Clinical Laboratory COVID-19 Response Call

Monday, August 3rd, 2020 at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, Division of Laboratory Systems, CDC
- **Update on Laboratory Data Reporting**
  - Sara Brenner, HHS Laboratory Reporting
- **Tri-Agency Pooling Update**
  - Reynolds (Ren) Salerno, Division of Laboratory Systems (DLS), CDC
  - Amy Zale, Centers for Medicare and Medicaid Services (CMS)
  - Toby Lowe, U.S. Food and Drug Administration (FDA)
- **Risk Assessment**
  - Bev Dickson, Texas Health Presbyterian Hospital
- **FDA Update**
  - Tim Stenzel, U.S. Food and Drug Administration (FDA)

Schedule for Clinical Laboratory COVID-19 Response Calls

The next call is scheduled for **Monday, August 17th** from 3:00 PM to 4:00 PM EDT.

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/

- **IVD Industry Connectivity Consortium**
  https://ivdconnectivity.org/livd/

- **LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests**
  https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html

Proficiency Testing (PT) for SARS-CoV-2

Programs that offer PT for SARS-CoV-2 molecular and/or antibody tests:

- **Accutest**
  - Website: www.oneworldaccuracy.com/1wa/#/ Contact: support@1wa.org
- **American Academy of Family Physicians**
  - Website: www.aafp.org/pt Contact: (800)274-7911 or pt@aafp.org
- **American Association of Bioanalysts Proficiency**
  - Website: www.aab-pts.org Contact: (800)234-5315 or customerservice@aab-pts.org
- **American Proficiency Institute**
  - Website: www.api-pt.com Contact: (800)333-0958 (Customer Service)
- **College of American Pathologists**
  - Website: www.cap.org Contact: (800)323-4040, option 1
- **Wisconsin State Laboratory of Hygiene**
  - Website: www.wslhpt.org Contact: (800)462-5261 or ptservice@slh.wisc.edu

Share Your Feedback!

Help us improve these calls by taking a short 5-minute survey!

Take the Survey Here:

https://www.surveymonkey.com/r/CLCRAug3

We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

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 and submit it – be sure to include your email address so we can get back to you
  - Please do not submit a question using the chat button

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

- If you are a patient, please direct any questions to your healthcare provider

Pooling Procedures for SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing

Reynolds (Ren) M Salerno, PhD, Director
CDC Division of Laboratory Systems

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

Quick Overview

- Pooling is the combining of respiratory samples from several people and conducting one laboratory test on the combined pool of samples to detect SARS-CoV-2
- Pooling allows laboratories to test more samples with fewer testing materials, potentially increasing testing capacity
- Pooling should be used only in areas or situations where the number of positive test results is expected to be low
- If a pooled test result is negative, then all the samples can be presumed negative with the single test
- If the pooled test result is positive, each of the samples in the pool need to be tested individually to determine which samples are positive

Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing

- Definitions of diagnostic, screening, and surveillance testing
- Regulatory requirements
- Reporting results to patients and health departments
- Technical limitations

Pooled Testing for SARS-CoV-2

	Surveillance Testing	Screening Testing	Diagnostic Testing
CLIA-Certified Laboratory	Yes	Yes	Yes
Non-CLIA-Certified Laboratory	Yes	No	No
CLIA Requirements Apply to Pooled Testing Procedure	No	Yes	Yes
Test System must be FDA Authorized or Offered under the Policies in FDA's Guidance	No	Yes	Yes

Reporting of Pooled SARS-CoV-2 Testing Results to State/Tribal/Local/Territorial (STLT) Health Departments

	Surveillance Testing	Screening Testing	Diagnostic Testing
Negative (-)	Return pooled results in aggregate to requesting institution (e.g., a university) as presumptive negative. Do not report to STLT health department as a diagnostic or screening result.	Report each individual in pool as negative to the STLT health department.	Report each individual in pool as negative to the STLT health department.*
Positive (+) or Indeterminate (+/-)**	Do not report pooled result. Perform individual testing and report individual results (+/-) in aggregate to requesting institution (e.g., a university). Do not report to STLT health department as a diagnostic or screening result.	Do not report pooled result. Perform diagnostic testing of individual specimens, and report each as (+) or (-) to the STLT health department.	Do not report pooled result. Perform diagnostic testing of individual specimens, and report each as (+) or (-) to the STLT health department.

