

Clinical Laboratory COVID-19 Response Call

Monday, May 16, 2022, at 3:00PM ET

- **Welcome**
 - Sean Courtney, Division of Laboratory Systems, CDC
- **SARS-CoV-2 Variants Update**
 - Natalie Thornburg, Laboratory and Testing Task Force, CDC
- **CLIA SARS-CoV-2 Test Result Reporting Update**
 - Sarah Bennett, Centers for Medicare and Medicaid Services (CMS)
- **Scent Discriminating Canines as a Tool for COVID-19 Management**
 - Julian Mendel, Florida International University
- **Supply Chain Challenges and Solutions**
 - Gregory Sossaman, Ochsner Health

About DLS

Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

Mission

Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.

Four Goal Areas



Quality Laboratory Science

- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance



Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories



Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care

CDC Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html>

Find CLCR call information, transcripts, and audio recordings on this page

The screenshot shows the 'Prepared Laboratories' section of the CDC website. The main heading is 'Clinical Laboratory COVID-19 Response Calls'. Below the heading is a banner image of a coronavirus particle. The text describes the calls as regular meetings where the CDC's Division of Laboratory Systems (DLS) discusses the nation's clinical laboratory response to COVID-19. It states that calls occur on the third Monday of each month at 3:00 PM Eastern time. A sidebar on the left lists the months from March 2022 to September 2021. Social media icons for Facebook, Twitter, LinkedIn, and YouTube are visible in the top right corner.

Prepared Laboratories

Prepared Laboratories > Outbreak & Response

- Prepared Laboratories
- Preparedness Initiatives
- Outbreak & Response**
- COVID-19
- Clinical Laboratory COVID-19 Response Calls**
- March 2022
- February 2022
- January 2022
- December 2021
- November 2021
- October 2021
- September 2021

Clinical Laboratory COVID-19 Response Calls

CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place on the third Monday of each month at 3:00 PM Eastern time. Audio and transcripts are posted online after each call.

To submit questions for consideration, email DLInquiries@cdc.gov in advance or use the question and answer (Q&A) function in Zoom during the call. Because we anticipate a large number of participants on this call, and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content of future calls accordingly. We want this call to be useful and relevant to your COVID-19 response activities - we are all in this together.

To join from a PC, Mac, iPad, iPhone or Android device:

Next Scheduled Call

The next call will be on

Monday, June 27 @ 3:00 PM to 4:00 PM ET



We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov



How to Ask a Question

- **Using the Zoom Webinar System**

- Click the **Q&A button** in the Zoom webinar system
- Type your question in the **Q&A box** and submit it
- **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



Division of Laboratory Systems

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.



Division of Laboratory Systems

SARS-CoV-2 Variants Update

Natalie Thornburg

Laboratory and Testing Task Force, CDC





CLIA SARS-CoV-2 Test Result Reporting Update



Sarah Bennett

Technical Director

Division of Clinical Laboratory

Improvement and Quality

May 16, 2022

Disclaimer

This presentation was prepared for informational purposes and is not intended to grant rights or impose obligations. Every reasonable effort has been made to assure the accuracy of the information within these pages.

This publication is a general summary that explains certain aspects of the Clinical Laboratory Improvement Amendments (CLIA) Program, but is not a legal document. The official CLIA Program provisions are contained in the relevant laws, regulations, and rulings. Links to the source documents have been provided within the document for your reference.

The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of CLIA information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

- Updated CLIA SARS-CoV-2 Test Result Reporting Requirements
- CLIA Reporting Requirements, Additional Information

Updated CLIA SARS-CoV-2 Test Result Reporting Requirements

Policy Memo, SARS-CoV-2 Test Reporting: [QSO-21-10-CLIA REVISED](#) (released 4/15/2022)

CLIA Certificate Type	Authorized Laboratory Setting/Test complexity Waived (W), Moderate (MC) or High complexity (HC)	Test platform	Reporting of SARS-CoV-2 positive results	Reporting of SARS-CoV-2 negative and inconclusive results
COW/PPM	W	Antigen	Required	Optional
		Molecular (NAAT)	Required	Optional
		Serology (Antibody)	Optional	Optional
COC/COA/COR	W, MC or HC	Antigen	Required	Optional
	MC or HC	Molecular (NAAT)	Required	Required
	W	Molecular (NAAT)	Required	Optional
	W, MC or HC	Serology (Antibody)	Optional	Optional

CLIA Reporting Requirements, Additional Information

- CLIA surveying against CLIA requirements for SARS-CoV-2 test result reporting
- CLIA is only assessing if labs have reported, or attempted to report, test results
- Laboratory must have documentation it has reported, or attempted to report results
- The data elements and timelines for reporting in the HHS Secretary's guidance are outside the scope of CLIA.

