
Information is for educational use only and current as of June 23, 2020.

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Disclosures

- Consultant and presentation honorarium for Roche Diagnostics
- UC Davis is a Roche Diagnostics Molecular Center of Excellence
- Co-Inventor of UC Davis Intellectual Property for Machine Learning software
Learning Objectives

- Describe the current state of COVID-19 in the United States and California.
- Describe how hospitals responded to COVID-19, and in particular, UC Davis response.
- Identify laboratory challenges and limitations during the COVID-19 pandemic.
- Describe where COVID-19 testing is going and where we would like to be by Fall 2020.
COVID-19 PANDEMIC
GLOBAL NUMBERS: >8.63 MILLION (as of June 19, 2020)
QUICK STATISTICS - NATIONAL

**Reported Cases**
- Gold: 0 to 1,000
- Orange: 1,001 to 5,000
- Dark Orange: 5,001 to 10,000
- Red: 10,001 to 20,000
- Maroon: 20,001 to 40,000
- Purple: 40,001 or more

**TOTAL CASES**: 2,178,710  
23,138 New Cases*

**TOTAL DEATHS**: 118,365  
733 New Deaths*

*Compared to yesterday's data

Last updated on June 19, 2020

*About the Data*
QUICK STATISTICS – LOCAL (CALIFORNIA)

June 19, 2020
Total cases: >161k
Total deaths: >5k
Core Areas (Examples)
- Acute Care Diagnostics
- MIND and Alzheimer's Research
- Infectious Diseases
- Cancer Center

Technology Clinical Validation Pipeline
- Novel Diagnostics
- New Therapeutic Targets
- Improved Efficiency

Diagnostic Impact
- CAP Accredited Biobank and Clinical Services

Clinical Impact
- Quality of care
- Cost-effectiveness
- Patient experience
- Machine Learning
Innovation Driven Test Development and Implementation

- **February 29**
  - FDA Relaxation of Regulations

- **March 19**
  - UCDH deployment SARS-CoV-2 assay deployed

- **March 28**
  - UCDH Roche cobas 6800 assay deployed

- **April 20**
  - UCDH Serology (IgM/IgG) Assay Deployed

- **April 20**
  - Second cobas 6800 arrives

- **April 30**
  - Rapid SARS-CoV-2 PCR Deployed

- **April 30**
  - First Known Community Acquired COVID-19 Case
First Known Community Acquired COVID-19 Case

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Innovation Driven Test Development and Implementation

Establishment of “Respiratory Infection Biobank” using Pathology Biorepository Infrastructure for validation of PCR and serology assays
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Partnership with Center for Immunology and Infectious Diseases (CIID) to culture SARS-CoV-2 for assay development and research
Innovation Driven Test Development and Implementation

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CIID collaborations facilitated convalescent serum studies in non-human primates and serology assay development. Also facilitated vaccine research studies.
First Case of Community Transmitted COVID-19 in the United States: Background

Background: A patient in their 40s without travel history to high risk countries presented to an outside facility with 3-4 days of flu-like symptoms.

Chest X-ray upon admission showed a right upper lobe consolidative process with air bronchograms.

Developed ARDS and septic shock.

Sanville B, et al, CID 2020
First Case of Community Transmitted COVID-19 in the United States: Clinical Course

Patient transferred to UC Davis for consideration of ECLS by end of Day 2.

CDC originally denied COVID-19 testing around Day 6.

Sanville B, et al, CID 2020
What most people think about COVID-19 testing

MOLECULAR APPROACHES
• Detects viral genetic material
• Can be very sensitive and specific

Note: SARS-CoV-2 is an RNA virus, therefore reserves transcriptase real-time PCR is used.
Example of PCR Targets for SARS-CoV-2

CDC
TaqPath™

Charite
Superscript III One Step RT-PCR with Platinum® Taq polymerase

Thermo
TaqPath™ TaqMan Fast Virus 1-step

Japan
Quick Taq HS Dyemix

Hong Kong University
TaqMan Fast Virus Master mix

https://labmedicineblog.com/2020/03/05/how-to-validate-a-covid-19-assay/
UC DAVIS SARS-COV-2 ASSAY PERFORMANCE – FOR EDUCATIONAL USE

