Clinical Laboratory COVID-19 Response Call

- **Welcome and Introductions**
  - Jasmine Chaitram, CDC Division of Laboratory Systems
- **The Reference Lab Experience: Lessons Learned and Ongoing Lessons**
  - Marc Couturier, ARUP Laboratories
- **New York State Public Health Laboratory Experience**
  - Kirsten St. George, New York State Public Health Laboratory at Wadsworth
- **Serology Testing Update**
  - Michele Owen, CDC Laboratory Task Force
- **Home Specimen Collection Kits, Home Testing, Serology, Point-of-Care Testing, and Other Topics**
  - Tim Stenzel and Sara Brenner, U.S. Food and Drug Administration (FDA)
- **Working with Healthcare Providers to Obtain Demographic Data**
  - Janet Hamilton, Council for State and Territorial Epidemiologists (CSTE)
- **Category B vs. Materials of Trade (MOT) Specimen Packaging and Shipping**
  - Stuart Streck, U.S. Department of Transportation (DOT)
- **Laboratory Biosafety Update for COVID-19**
  - Bill Arndt, CDC Division of Laboratory Systems

To Ask a Question

- Using the Webinar System
  - Click the **Q&A** button in the Zoom webinar system
  - Type your question in the **Q&A** box
  - Submit your question
  - Please do not submit a question using the chat button

- For media questions, please contact CDC Media Relations at media@cdc.gov.

The Reference Lab Experience

Lessons learned and ongoing lessons.

Marc Roger Couturier Ph.D., D(ABMM)

Medical Director, Infectious Disease – ARUP Laboratories
Associate Professor of Pathology – University of Utah

Operational Challenges with Specimens

- Leaking and improperly packaged specimens
  - »Swabs jammed into tubes
    - Incompatible length/not broken off (bent to fit)
  - »Parafilm wrapping tubes
    - Theory: makes it more secure
    - Reality: under airplane pressure, these can actually cause the cap to unscrew itself!

Respiratory Viral Culture Concerns

- Specimens from all over the USA
- Working blind on what we were receiving
  - » Source labeling…
- Areas with high prevalence of SARS-CoV-2, likely to grow unknowingly
- Stopped using Rmix cell line. RhMK cells also a concern
- Ceased respiratory viral culture in abundance of caution

DISCLAIMER on ARUP's role in NAAT

- ARUP not currently offering NAAT nationally
  - »Initially offered test to national clients on 3/12
  - »Initial demand overwhelmed capacity/supplies
  - »On 3/16, stopped accepting national orders
  - »Currently serving Utah and the neighbouring region to stay within capacity and preserve meaningful TAT

NAAT Specimen Challenges

- In a true reference setting you get whatever people send you.
  - »U of Utah = highly controlled
  - »Other partners:
    - Swab/source variability
      - › Constant questions of source vs other sources
    - Questionable specimen labeling
    - Changing specimen recommendations and changing IT interfaces

NAAT Challenges

- Different specimen/collection types and transport media outlined by FDA & not having our own data for comparative performance.
  - » Even in a reference lab, difficult to verify or compare them all.
    - Reagent burn…
- Repeat testing of initial negatives
  (suspicion of “clinical false negatives”)
  - » Sometimes not done
  - » Sometimes overdone

NAAT Performance Challenges

- Supporting multiple platforms in-house/system & for different purposes
- Multiple different platforms across Utah
  - »Not really knowing how they compare.

- Trying to establish a local PT exchange.
- Awaiting agency PT materials

Serology Challenges

- Too many rapid tests on the market to sort out the noise
  - » Unclear vendor reliability and performance characteristics
  - » Not amenable to high volume needs of reference lab
- No clear proven utility to IgA & IgM at this time
- How will physicians/systems use these results?
- Supply chain concerns
- Collaboration (among reference labs) has been key

The Value of Collaboration and Communication

- Working openly and collaboratively with:
  - » Local/state government officials
  - » PHL and state epi
  - » Other local healthcare system labs
- 3x a week calls with all local lab partners.
- Harmonizing uniform and consistent criteria for who can get tested and what priority
  - » That has helped our pre-test probably.
- Lending reagents and workspace where needed in crisis situations

ARUP LABORATORIES

A nonprofit enterprise of the University of Utah and its Department of Pathology

New York State Public Health Laboratory Experience

Kirsten St. George, PhD
New York State Public Health Laboratory at Wadsworth

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Serology Testing Update

Michele Owen, PhD
CDC Laboratory Task Force

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CDC Laboratory Task Force – COVID-19 Testing

CDC guidance on specimen collection and transport for COVID-19 testing

https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

CDC guidance on evaluating and testing persons for coronavirus disease

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html

CDC Laboratory Task Force – COVID-19 Testing

For laboratories using the CDC EUA assay, please contact respvirus@cdc.gov for laboratory testing guidance.