Returning of Pooled SARS-CoV-2 Testing Results to the Individuals in the Pool

	Surveillance Testing	Screening Testing	Diagnostic Testing
Negative (-)	Do not report to individuals in the pool.	Report to individual, individual's healthcare provider, employer, etc. according to the FDA-authorized assay's instructions for use.*	Report to individual, individual's healthcare provider, employer, etc. according to the FDA-authorized assay's instructions for use.*
Positive (+)	Do not report to individuals in the pool.	Do not report positive pooled results. Perform diagnostic testing of individual specimens, and then report to individual, individual's healthcare provider, employer, etc. as (+) or (-).	Do not report positive pooled results. Perform diagnostic testing of individual specimens, and then report to individual, individual's healthcare provider, employer, etc. as (+) or (-).
Indeterminate (+/-)	Do not report to individuals in the pool.	Do not report indeterminate pooled results. Perform diagnostic testing of individual specimens, and then report to individual, individual's healthcare provider, employer, etc. as (+) or (-).	Do not report indeterminate pooled results. Perform diagnostic testing of individual specimens, and then report to individual, individual's healthcare provider, employer, etc. as (+) or (-).

FDA Information on Pooled Testing

- EUA Templates
  - Molecular Diagnostic Template for Commercial Manufacturers (updated July 28, 2020)
  - Molecular Diagnostic Template for Laboratories (updated July 28, 2020)
- FAQs on Testing for SARS-CoV-2
  - What is the difference between surveillance, screening, and diagnostic testing for COVID-19 testing?
  - Are EUA-authorized SARS-CoV-2 diagnostic tests limited to use in individuals who are symptomatic for COVID-19?
  - Can I offer my SARS-CoV-2 diagnostic test for screening of asymptomatic individuals for COVID-19?
  - Does FDA have validation or other recommendations regarding SARS-CoV-2 diagnostic/screening tests for use with sample pooling?
  - Can an EUA-authorized SARS-CoV-2 diagnostic test be used for surveillance for COVID-19?
- In Vitro Diagnostics EUAs
  - Each test authorized for use with pooled specimens includes “pooling” in the attributes listed in the EUA table, as well as detailed information in the Letter of Authorization and the Instructions for Use