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test TAT</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Status at UC Davis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche cobas 6800 SARS-CoV-2 EUA(^3)</td>
<td>3 h(^d) (batches of 94)</td>
<td>&gt;97.5</td>
<td>&gt;99.9</td>
<td>Deployed March 27(^{th}) (reagent allotment restricted)</td>
</tr>
<tr>
<td>IDT CDC SARS-CoV-2 qPCR Assay(^1,(^a)</td>
<td>4 h (after batch of 21 achieved)</td>
<td>&gt;97.5</td>
<td>99.9(^a)</td>
<td>Deployed March 19(^{th}) (reagent allotment restricted)</td>
</tr>
<tr>
<td>GenMark ePlex SARS-CoV-2 EUA(^2,(^b)</td>
<td>1.5-2 h</td>
<td>94.4</td>
<td>99.9</td>
<td>Deployed April 30 for special populations</td>
</tr>
</tbody>
</table>

**Abbreviations:** EUA, emergency use authorization; h, hours; LoD, limit of detection; TAT, turnaround time; TBD, to be determined

**References:** \(^1\)IDT CDC kit [https://www.fda.gov/media/134922/download](https://www.fda.gov/media/134922/download) , \(^2\)GenMark EUA, [https://www.fda.gov/media/136282/download](https://www.fda.gov/media/136282/download); \(^3\)Roche EUA, [https://www.fda.gov/media/136049/download](https://www.fda.gov/media/136049/download)
## An Elusive Virus: Viral Load Matters

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Positivity Rate</th>
<th>Mean Viral Load</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchoalveolar Lavage</td>
<td>14/15 (63%)</td>
<td>&gt;10^8 copies/mL</td>
</tr>
<tr>
<td>Nasopharyngeal Swab</td>
<td>5/8 (63%)</td>
<td>10^6 copies/mL</td>
</tr>
<tr>
<td>Oropharyngeal Swab</td>
<td>126/398 (32%)</td>
<td>10^5 copies/mL</td>
</tr>
<tr>
<td>Saliva Samples</td>
<td>???</td>
<td>???</td>
</tr>
</tbody>
</table>

**Note:** UC Davis presently only supports NP swab samples. Other specimen types are being validated as supply chains improve.

Zou L, et al. NEJM 2020;382;12
Viral Kinetics Matters

- SARS-CoV-2 viral load varies and the kinetics in asymptomatic patients is unclear.

- Possible that asymptomatic patients may have viremia below the detection limit.

- It is believed that viremia can occur before symptoms, and potentially peaking at symptom onset.

- So PCR testing problematic in finding patients, and likewise challenging for monitoring patients.

Role of Biochemical Monitoring in COVID-19

Role of Biochemical Monitoring in COVID-19

What most people think about COVID-19 testing

**MOLECULAR APPROACHES**
- Detects viral genetic material
- Can be very sensitive and specific

**IMMUNOASSAY APPROACHES**
- Targets viral antigens or
- Targets host response to infection (serology)

*Note: SARS-CoV-2 is an RNA virus, therefore reserves transcriptase real-time PCR is used.*
Quick Facts

- COVID-19 antibody production can be as early as 3-days.
- On average, IgM is usually detectable in most patients by Day 7.
- Most patients should have IgM and IgG detectable by Day 14.
- Some suggestion that IgG is produced with IgM, so may not need to measure IgM.
• Initial serology tests “available” on the market were unsuitable for use.

• These “rapid” serology tests were known in the laboratory community to be inferior and had high amounts of false positives.

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**Coronavirus Antibody Tests: Can You Trust the Results?**

A team of scientists worked around the clock to evaluate 14 antibody tests. A few worked as advertised. Most did not.

By Apoorva Mandavilli

Published April 24, 2020 | Updated April 25, 2020, 10:50 a.m. ET

**Results**

Among specimens from SARS-CoV-2 RT-PCR-positive individuals, the percent seropositive increased with time interval, peaking at 81.8-100.0% in samples taken >20 days after symptom onset. Test specificity ranged from 84.3-100.0% in pre-COVID-19 specimens. Specificity was higher when weak LFA bands were considered negative, but this decreased sensitivity. IgM detection was more variable than IgG, and detection was highest when IgM and IgG results were combined. Agreement between ELISAs and LFAs ranged from 75.8-94.8%. No consistent cross-reactivity was observed.

**Conclusion**

Our evaluation showed heterogeneous assay performance. Reader training is key to reliable LFA
• Initial serology tests “available” on the market were unsuitable for use.