- CLIA Website: [Clinical Laboratory Improvement Amendments \(CLIA\)](#)
- [CMS Emergencies Page](#)
- Policy Memo, SARS-CoV-2 Test Reporting: [QSO-21-10-CLIA REVISED](#)



Any
Questions

Scent discriminating canines as a tool for Covid-19 management

Julian Mendel, Ph.D.
Florida International University

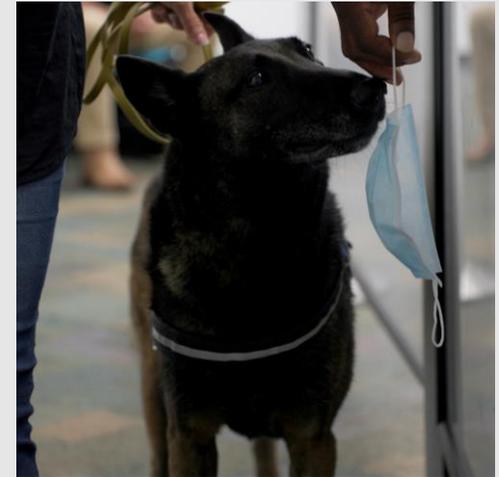
Canine Olfaction in Law Enforcement

- Drugs
- Money
- Explosives & Accelerants
- Trailing & Human Scents
- Guns & Ammunition
- Wildlife Trafficking
- Food



K-9 officer in training Tuco. (Image credit: Massachusetts Vest-a-Dog)

Outside Law Enforcement



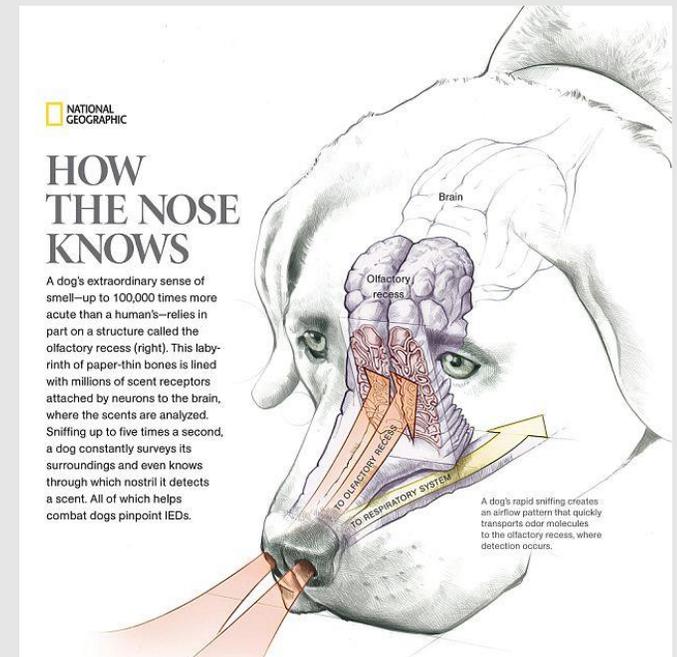
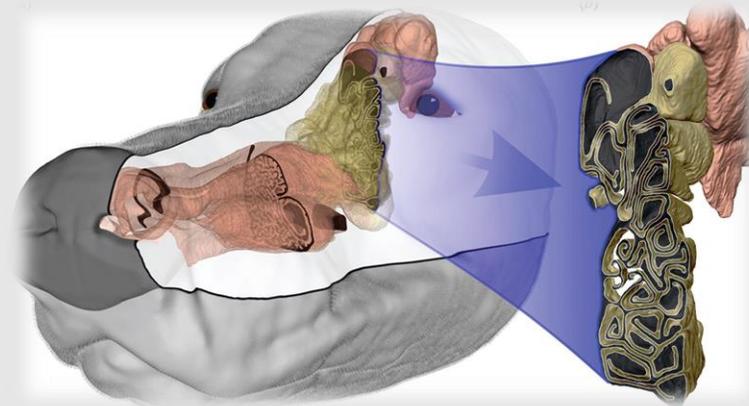
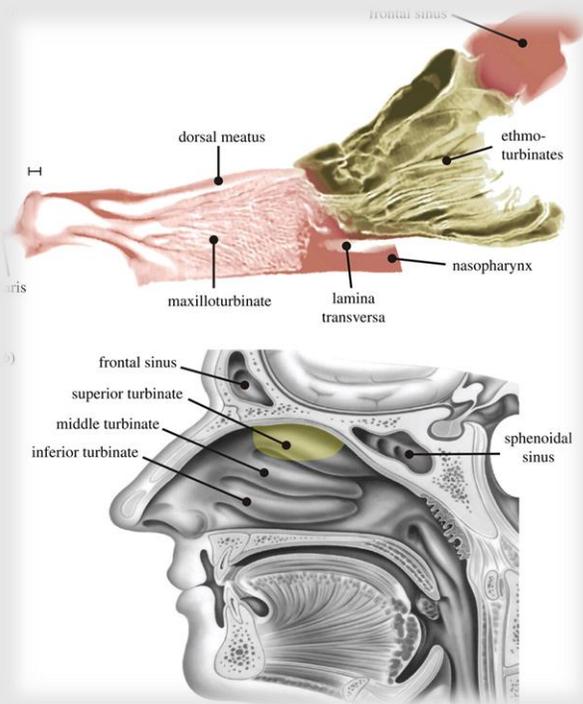
Environmental:
Fungi, Mold

