have not previously tested positive for COVID-19.

**Exclusions**
- Does not apply to patient populations with expected COVID-like symptoms, such as COPD, Heart Failure, etc.
- Does not apply to patients coming from high-risk facilities, such as assisted living facilities, correctional facilities, etc.
- Does not apply to patients who have recovered from COVID-19, exceeding 14 days since temperature onset and 72 hours since fever resolution and symptom improvement.

**Schedule Appointment¹**

**Screen for Symptoms¹**
*(Phone screen up to 2 days prior)*

**Symptoms**
- **Clinic Outpatient Visits**
- **Screen for Symptoms²** *(In-person day of visit)*
  - **No Symptoms**
  - **Symptomatic**
    - **Postpone visit and order test (refer to slide 3)**
    - **Proceed with visit**

**No Symptoms**
- **Outpatient AGP Visit**
- **Outpatient Non-AGP Visit**

**Schedule test two calendar days prior to AGP visit**

¹Refer to “COVID-19 Ambulatory Pre-Visit Screening: Telephone”
²Refer to “COVID-19 Ambulatory Pre-Visit Screening: On-Site Arrival”

AGP: Aerosol-Generating Procedure
Healthcare Worker Testing: Policy

1. All healthcare workers will self-monitor and screen themselves twice daily for COVID-19 symptoms and fever checks

2. All patient-facing healthcare workers shall be intermittently tested to identify those who may be asymptomatic carriers of the virus
   a. Testing will be strongly encouraged for those who qualify; however, will not be mandatory for any employee

3. All patient-facing and non-patient-facing healthcare workers who become symptomatic shall self-isolate and call the YNHHS COVID Call Center
Healthcare Worker Testing

Twice Daily Self-Monitoring

Patient-Facing Workers
(i.e. providers, nurses, techs, EVS, dietary, etc.)

Symptomatic
TEST

No Symptoms
INTERMITTENT TEST

Non-Patient Facing Workers

Symptomatic
CALL YNHHS COVID CALL CENTER

No Symptoms
DO NOT TEST

Summary statement: As of 4/21/2020 the CT DPH, CDC, WHO, and Infectious Disease Society of America recommend against serologic testing for clinical decision-making, staff distribution, or to adjust measures aimed at reducing infectious exposure.

Situation: There is high interest in the potential role for SARS-CoV-2 serologic testing to identify immune protection from Covid-19. The concept of an “immune passport” has been suggested to inform decisions about social distancing measures, staff distribution, and return to work. Use of serology has been proposed for documenting past Covid-19 exposure. Guidance on test indications and interpretation is urgently needed.

Background: High sensitivity and specificity for detection of SARS CoV-2 exposure by serology has been reported in hospitalized patients 14 days after symptom onset. Sensitivity and specificity for determination of immunity or viral exposure in non-hospitalized patients is unknown. As a result:

1. Positive serologic testing may indicate prior infection and may help document infection in those who were not tested for virus or tested negative for viral RNA.
2. False negative results may occur if tested <11d post symptom onset, prior to IgG rise.
3. It is unknown if a detectable antibody response is required for immune protection.
4. It is unknown if positive serologic testing indicates short term or long-term immunity.
5. Serologic testing does not currently provide any information on risk of infecting others.
6. High false negative and false positive rates may occur with unproven assays, such as due to cross reactivity with other coronaviruses, which could dangerously lead to a false sense of security.
**Assessment:** Uncertainty in serologic test performance is mainly a result of limited understanding of this new disease and lack of test experience in non-hospitalized individuals.

Until more data is available, serologic testing has limited utility. Inappropriate use may create risks to those who presume they are protected and to those with whom they interact. Ongoing studies will clarify the role of serologic testing at both the individual and public health level.

**Recommendations**

- Routine serological testing is not currently recommended in any patient population although positive result may indicate prior infection
- Serology should not be used to diagnose acute Covid-19; use RNA test (e.g. PCR) instead
- If ordered, serologic testing should be
  - performed a minimum of 11 days after onset of symptoms
  - limited to IgG at this time
- Clinical decision making should not be influenced by serologic status. Importantly, adjustment of infection precaution measures should not be based on serologic testing results
- Beware of testing scams including direct-to-consumer labs and fraudulent test kits
YNHHS/YM Recommendations for Discontinuation of Self-Isolation in the Ambulatory Setting After COVID Diagnosis, as of 5/3/20

Background and scope
- Recommendations for discontinuing isolation are critical to containing the current Covid-19 pandemic
- This guidance applies to the general patient population as well as high risk populations and most healthcare staff
- This guidance is intended to support return-to-clinic policies for various patient groups including with underlying increased risk
- Current recommendations are based on existing data on duration of infectivity and may change as more data becomes available
- Isolation in the inpatient setting is determined by Infection Prevention and is not covered in this document
- Certain cases may benefit from individualized management
- Recommendations and policies for discontinuation of isolation may differ between workplaces and employers. Yale University healthcare staff and YNHHS employees (including all delivery networks) may not return to work without formal clearance from Employee Health (YU) or Occupational Health (YNHHS)

Rationale
- Viral replication generally starts 24-48 hours prior to and peaks 3–5 days from symptom onset.
- Viral load is generally elevated at 7 days after symptom onset and higher viral loads are associated with a higher risk for transmission.
- Limited studies show declining viral loads over the next 2 weeks but ongoing PCR positivity in a significant proportion of individuals continuing up to 14-21 after symptom onset
- The significance of ongoing PCR positivity weeks after symptom onset and resolution is unclear. Limited data suggest that prolonged PCR positivity may not reflect shedding of viable, infectious virus.
- Therefore, we recommend 14 days after symptom onset AND 3 days from resolution of fever and improvement in symptoms as the required period for discontinuation of self-isolation. Note that this differs from the current CDC symptoms-based strategy cutoff of 10 days and 3 days following fever resolution and improvement in symptoms.

RECOMMENDATIONS

Time and symptom-based strategy is recommended for discontinuation of self-isolation and in most cases for return-to-clinic or return-to-work*
Symptom-Based Strategy to Discontinue Isolation for Persons with COVID-19


2. At this time, replication-competent virus has not been successfully cultured more than 9 days after onset of illness. The statistically estimated likelihood of recovering replication-competent virus approaches zero by 10 days (CDC unpublished data, Wölfel 2020, Arons 2020).
Conclusions

- Sample collection – NP ➔ Mid-Turbinate ➔ Saliva (could change)
- RT-PCR; TAM is the current standard of testing
- High sensitivity POC testing is not yet available
- Need to test ALL symptomatic patients
- Will test all admitted patients
- Will test all patients prior to AGPs
- Will test asymptomatic HCPs
- Replicating virus may not be present beyond 10 days from infection
- Serology testing still under consideration