• These “rapid” serology tests were known in the laboratory community to be inferior and had high amounts of false positives.

• Some countries had buyer’s remorse after purchasing these rapid tests.

**Is Serology the Answer to Everything?**

**U.K. Paid $20 Million for New Coronavirus Tests. They Didn’t Work.**

Facing a global scramble for materials, British officials bought millions of unproven kits from China in a gamble that became an embarrassment.

LONDON — The two Chinese companies were offering a risky proposition: two million home test kits said to detect antibodies for the coronavirus for at least $20 million, take it or leave it.

The asking price was high, the technology was unproven and the money had to be paid upfront. But the buyer would be required to pick up the cargo loads of test kits from a facility in China.

Yet British officials took the deal, according to a senior civil servant involved, then confidently promised tests would be available at pharmacies in as little as two weeks. “As simple as a pregnancy test,” gushed Prime Minister Boris Johnson. “It has the potential to be a total game changer.”

There was one problem, however. The tests did not work.

Found to be insufficiently accurate by a laboratory at Oxford University, half a million of the tests are now gathering dust in storage. Another 1.5 million bought at a similar price from other sources have also gone unused. The fiasco has left embarrassed British officials scrambling to get back at least some of the money.
Is Serology the Answer to Everything?

• Initial serology tests “available” on the market were unsuitable for use.

• These “rapid” serology tests were known in the laboratory community to be inferior and had high amounts of false positives.

• Some countries had buyer’s remorse after purchasing these rapid tests.

• Bad data from studies rushing to determine seroprevalence.
What can serology testing do?

Quick Facts

• Serology tests can determine if you may have had a SARS-CoV-2 infection or not.

• Typical serology tests measure antibodies made against parts of the virus.

• However, some tests may misidentify antibodies made against non-SARS-CoV-2 coronaviruses and cause false positive results.

• “Neutralizing” antibodies are also of interest since they may confer immunity.

• However we don’t know if immunity occurs and if it does, how long it lasts!

<table>
<thead>
<tr>
<th>PCR</th>
<th>IgG</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>-</td>
<td>Patient may be in the early stage of infection (less than 14 days post-infection)</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>Patient in the active stage of infection</td>
</tr>
<tr>
<td>-</td>
<td>+</td>
<td>Patient may have had a past COVID-19 infection</td>
</tr>
<tr>
<td>-</td>
<td>-</td>
<td>No previous exposure or potentially in early asymptomatic period with low viral load. Re-testing by PCR and serology in 1-2 weeks may be necessary.</td>
</tr>
</tbody>
</table>
How do we make more antibodies against SARS-CoV-2?

**Challenges**

- Some patients don’t make detectable antibodies after infection.
- Patients with more severe disease (or presenting with symptoms) make more antibodies versus those that don’t.
- Less antibodies found in the convalescent phase versus acute phase of infection.

COVID-19 Testing Best Practice

Current Practice
- NP Swab only
  - Symptomatic individuals
  - COVID+ Return to Work
  - Asymptomatic patients with lab-based assay.

Asymptomatic Patients
- NP Swab + Serology
  - Asymptomatic Screening
  - Return to work COVID-19+ patients

Population Screen
- Serology Only
  - Prior PCR+ Individual
  - Population screening
  - Identify convalescent plasma donors
COVID-19 SEROLOGY ASSAY PERFORMANCE – FOR EDUCATIONAL USE

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Test TAT</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Status at UC Davis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazyme DZ-Lite 3000 COVID-19 IgM/IgG</td>
<td>2-3 hours (batches of 90)</td>
<td>IgG: 90.0&lt;br&gt;IgM: 80.0</td>
<td>IgG: 97.0&lt;br&gt;IgM: 97.5</td>
<td>Deployed April 20, 2020</td>
</tr>
<tr>
<td>Diasorin Liaison XL COVID-19 S1/S2 IgG</td>
<td>2-3 hours (batches of 170)</td>
<td>&gt;97.0</td>
<td>&gt;99.9</td>
<td>Deployed June 16, 2020</td>
</tr>
</tbody>
</table>

Notes: Due to the FDA EUA pathway, the sensitivity and specificity for assays is not defined. Test TAT is the time from sending out to results as quoted by Quest. "Quest has not provided the sensitivity and specificity of their assay and these are estimated based on available literature evidence including from experience at UC Davis.

Abbreviations: TAT, turnaround time

Prevalence Matters for Antibody Testing!