CMS Frequently Asked Questions on SARS-CoV-2 Surveillance Testing

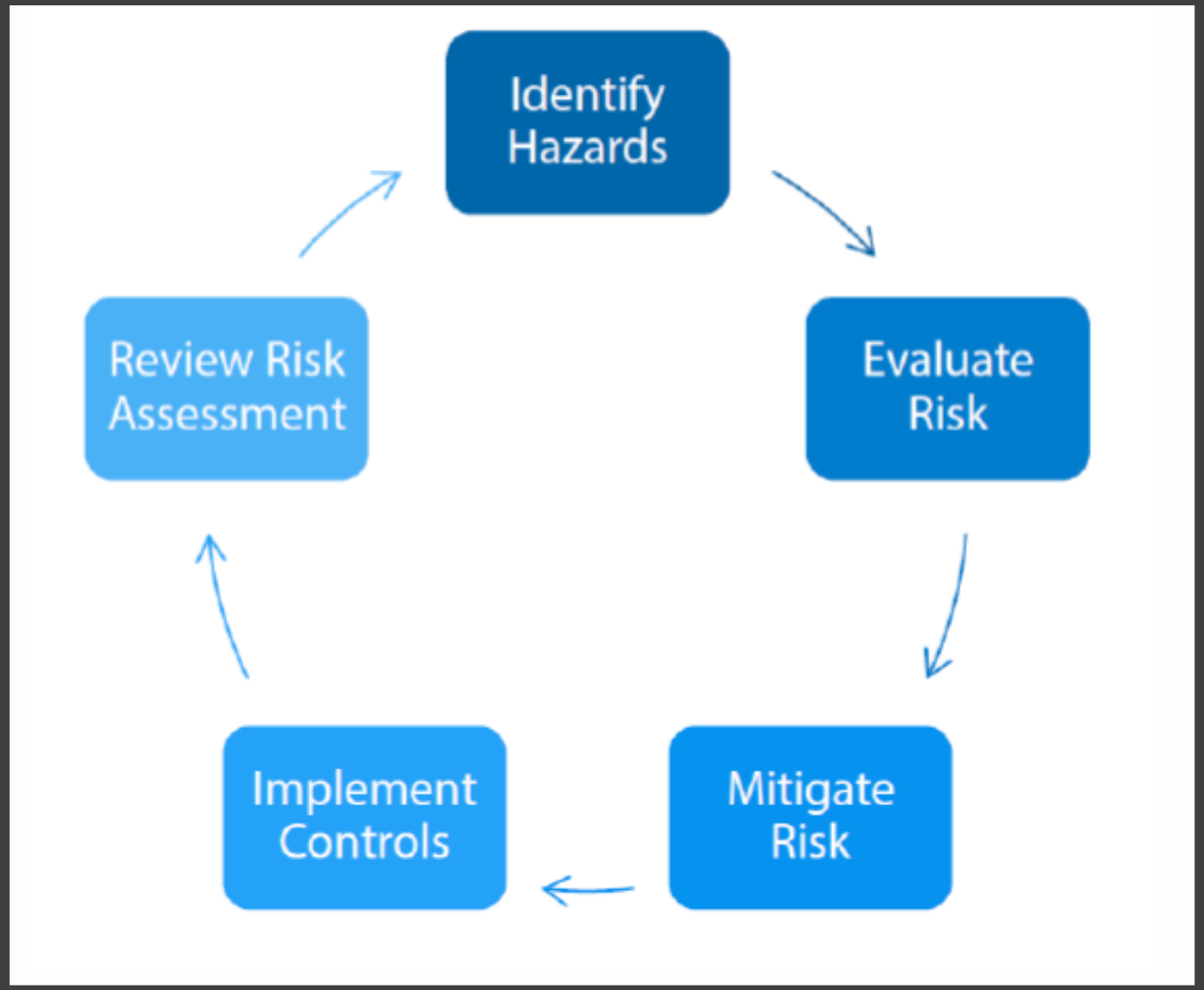
- During the COVID-19 public health emergency and associated authorizations, "facilities performing SARS-CoV-2 surveillance testing using a pooled sampling procedure to report ***non patient-specific*** SARS-CoV-2 cohort results will not require CLIA certification."

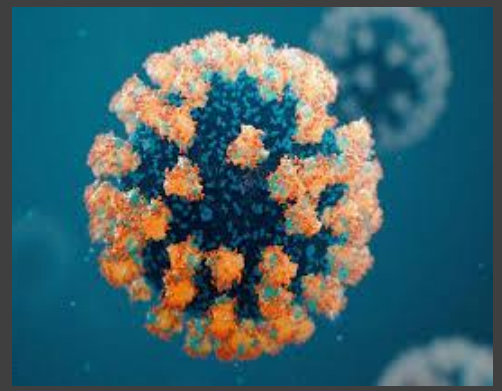
https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf

For More Information

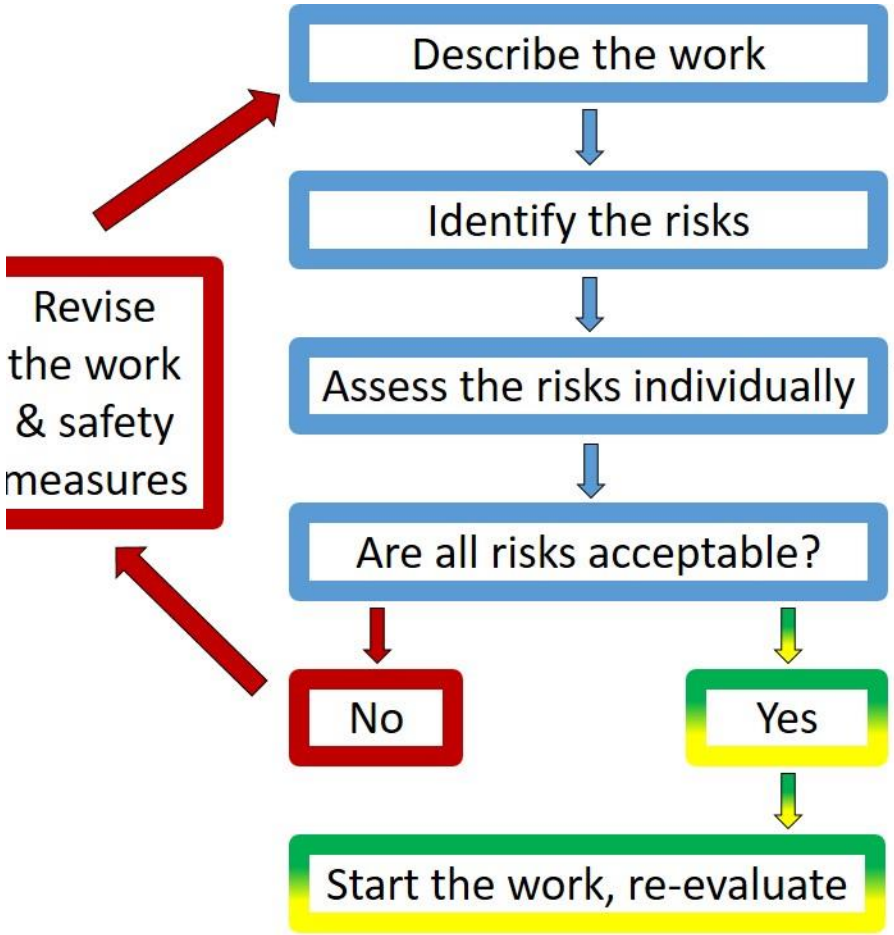
Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing

https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html





RISK ASSESSMENT IN THE AGE OF COVID



Frequency of accident

5: Very common 1/10
4: Common 1/100
3: Regular 1/1.000
2: Unlikely 1/10.000
1: Very unlikely 1/100.000

Risk = Frequency*Severity

5	10	15	20	25
4	8	12	16	20
3	6	9	12	15
2	4	6	8	10
1	2	3	4	5
1: No injury/disease	2: Minor injury or disease	3: Injury or disease	4: Serious injury or disease	5: Fatality, or permanent injury or disease

Severity of accident

Very serious risk
Serious risk
Some risk
Small risk
Negligible risk

10+ The work may not begin
5-9 Start the under close supervision, re-evaluate
1-4 Start the work

