COVID-19 Update
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Monday August 17th
Testing Questions

- Does the person have COVID-19?
- Are they infectious?
- Will they become infectious?
- Are they immune?
RT-PCR

- These have been the ‘Gold Standard’ for testing
- Sensitive and specific
  - Up to 30% false negatives in first few days
  - Potential false positives during recovery
  - Technical and technique issues

- Problems with PCR testing in USA today:
  - Insufficient tests and test reagents and pipettes
  - Cost and lack of easy access discourages testing
  - Testing is unpleasant
  - Turn around is slow (1+ weeks)
Scaling Up Testing

High throughput next-generation screening:

- **Ginkgo Bioworks, Boston:**
  - Process tens of thousands of individual saliva tests at once.
  - 50,000 tests per day September 2020 and 100,000 per day by end 2020

- **Helix OpCo, San Mateo, California**
  - Standardized kits in bulk for the collection of nasal swabs to collect tens of thousands of samples – results 24-48 hour
  - 50,000 samples a day by end of Sep and 100,000 per day by end 2020

- **Fluidigm, South San Francisco, California**
  - Capacity to process thousands of SARS-CoV-2 PCR tests per day with a primary focus on saliva samples.
  - With many existing Fluidigm instruments in clinical and research labs, scale up and deployment can provide tens to hundreds of thousands of new tests per day in fall 2020

Pooled Testing

Negative = All negative

Positive = All PCR test = All quarantine
Antigen Testing

- Point of care
- Need proprietary reader
- Quick – results in 10-15 minutes
- Cheaper (around $25)

Accuracy
- Positive Predictive Agreement (PPA) – 96.7%
- Negative Predictive Agreement (PPA) – 100%

Test systems:
- BD Veritor
- Quidel Sofia SARS Antigen test
Paper and CRISPR Tests

### Paper Tests
- Cheap - $1-$10 (TBD)
- Rapid – results in 15 minutes
- Self use/self read
- Nasal or saliva
- Examples:
  - e25Bio lateral flow immunochromatographic assay

### CRISPR
- Cheap - <$15 (TBD)
- Rapid – results in 15 minutes
- Self use/self read
- Nasal or saliva
- Examples:
  - Sherlock INSPECTR™
  - Sherlock SHERLOCK™
Potential Issues

- Sensitivity and specificity much lower than RT-PCR tests
  - Sensitivity 40-70% (probably >50%)
  - Specificity 90%
  - Will the FDA approve?
- While sensitivity may be low – tests may pick up people who are highly contagious
Testing and Contagiousness

- Highly Contagious: RNA (+), Antigen (+)
- Poorly Contagious: RNA (+), Antigen (+)
- Antibody (+)

Virus Particles / mL

- 10^5
- 10^6
- 10^7
- 10^8
- 10^9

Days

Symptoms Appear

Antibodies

- PCR Detectable
- Antigen Detectable
- CRISPR / Laminar Flow Detectable
Deployment

- India has deployed a $1 paper test that is 50% sensitive\(^1\)
  - 25-35% of tests using these new tests
- High false negative rate is an issue when used as a single diagnostic test – potential strength if used on a regular basis e.g. 3x/week or daily. Example:

Day 1
- 1,000 Employees
- 995 negative (5 false negative)
- 5 positive
- Quarantined

Day 2
- 992 negative (2 false negative)
- 3 positive
- Quarantined

Day 3
- 990 negative (1 false negative)
- 2 positive (1 a new case)
- Quarantined

Commuting

75% recycled but on average air replaced by fresh air every 3 minutes 20 seconds
Subway cars use filters that are rated MERV-7 and are replaced every 36 days
Particle Spread

Sneezing with a mask on

14.7 seconds

Sneezing without a mask
Questions