Positive predictive value (PPV) and prevalence

<table>
<thead>
<tr>
<th>Prevalence (%)</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100</td>
<td>99.81</td>
<td>84</td>
</tr>
<tr>
<td>5</td>
<td>100</td>
<td>99.81</td>
<td>97</td>
</tr>
<tr>
<td>10</td>
<td>100</td>
<td>99.81</td>
<td>98</td>
</tr>
</tbody>
</table>

Why we have a prevalence problem...

The PPV takes into account the specificity and sensitivity of a test, but also the prevalence of the disease in the population, as this sets the baseline for how likely it is that a person is positive for a disease.

- Positive predictive value (PPV) is the probability of a patient testing positive for the disease actually having the disease.
- Specificity is the true negative rate of a test, or alternately the 1 – specificity is the false positive rate.
- For a test with a given specificity, the prevalence of disease influences your PPV.
- A high PPV with COVID-19 serology is desirable since you want a positive result be considered “real”.
- This is why CDC, State Task Force, and UCD recommends assays to have a specificity of >99%
Role of Biochemical Monitoring in COVID-19

Sars-CoV-2

Infection

Overt Disease

Death

Recovery

Laboratory Diagnostics

Epidemiological Surveillance

RT-PCR, Anti-SARS-CoV-2 antibodies

Diagnosis

RT-PCR (See Diagnostic Testing)

Anti-SARS-CoV-2 antibodies

Epidemiological Surveillance

Role of Biochemical Monitoring in COVID-19

First Case of Community Transmitted COVID-19 in the United States: Clinical Course

Patient transferred to UC Davis for consideration of ECLS by end of Day 2.

CDC originally denied COVID-19 testing around Day 6.

Sanville B, et al, CID 2020
First Case of Community Transmitted COVID-19 in the United States: Clinical Course

Procalcitonin: 5.86 ng/mL
Albumin: 2.1 g/dL
AST: 81 U/mL
LDH: 490 U/L
GGT: 509 U/L
Direct Bilirubin: 0.5 mg/dL
Creatinine: 1.89 mg/dL
D-Dimer: 2480 ng/mL
Fibrinogen: 456 mg/dL
Respiratory viral panel negative for all pathogens
<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Abnormalities</th>
<th>Potential clinical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete blood count</td>
<td>Increased white blood cell</td>
<td>Bacterial (super)infection</td>
</tr>
<tr>
<td></td>
<td>Increase neutrophil count</td>
<td>Bacterial (super)infection</td>
</tr>
<tr>
<td></td>
<td>Decreased lymphocyte count</td>
<td>Decreased immunological response to the virus</td>
</tr>
<tr>
<td></td>
<td>Decreased platelet count</td>
<td>Consumption (disseminated) coagulopathy</td>
</tr>
<tr>
<td>Blood gases</td>
<td>Estimated modifications</td>
<td>Important in critical care management</td>
</tr>
<tr>
<td>Albumin</td>
<td>Decreased</td>
<td>Impairment of liver function</td>
</tr>
<tr>
<td>LDH</td>
<td>Increased</td>
<td>Pulmonary injury and/or widespread organ damage</td>
</tr>
<tr>
<td>ALT</td>
<td>Increased</td>
<td>Liver injury and/or organ damage</td>
</tr>
<tr>
<td>AST</td>
<td>Increased</td>
<td>Liver injury and/or organ damage</td>
</tr>
<tr>
<td>Total bilirubin</td>
<td>Increased</td>
<td>Liver injury</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Increased</td>
<td>Kidney injury</td>
</tr>
<tr>
<td>Urea</td>
<td>Estimated Increase</td>
<td>Kidney injury</td>
</tr>
<tr>
<td>Cardiac troponin</td>
<td>Increased</td>
<td>Cardiac injury</td>
</tr>
<tr>
<td>D-Dimer</td>
<td>Increased</td>
<td>Activation of blood coagulation and/or disseminated coagulopathy</td>
</tr>
<tr>
<td>Prothrombin Time</td>
<td>Increased</td>
<td>Activation of blood coagulation and/or disseminated coagulopathy</td>
</tr>
<tr>
<td>Procalcitonin</td>
<td>Increased</td>
<td>Bacterial (super)infection</td>
</tr>
<tr>
<td>C-reactive protein</td>
<td>Increased</td>
<td>Severe viral infection/viremia/viral sepsis</td>
</tr>
<tr>
<td>Ferritin</td>
<td>Increased</td>
<td>Severe inflammation</td>
</tr>
<tr>
<td>Cytokines (IL-6)</td>
<td>Increased</td>
<td>Cytokine storm syndrome</td>
</tr>
</tbody>
</table>