Uppsala University web portal

A STEPWISE SIMPLE RISK ASSESSMENT TOOL

STEP 1

- Briefly Explain Situation

STEP 2

- Provide Background Information

STEP 3

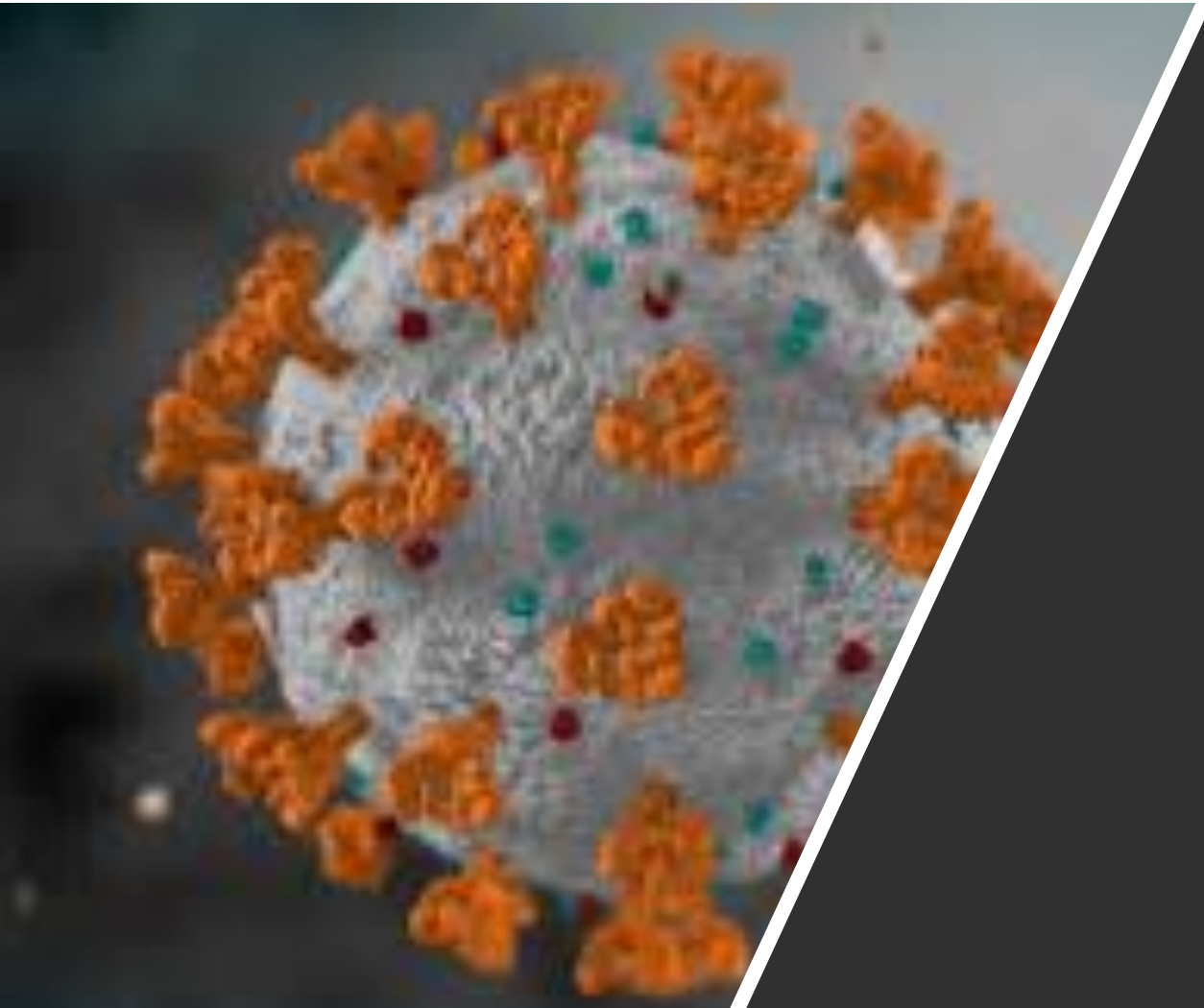
- Develop supportive argument for the process

STEP 4

- Develop possible opposition to proposed process

SAFETY OF TRANSPORTING COVID SPECIMENS BY PNEUMATIC TUBE

STEP 1
SITUATION



S: Assess the risk of sending clinical specimens during Covid respiratory virus pandemic through the pneumatic tube system.

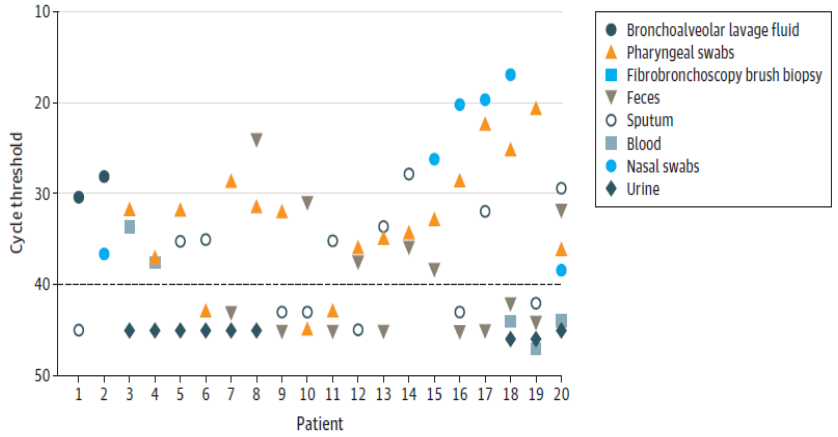
B: For a tertiary care hospital campus, the pneumatic system is vital to timely TAT and efficient workflow for diagnostic care. Published guidelines for Covid Sample pneumatic tube transport are discordant. (2/ 2020) CDC advises specific risk assessments, while WHO does not recommend use.