Pests:
Bedbugs, Termites

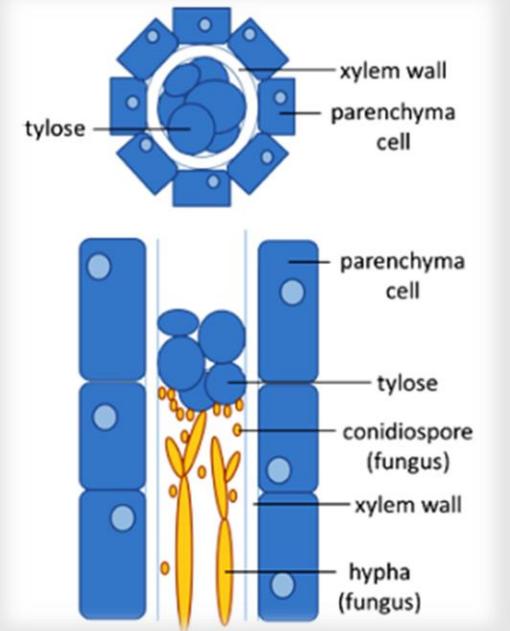
Diseases:
Cancer, Parkinson's,
Diabetes, Malaria, COVID-19

Canine Olfaction

- 10,000 – 100,000 times more sensitive than humans
- >100 times olfactory receptor cells
- Olfactory recess-lined with epithelium and cilia



Laurel Wilt Disease



Xyleborus glabratus

Raffaelea lauricola

Laurel Wilt Disease

- 500 MILLION Laurel trees dead
- ≈25,000 avocado trees dead, 1/3



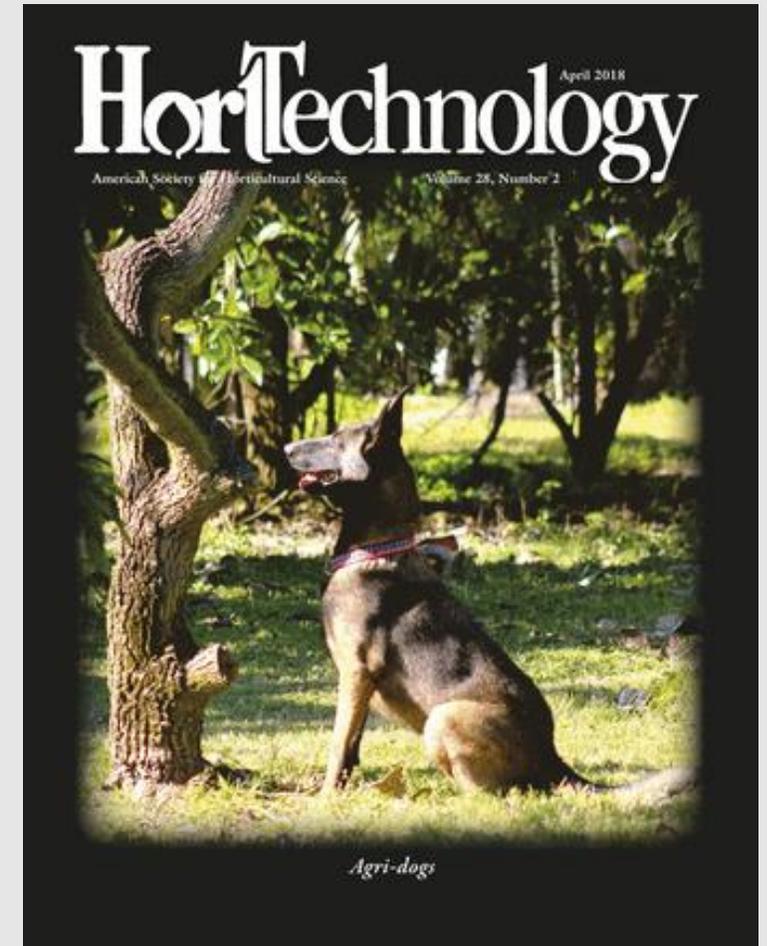
Detection Dogs have ~98% Average Accuracy