Home Specimen Collection Kits, Home Testing, Serology, Point-of-Care Testing, and Other Topics

Tim Stenzel, MD, PhD
Sara Brenner, MD, MPH
U.S. Food and Drug Administration (FDA)

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Food and Drug Administration (FDA)

COVID-19 Emergency Use Authorization (EUA) Information: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

COVID-19 Frequently Asked Questions: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions

COVID-19 Updates: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov

Food and Drug Administration (FDA)

COVID-19 Diagnostic Development: CDRH-EUA-Templates@fda.hhs.gov

Spot Shortages of Testing Supplies: 24 hour support available

1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (*)

Working with Healthcare Providers to Obtain Demographic Data

Janet Hamilton, MPH
Council for State and Territorial Epidemiologists (CSTE)

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Materials of Trade and Category B Training and Packaging

Stuart Streck

U.S. Department of Transportation (DOT)

Materials of Trade and Category B Training and Packaging

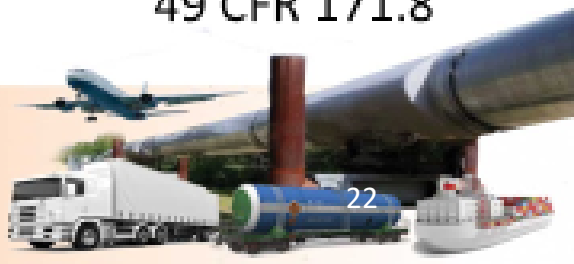
Stuart Streck
U.S. Department of Transportation (DOT)

Materials of Trade (MOTS) Definition:

Material of trade means a hazardous material, other than a hazardous waste, that is carried on a motor vehicle—

- (1) For the purpose of protecting the health and safety of the motor vehicle operator or passengers;
- (2) For the purpose of supporting the operation or maintenance of a motor vehicle (including its auxiliary equipment); or
- (3) By a private motor carrier (including vehicles operated by a rail carrier) in direct support of a **principal business that is other than transportation by motor vehicle.**

49 CFR 171.8



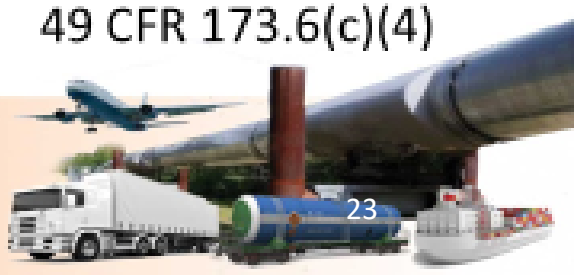
Training Requirements
MOTS vs. Category B

- Training requirements for Category B
  - "Each person who offers or transports a Category B infectious substance under the provisions of this section **must know about the requirements of this section.**" *Bolded for emphasis*

49 CFR 173.199(e)

- Knowledge requirements for MOTS:
  - "The operator of a motor vehicle that contains a material of trade must be informed of the presence of the hazardous material (including whether the package contains a reportable quantity) and **must be informed of the requirements of this section (49 CFR 173.6)**" *Bolded for emphasis*

49 CFR 173.6(c)(4)

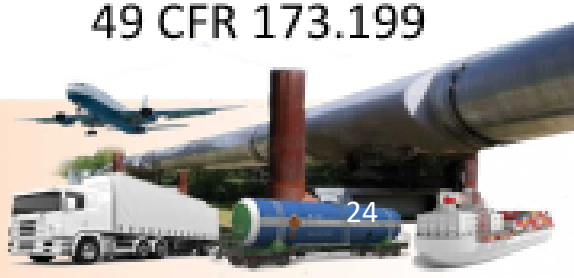


Packaging Requirements for Category B

Abbreviated discussion points

- Not for Category A
- Combination Packaging:
  - Triple packaging consisting of Primary receptacle, Secondary & Rigid Outer
- Absorbent and Cushioning material
- Marking of UN ID#, Shipping Name
- 95 kPa packaging for aircraft shipments

49 CFR 173.199



Packaging Requirements for MOTS

Abbreviated discussion points

- Not for Category A
- Combination Packaging: Inner and Outer
- Liquids requires leakproof inner packaging with enough absorbent to absorb entire contents.
- "Packagings must be leak tight for liquids and gases, sift proof for solids, and be securely closed, secured against shifting, and protected against damage."
- "A non-bulk packaging other than a…must be marked with a common name or proper shipping name to identify the material it contains…"

49 CFR 173.6

Hazardous Material Info-Center

1-800-HMR-4922

(1-800-467-4922)

E-mail: infocntr@dot.gov

HAZMAT.dot.gov

Hours of Operation: 9 am – 5 pm ET

- Obtain answers to HMR questions
- Request copies of Federal Register, special permits or training materials
- Report HMR violations
- Fax on Demand

Laboratory Biosafety Update for COVID-19

Bill Arndt, PhD
CDC Division of Laboratory Systems

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Biosafety Resources

COVID-19 Information for Laboratories page:
https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html

Interim Laboratory Biosafety Guidelines:
https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

Laboratory Biosafety Frequently Asked Questions:
https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html

Send Inquiries to: DLSInquiries@cdc.gov

CDC Information for Laboratories

Interim Guidance for Collecting, Handling, and Testing Clinical Specimens
https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Diagnostic Tools and Virus
https://www.cdc.gov/coronavirus/2019-ncov/lab/tool-virus-requests.html

Emergency Preparedness for Laboratory Personnel
https://emergency.cdc.gov/labissues/index.asp

CDC's Laboratory Outreach Communication System (LOCS)
https://www.cdc.gov/csels/dls/locs/

CDC Social Media

Facebook: https://www.facebook.com/CDC

Twitter: https://twitter.com/cdcgov

LinkedIn: https://www.linkedin.com/company/cdc

Thank You For Your Time!