A: Blood, urine, and respiratory specimens are transported routinely on inpatients and ED patients through the pneumatic tube system.
Can this be done safely in this pandemic? Perform Risk Assessment to determine risk of pneumatic tube transport of various clinical specimens

R: Risk Assessment:

STEP 2: Background Information

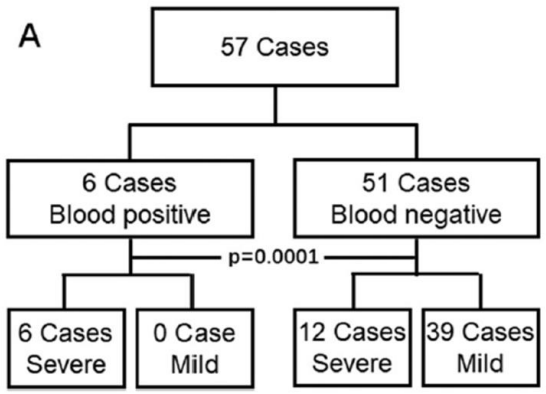
Figure. Severe Acute Respiratory Syndrome Coronavirus 2 Distribution and Shedding Patterns Among 20 Hospitalized Patients



The specimen with a cycle threshold value above the dashed line is interpreted as positive for SARS-CoV-2 RNA; those under, negative.

jama.com

JAMA Published online March 11, 2020



Emerging Microbes & Infections
2020, VOL. 9
https://doi.org/10.1080/22221751.2020.1732837

HSE information sheet

HSE Health & Safety Executive

Safe use of pneumatic air tube transport systems for pathology specimens

STEPS 3 & 4: BUILD A CASE

Pneumatic Tube Transport :

Biosafety Control Assessment And Evaluation

- Covid specimen swabs are submitted in screw top tubes with 1-3 cc transport media.
- Specimens transported with secondary containment (sealed in biohazard bags x 2) *
- Bagged specimens of known/PUI Covid patients are sanitized prior to tube transport *
- Tube carrier (tertiary container) is composed of durable plastic with rubber gaskets to deter spillage into the tube transport system proper
- Tube carrier is transparent for easy visual detection in case of breakage or spillage
- Tube carrier is snap closure type , less risk of accidental opening
- On arrival to lab each carrier is individually visually inspected and opened by a gloved and masked lab employee *
- Viral respiratory swab collections contain a maximum of 3 cc liquid so spillage/leakage would be minimal and would be contained by secondary (bags) and tertiary (carrier) containment
- Non-respiratory specimens contain much lower viral load of SARS CoV-2 similar to other known respiratory viruses, ie: influenza. (literature review), thus less risk of transmission from exposure
- Tube carriers are periodically wiped down with suitable EPA disinfectant solution *
- Historically, at THD leakage has only been known to occur into carrier from urine cup specimens, which are no longer acceptable for pneumatic transport
- Historically, single bagged respiratory swab specimens have not been known to produce aerosolization during pneumatic transport (no evidence to support infection from viral transmission) from enhanced biosafety precautions
- The Reliability Learning Tool will be utilized to track and trend
- The Bloodborne Pathogen policy will be employed for exposures