Interleukin-6 as a COVID-19 Biomarker

- Procalcitonin is a sepsis biomarker usually used for bacterial infections.
- Procalcitonin is usually low in viral infections.
- Some COVID-19 patients may have high procalcitonin – suggesting higher disease severity.
Interleukin-6 as a COVID-19 Biomarker

- IL-6 plays an important role in cytokine release syndrome during COVID-19.

- Treatment of the “cytokine storm” could provide value and is now included for multisystem inflammatory syndrome in children.

- IL-6 may be targeted for therapy.
Interleukin-6 as a COVID-19 Biomarker

Interleukin-6 as a COVID-19 Biomarker

Interleukin-6 as a COVID-19 Biomarker

- Anti-IL-6 receptor therapy may reduce mortality and pulmonary inflammation.
- Monitoring IL-6 could help determine treatment efficacy.

Role of Sarilumab in COVID-19

Phase 2 data for critical patients in the 400-mg group (n=145) compared with placebo (n=77), respectively, included the following:

- Change from baseline C-reactive protein level: -79% versus -21%
- Died: 23% versus 27%
- Remained on ventilator: 9% versus 27%
- Clinical improvement: 59% versus 41%

Other Anti-IL-6 Receptor Drugs: Tocilizumab

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April 45
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April 30
Rapid SARS-CoV-2 PCR Deployed

April 30
Reagents for SARS-CoV-2 testing were in short supply. CDC-based assay reagents were limited and extraction kits became worth their weight in gold. **Avoided challenges by diversifying platforms quickly.**
Barriers and Challenges

Reagents for SARS-CoV-2 testing were in short supply. CDC-based assay reagents were limited and extraction kits became worth their weight in gold. Avoided challenges by diversifying platforms quickly.
PPE usage was appropriately highly regulated due to anticipated surge. Laboratory staff require PPE when working with suspected and/or confirmed cases.
Shortages of collection swabs became the next challenge. Can’t test without swabs!
Shortages of collection swabs became the next challenge. Can’t test without swabs!

CA Testing Task Force opened up new swab supply chains which remain today. Thousands of swab became available by late April.
CA Testing Task Force opened up new swab supply chains which remain today. Thousands of swab became available by late April.

As swab supplies improved, collection media became the next shorted item. No media = no testing.
UC Davis early on identified potential shortages and started work on producing our own media and 3D printed swabs. Latter now evaluating to outsource for higher capacity.
COVID-19 Laboratory Testing in Limited Settings

Challenges Faced by Clinical Laboratories during COVID-19

• Personnel shortages
COVID-19 Laboratory Testing in Limited Settings

Challenges Faced by Clinical Laboratories during COVID-19

• Personnel shortages

What we thought
COVID-19 Laboratory Testing in Limited Settings

Challenges Faced by Clinical Laboratories during COVID-19

• Personnel shortages
COVID-19 Laboratory Testing in Limited Settings

Challenges Faced by Clinical Laboratories during COVID-19

- Personnel shortages
- Fear, anxiety, and concern by bedside providers → faster results!
So where do we go from here?

- Prevalence of COVID-19 is increasing again.

- We now have access to testing and can provide testing quickly and high volumes...however....

- Testing needs increasing across the region, CA and the US which puts a strain on reagents, swabs, and media.

- Schools and companies opening up again, should we test, how do we test, who do we test?
ASSUMPTIONS

• Perception to test more versus clinical need to test.

• Supply chain problems will persist due limitations in testing capacity (both for reagents and personnel).

• Fall COVID-19 surge could lead to additional restrictions and limiting resources for testing and contacting trace – if we don’t prepare now.