An Evaluation of Scent-discriminating Canines for Rapid Response to Agricultural Diseases

Julian Mendel, Kenneth G. Furton, and DeEtta Mills

Agri-dogs: Using Canines for Earlier Detection of Laurel Wilt Disease Affecting Avocado Trees in South Florida

Julian Mendel, Christina Burns, Beatrice Kallifatidis, Edward Evans, Jonathan Crane, Kenneth G. Furton, and DeEtta Mills

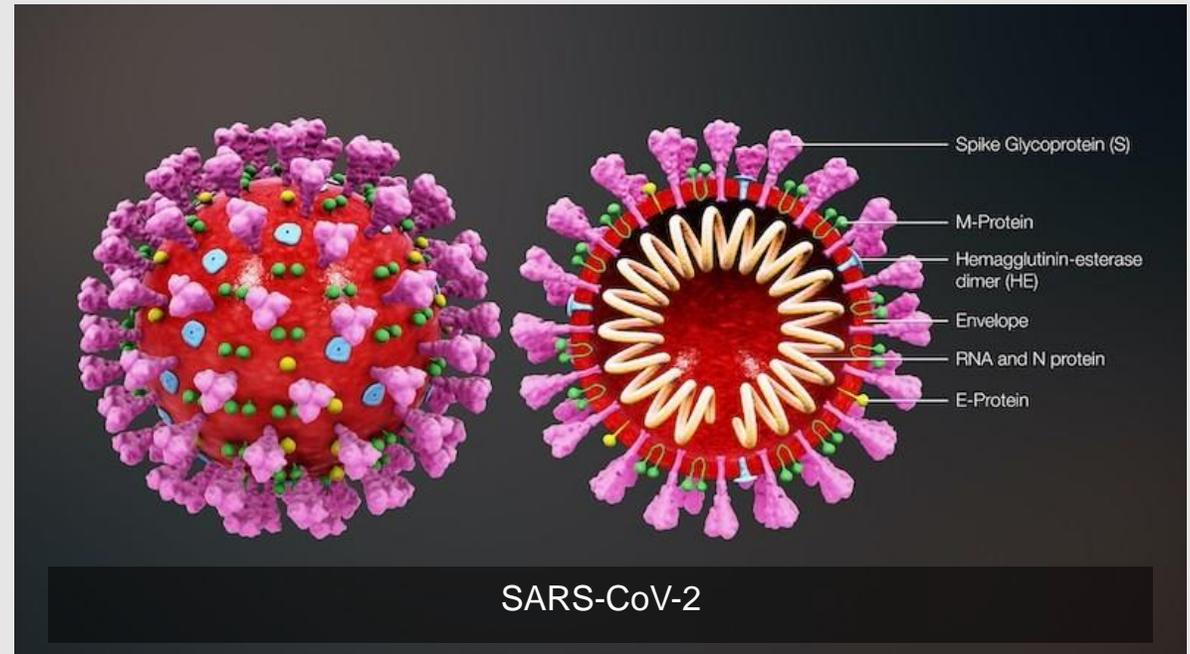


FIU

Global Forensic
and Justice Center

COVID-19

- **Baptist Hospital Collaboration**
 - Provided PPE from patients
 - Positive and Negative
- **Global Forensic and Justice Center**
 - Experimental Design
 - Chemistry
 - Training aids
- **Redland Ahead**
 - Training and Deployment