* Enhanced control

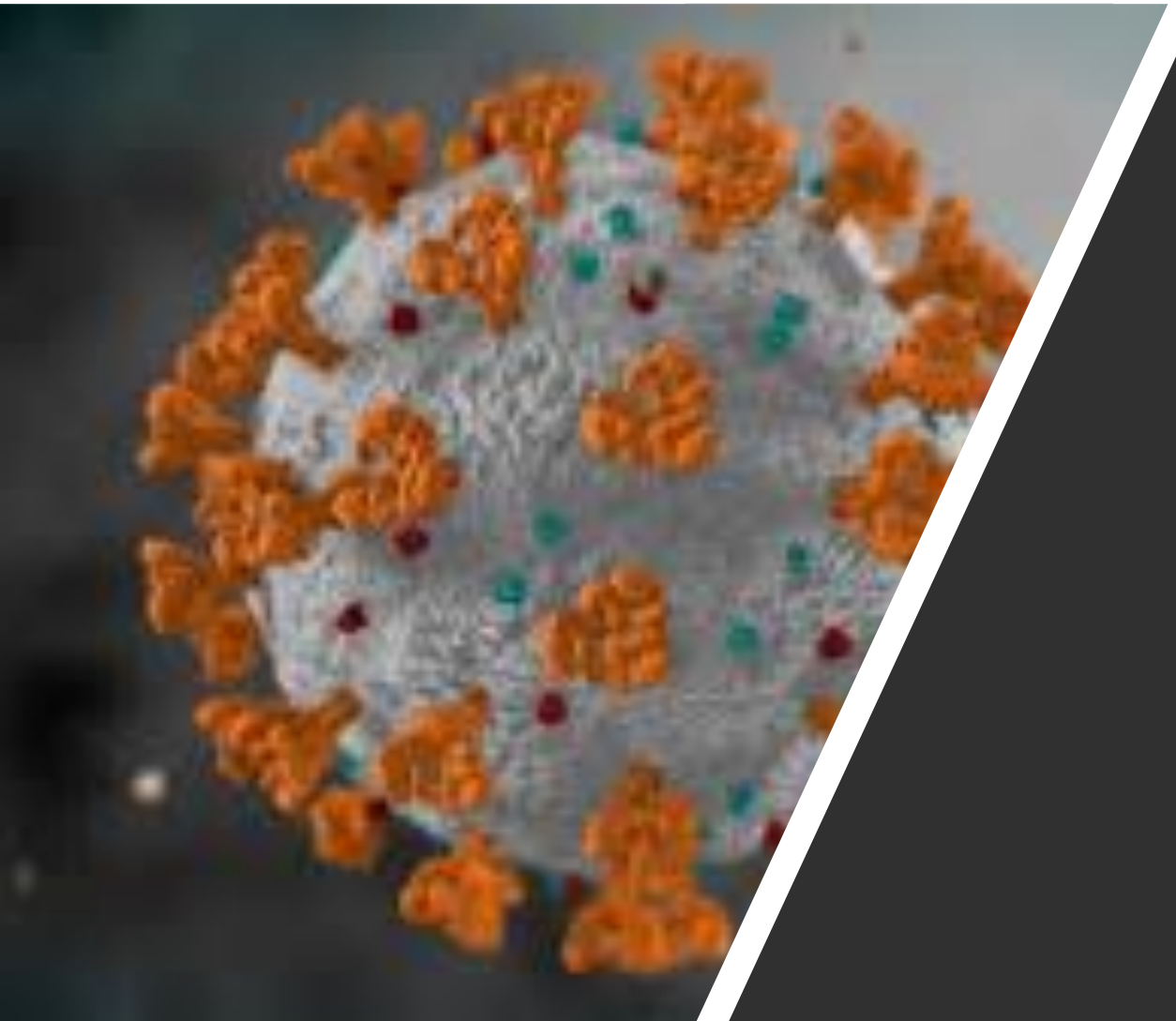
STEP 5: ASSESSMENT & EVALUATION

Risk Event/ Risk Reduction Strategy	Probability Risk will Occur (How frequent is the cause likely to occur?)				Potential Severity if Risk Occurs (How severe is the effect?)				Detectability: (How likely is risk event identified? Low detection = low preparedness)				Risk Priority
	Frequent	Probable/ Likely	Occasional	Remote/ Rare	Life Threatening	Permanent Harm	Temp Harm	None	None	Low/ Unlikely	Likely/ Moderate	High/ Very Likely	>11 = High Risk
(Probability + Severity) x Preparedness = Risk Score	4	3	2	1	4	3	2	1	4	3	2	1	
Risk													
COVID-19 specimen spilling into pneumatic tube system and contaminating system.				x	x							**x**	4

1 X 4 X 1 = Score 4
Risk Priority Score 4
Score Range 1- 64

RISK IN THE AGE OF COVID

STEP 6 RECOMMENDATION POST ANALYSIS



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R: Risk Assessment determination is that risks to employees and public from use of the pneumatic system to transport blood, urine and respiratory swab specimens during the Covid pandemic is very low due to enhanced controls and procedures as well as historical experience with transport of blood, urine, and swab specimens for other respiratory viruses . Monitor plan by RLT, track and trend, and report in system safety dashboard. Update policies and procedures for bloodborne exposure and appropriate use of pneumatic tube system in the age of Covid,.

FDA Update

Tim Stenzel and Sara Brenner
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 for Medical Devices**
  https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

- **COVID-19 In Vitro Diagnostic EUAs**
  https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

- **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

- **FDA Townhall Meetings**
  https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020

- **Independent Evaluations of COVID-19 Serological Tests**
  https://open.fda.gov/apis/device/covid19serology/

FDA U.S. FOOD & DRUG ADMINISTRATION

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 (*)

U.S. FOOD & DRUG ADMINISTRATION

CDC Social Media

https://www.facebook.com/CDC

https://twitter.com/cdcgov

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

Thank You For Your Time!

