Challenges and opportunities surrounding laboratory-developed tests as an essential component of the pandemic response

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Mayo Clinic’s response to COVID-19

February 17, 2020
15 confirmed COVID-19 cases in U.S.
“We need to be prepared”

January 20, 2020
1st COVID-19 case in U.S.
Mayo Clinic COVID-19 Rapid Response Team
Mayo Clinic’s response to COVID-19

- January 20, 2020: 1st COVID-19 case in U.S.
- February 17, 2020: 15 confirmed COVID-19 cases in U.S. “We need to be prepared”
- March 12, 2020: Began clinical testing
- April 21, 2020: Received FDA Emergency Use Authorization
Challenges Faced Along the Way

- Access to validation material, critical supplies, equipment
- Complexities of EUA process
  - Resource intense process when labs were already extremely busy
  - Fluid process – difficult to predict
- High quality labs will produce high quality tests
Challenges Faced Along the Way

• Transportation issues:
  • Specimens
  • Supplies/equipment
  • People (installation/service)

• Questions surrounding test utilization and interpretation:
  • Molecular (Re-test?; $C_t$ values?)
  • Serology (When to use?)
  • Antigen (Should we use?)
Why an LDT was essential in the Mayo Clinic response

• Provided earlier access to testing for patients in local communities

• Key component in MN testing response
  • >560,000 tests
  • ~35,000 positive cases

• Assisted with validation of commercial systems (n = 14 across all Mayo sites)
  • >4M tests performed across Mayo
Opportunities and lessons learned

• Widespread testing during the **early** phase of an outbreak is needed to prevent broad community transmission

• Clinical labs = near patients

• LDTs helped to provide increased access to testing

• Partnership between public health, industry, clinical labs and government is essential
Opportunities and lessons learned

• Developing and validating LDTs, along with EUA process, requires significant resources and time

• Time is of the essence in earliest days of pandemic/outbreak of emerging disease

• Could network of testing be rapidly expanded through ‘Centers of Excellence’ model?
Pandemic/Emerging Disease ‘Centers of Excellence’ Testing Network
Opportunities to rapidly expand testing capabilities

• Public Health:
  • Assay design, development and validation
  • Industry involvement

• FDA:
  • Review and EUA

• Industry:
  • Mass production of reagents

• Government:
  • National stockpile of swabs, transport media, blood vials, PPE. Logistics and distribution.
Opportunities to rapidly expand testing capabilities

• Clinical laboratories:
  • Apply to be certified testing site
    • Required equipment on site
    • Pre-inspection process
    • Demonstrate ability to follow CDC protocol
  • Recertification process
  • Prior to clinical testing
    • Internal validation and pass blinded proficiency panel distributed by CDC/FDA

Would take place outside pandemic period
Summary

• Testing with quick TAT is critical to prevent widespread transmission of novel infectious diseases

• LDTs played a key role in COVID-19 response

• Development/validation of LDTs in clinical labs required valuable time

• Broad/early testing capabilities (public health labs, reference labs and clinical labs) is needed

• Partnership between public health, clinical labs, industry and government is essential
References


Thank you!