• New antigen tests are insufficiently sensitive.
COVID-19 Testing Pathways at UC Davis Health

- **All Asymptomatic Patients**
  - PCR with or without serology

- **Contact Tracing of Individuals (Patients and Employees)**
  - Combination of PCR and serology based on concentric circle model
  - Sequencing of SARS-CoV-2 to aid in contact tracing

- **Symptomatic and At-Risk Individuals (Patients or Employees)**
  - PCR and serology
Strategy for COVID-19 Contact Tracing of Individuals

Low Risk Individuals
- No PCR Testing if asymptomatic and no prior risk
- Serology optional for community screening

High Risk Individuals
- PCR + Serology

Index Case
- PCR testing only
- Criteria defined by hospital ID/IP, CDC, CDPH

LESS TIME + GREATER DISTANCE = LOWER RISK
Strategy for COVID-19 Contact Tracing of Individuals

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No PCR Testing if asymptomatic and no prior risk
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**Low Risk Individuals**
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Serology optional for community screening

**High Risk Individuals**
PCR + Serology

**Index Case**
PCR testing only

Identification of the index case quickly based on symptoms and providing rapid access to PCR testing is critical. Outside hospital settings, need rapid response teams to quickly obtain samples, quarantine/contain, and begin contact tracing.
Strategy for COVID-19 Contact Tracing of Individuals

LESS TIME + GREATER DISTANCE = LOWER RISK

PCR+ Contact Tracing (Traditional + Sequencing)

Serology + Prior Exposure(?)

Return to work / community.
Genomic Confirmations

The remaining nine samples come from a subclade of A2.

- All members of cluster 3 and one member of putative cluster 4 share an identical genome. This is consistent with transmission within cluster 3.
- Both members of cluster 1 differ by a single SNP, which is consistent with a transmission event.
- Both members of cluster 2 also differ by a single SNP, which is consistent with a transmission event.
Genomic Confirmations

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- **Both members of cluster 2** also differ by a single SNP, which is consistent with a transmission event.

Patient Cluster
Multi-Tiered Approach for Testing within the Health System

LABORATORY BASED (TAT: 24-72 hours)
- High volume / high throughput
- Scheduled pre-op testing
- Contact Tracing
- Employee Screening
- All patients

RAPID RESPONSE (TAT: 2.5-3 hours)
- Moderate volume rapid testing
- Emergency Department testing of symptomatic patients
- Urgent transplant cases
- Urgent OB cases
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RAPID RESPONSE (TAT: 2.5-3 hours)
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- Urgent transplant cases
- Urgent OB cases

POINT-OF-CARE PCR
- Low volume rapid testing
- ED and PCN testing (?
- Currently in pre-FDA Submission and availability TBD.
Translating COVID-19 Testing for Academic Campuses

ASSUMPTIONS

• COVID-19 is a dynamic disease. PCR testing every student and employee only provides a “snapshot in time”.

• Pooling strategies can increase capacity from 2000 tests/day to perhaps 10,000 tests/day without increasing supply needs.

• Nasal, NP, OP samples remain ideal for testing, but swab/media supplies remain limited. Pool does not fix the swab/media problem.

• Not clear on saliva or self collected samples.

• New antigen tests are insufficiently sensitive.
COVID-19 Testing Pathways at Academic Campuses

**All Asymptomatic Students**
- PCR testing not indicated → need routine screening by other means
- Serology testing optional for epidemiological reasons
- Consider serial serologies to monitor over time

**Contact Tracing of Individuals (Students, Patients, and Employees)**
- Combination of PCR and serology based on concentric circle model
- Sequencing of SARS-CoV-2 to aid in contact tracing

**Symptomatic and At-Risk Individuals**
- PCR and serology
Creating Access to Testing for Academic Campuses

UC DAVIS ACADEMIC CAMPUS: Requires a robust campus sign/symptom screening program to identify at-risk individuals quarantine, test, contain and contact trace quickly.
Summary

- We are still in a pandemic and dealing with high demands for SARS-CoV-2 testing in a resource constrained world.

- Not all tests are created equal and many institutions have had to resort to multiple platforms to overcome resource limitations.

- Fear, anxiety, and false knowledge/assumptions on testing is driving unnecessary demand and exacerbating the supply issue.

- Institutions, like UC Davis have established innovative measures to overcome barriers.
Public Health Policy Implications

- How do we define means to optimize testing – providing testing to people that need them to prevent infection, provide appropriate isolation, determine recovery?

- Should schools reopen, can sports resume if we provide routine testing at the cost of depleting resources for other populations?

- How do we increase manufacturing of needed supplies we can offer testing for as many people as possible?

- The confusion and lack of understanding of diagnostic testing beckons the question if we need to provide better education on this topic for both public health, medical community, and the general public.

- How do we support COVID-19 testing without compromising the regular testing services?
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Questions?