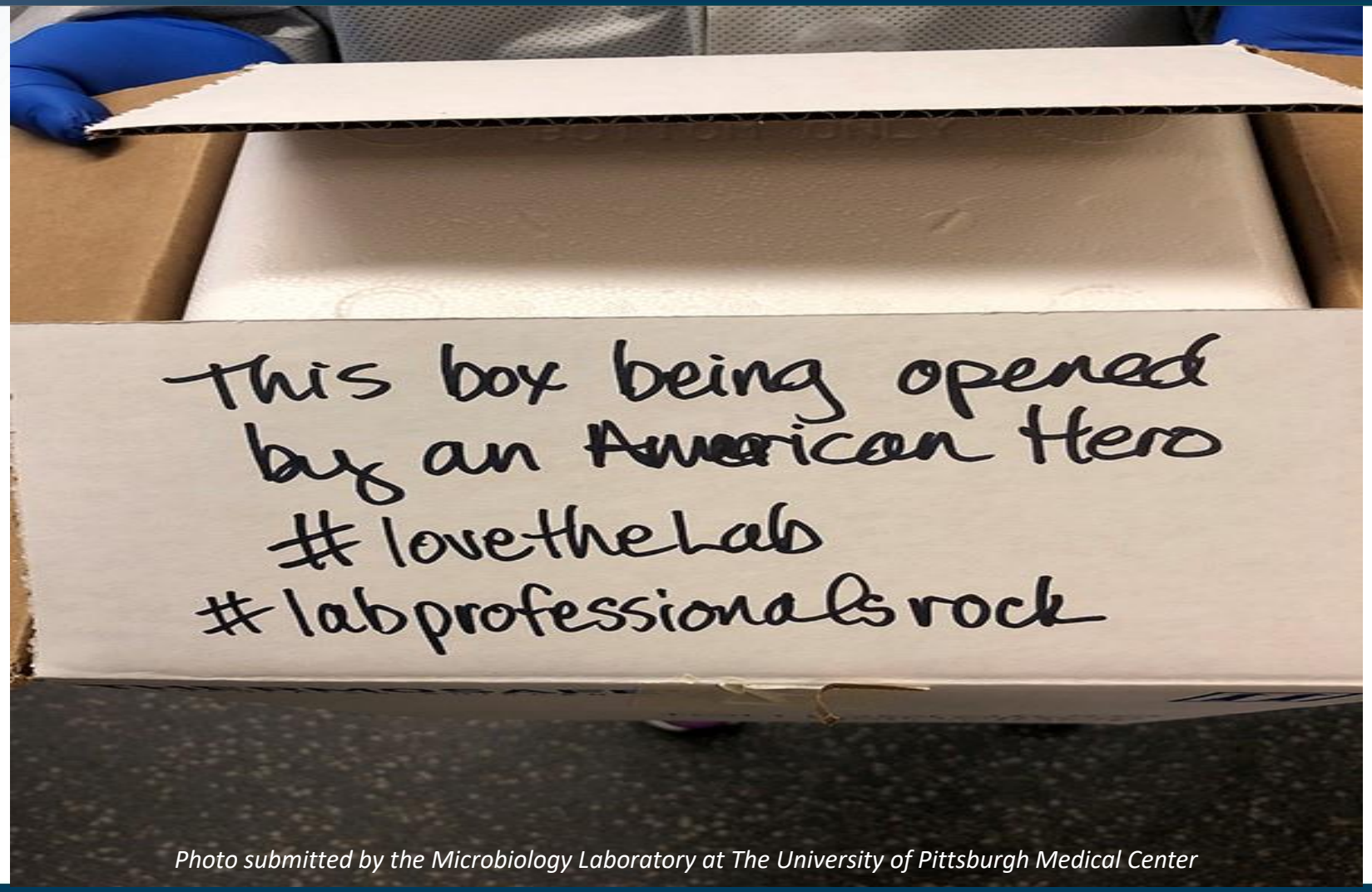

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center