COVID-19: Coronavirus Disease 2019

SARS-CoV-2
Highly contagious
Human-to-human spread by respiratory droplets

Incubation
2-14 days (median 5 days)

Disease spectrum
Asymptomatic to severe
US COVID-19 Cases, Deaths (as of May 26)

1,662,414 cases
98,261 deaths

SOURCE: CDC COVID Data Tracker
Symptoms of COVID-19

Clinical Assessment*
Cough, shortness of breath, fever, chills, headache, sore throat, muscle pain, loss of taste or smell

*Not all inclusive
Why Testing is Necessary

“Clinical assessment alone is not accurate in predicting COVID-19 diagnosis.”

— Infectious Disease Society of America Guidelines on the Diagnosis of COVID-19, May 2020
COVID-19 Progression: Viral markers

Weeks: -2, -1, 1, 2, 3, 4, 5, 6

- Symptom Onset
- Viral RNA
- Antibodies

Increasing probability of detection

No detectable viral markers

Likely infectious

Modified from Sethuraman et al. JAMA May 6
COVID-19 Molecular Test: Its Purpose

Diagnose acute infection by detecting viral RNA fragment

Virus may be viable or not viable

SARS-CoV-2

SARS-CoV-2 RNA
COVID-19 Molecular Test: From start-to-finish

1. COVID-19 Test
2. RNA isolated
3. RNA amplified
4. RNA detection
5. Test Results
Developing Molecular Test: A Complex Process

- Financial resources & experienced staff
- High-complexity clinical laboratory
- Test optimization & implementation
- Reagents and Samples
- Molecular diagnostic expertise
COVID-19 Molecular Tests: Performance

63 vendors and 28 laboratories with approved tests

**Analytical Sensitivity**
Ability to detect the virus

1,000-fold difference

**Analytical Specificity**
Ability to only detect the virus

99-100%

SOURCE: FDA COVID-19 EUA Information
### Initial Negative Test? When and why repeat

<table>
<thead>
<tr>
<th>Intermediate to high clinical suspicion</th>
<th>Repeat 24-48 hours</th>
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<tbody>
<tr>
<td>Low clinical suspicion</td>
<td>No re-testing</td>
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Infectious Disease Society of America Guidelines on the Diagnosis of COVID-19
COVID-19 Molecular Testing: Recap

Utility
Acute infection diagnosis through detection of viral RNA

Development
Requires significant expertise and investment

Interpretation
Clinical and laboratory guidance for optimal results interpretation
COVID-19 Diagnostics

QUESTIONS