NETEC COVID-19 Webinar Series:
Laboratory Operations, Challenges and Innovations for COVID-19
Welcome

Ted Cieslak, MD, MPH
Welcome: Ted Cieslak, MD, MPH

Operations: Jana Broadhurst, MD, PhD, DTM&H

Challenges: Tawny Arensmeyer, M.Ed., MLS(ASCP)CM

Innovations: Tawny Arensmeyer, M.Ed., MLS(ASCP)CM

NETEC Resources: Ted Cieslak, MD, MPH

Questions and Answers with NETEC
National Emerging Special Pathogens Training and Education Center

Mission statement
To increase the capability of the United States public health and health care systems to safely and effectively manage individuals with suspected and confirmed special pathogens

For more information
Please visit us at www.netec.org
or email us at info@netec.org
<table>
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<th>NETEC Overview</th>
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<tr>
<td><strong>Assessment</strong></td>
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| Empower hospitals to gauge their readiness using **Self-Assessment** | Provide self-paced education through **Online Trainings** | Onsite & Remote Guidance | Online Repository Built for rapid implementation of clinical research protocols |
| Measure facility and healthcare worker readiness using **Metrics** | Deliver didactic and hands-on simulation training via **In-Person Courses** | Compile **Online Repository** of tools and resources | Develop Policies, Procedures and Data Capture Tools to facilitate research |
| Provide direct feedback to hospitals via **On-Site Assessment** | COVID-19 focused **Webinars** | Develop customizable **Exercise Templates** based on the HSEEP model | Create infrastructure for a Specimen Biorepository |

**Cross-Cutting, Supportive Activities**

- Online Repository
- Research Network
- COVID-19 focused Webinars
Operations

Jana Broadhurst, MD, PhD, DTM&H
What does it take to test for a novel pathogen?
COVID-19 Diagnostic Tests with FDA EUA

THE WALL STREET JOURNAL
HONG KONG—Chinese scientists investigating a mystery illness that has sickened dozens in central China have discovered a new strain of coronavirus, a development that will test

Severe acute respiratory syndrome coronavirus 2 isolate Wuhan-Hu-1, complete genome (GenBank)

Diagnostic detection of 2019-nCoV by real-time RT-PCR

Charité Virology, Berlin, Germany
Considerations

- Type of test – PCR, serology, other
- Regulatory requirements – FDA, LDT, EUA
- Instrumentation
- Throughput
- Cost
- Specimen requirement
- Staffing
Laboratory: Operations

**FDA cleared test**
- Test has been fully reviewed by the FDA

**Laboratory Developed Test (LDT)**
- Designed, manufactured and used within a single laboratory

**Emergency Use Authorization (EUA)**
- FDA authorizes use of test in public health emergency situations
Implementation requirements are different for commercially available vs. laboratory developed tests.

- Equipment
- Expertise
- Validations
- Supplies
Instrumentation

- **Availability**
  - Is the instrument already in house?

- **Footprint**

- **Ease of use**

- **Installation requirements**
  - Power, interface, ventilation, etc.

- **Throughput**

- **Cost**
<table>
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<tr>
<td>Is there a manual component?</td>
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<td>Is it fully automated?</td>
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<td>Large vs. small capacity</td>
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Laboratory: Operations

- Cost
  - Instrument
  - Reagents
  - Consumables
  - Labor
Aerosol generating procedures should be done in BSC whenever possible.

### Aerosol generating procedures can include

- Centrifugation
- Pipetting
- Vortexing
- Mixing
- Shaking fluids
- Sonicating
- Removing caps
- Decanting liquids
- Preparing smears
- Flaming slides
- Aliquoting
- Loading specimens
- Loading syringes
- Manipulating needles, syringes or sharps
- Aspirating and transferring blood and body fluids
- Subculturing blood culture bottles
- Spilling specimens
- Cleaning up spills
Despite the high number of approved tests, our national testing capacity has not met the needs. Why?
Challenges & Innovations

Tawny Arensmeyer, M.Ed., MLS(ASCP)CM
“If you aren't in over your head, how do you know how tall you are?”

— T.S. Eliot
## Supply Chain Challenges

<table>
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<th>General delays and backorders</th>
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<tr>
<td>Equipment</td>
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<tr>
<td>• Open channel analyzer availability</td>
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<tr>
<td>• Test volume demands</td>
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<tr>
<td>Reagents</td>
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<tr>
<td>• Individual LDT reagent shortages</td>
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<td>• EUA test kit allocations</td>
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Supply Chain Challenges

Specimen collection and testing supplies

- Test specific transport media
- Test specific collection swabs
- Validations necessary – are results comparable?

Personal protective equipment

- Masks
- PAPRs
- Face shields
- Laundry delays
Potential Supply Chain Solutions

- Can available instrumentation be centralized to a high demand location?
- Can additional instruments be rented to meet temporary increases in demand?
- Can test kits on allocation be distributed by areas of greatest need or prevalence?
- Can testing be limited to certain populations?
- Can OP specimens be used if NP swabs are unavailable?
- Can other transport media be validated on the test system? Aimes? Saline?
Potential Supply Chain Solutions

- Is homemade media available? Perhaps from a research lab?
- Do test requirements allow for a lesser volume media? Can you "rob" swabs from other collection kits?
- Is a PPE decontamination program available to recycle and reuse PPE?
- Can homemade masks be worn in non-clinical areas or for non-aerosol generating procedures to conserve PPE?
- No N95 masks? Can you substitute a mask and face shield or goggles? PAPR?
Operational Challenges & Innovations

- Staffing and workload
- Surge planning
- Engineering control availability
- Communication overload
- Fear factor
Potential Operational Solutions

- Can batch testing frequency be increased during shifts with more staffing?
- Clearly communicate TAT limitations during short staffed periods. Can limited testing times be defined and advertised?
- Can lab staff assist areas experiencing a surge?
- Can you relocate a BSC?
- If not, can you implement PPE and a splash guard?
- Versatility in methods to help alleviate supply chain issues?
- Consider specific teams to aid in implementation?
NETEC Resources

Ted Cieslak, MD, MPH
NETEC will continue to build resources, develop online education, and deliver technical training to meet the needs of our partners.

Ask for help!

Send questions to info@netec.org - they will be answered by NETEC SMEs.

Submit a Technical Assistance request at NETEC.org.
Resources

- CDC website for Laboratory guidance (Biosafety, Specimen Collection & Testing)

- WHO interim Laboratory Biosafety Guidance related to COVID-19

- FDA Emergency Use Authorizations:
  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

- NETEC COVID-19 WEBINAR SERIES: HEALTHCARE WORKERS AND MASKS
  https://repository.netecweb.org/items/show/947

- COVID-19 PPE WEBINAR - EXTENDED USE, REUSE, AND INNOVATIVE DECONTAMINATION STRATEGIES
  https://repository.netecweb.org/items/show/861
Questions and Answers
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### Join the Conversation!

Use hashtag: #NETEC

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