Patented or Patent-Pending Training Aids



TANK-9



COMPS

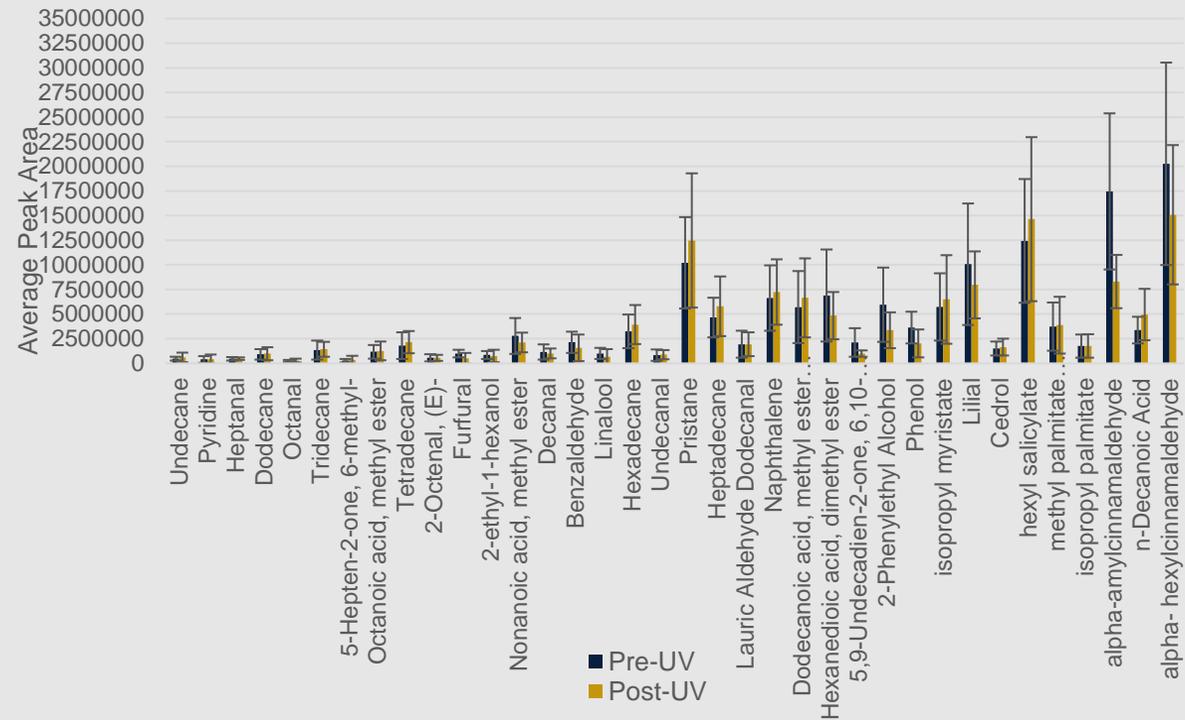


UDC

Safe Training Aids



HS-SPME-GCMS analysis of Human Scent Compounds
Pre and Post UV irradiation



Impact of 10-minute UV-C irradiation on a mixture of volatiles. A Student's T-test indicated no significant difference between peak areas of the compounds before and after UV-C treatment ($p > 0.05$)

Training



Results

217 Training runs prior to double blind trials

Canine name	Canine breed	Failure to alert (no.)	False alerts(#)^z	ACC/PPV (%)^y
Hubble	Border Collie Mix	15	6	96.3 /87.0
One Betta	Dutch Shepherd	15	3	98.1/93.0
Cobra	Belgian Malinois	20	1	99.4/97.6
Mac	Terrier mix	17	5	96.2/88.6

Double Blind Trials n=40 Using Healthy masks, and blank masks as distractors.

Results

- Headspace SPME-GC-MS
- Clear separation between individuals
- Work ongoing

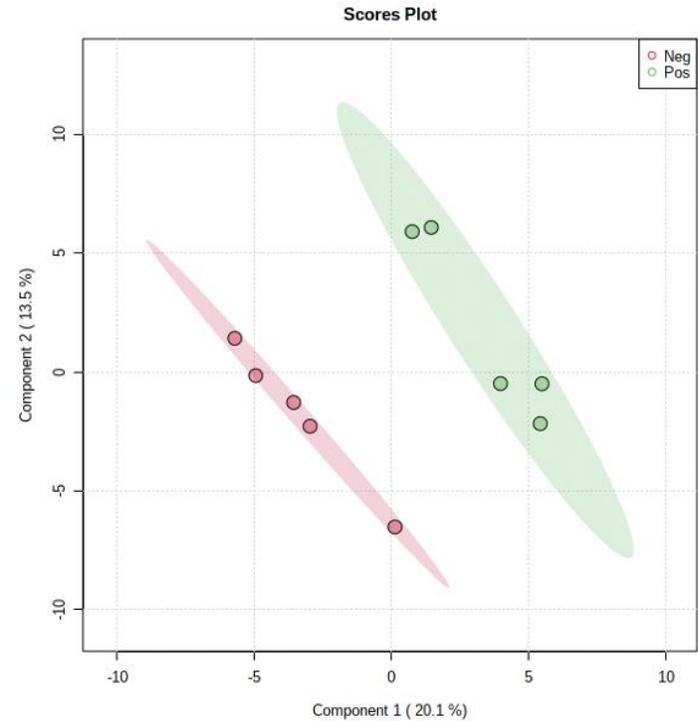


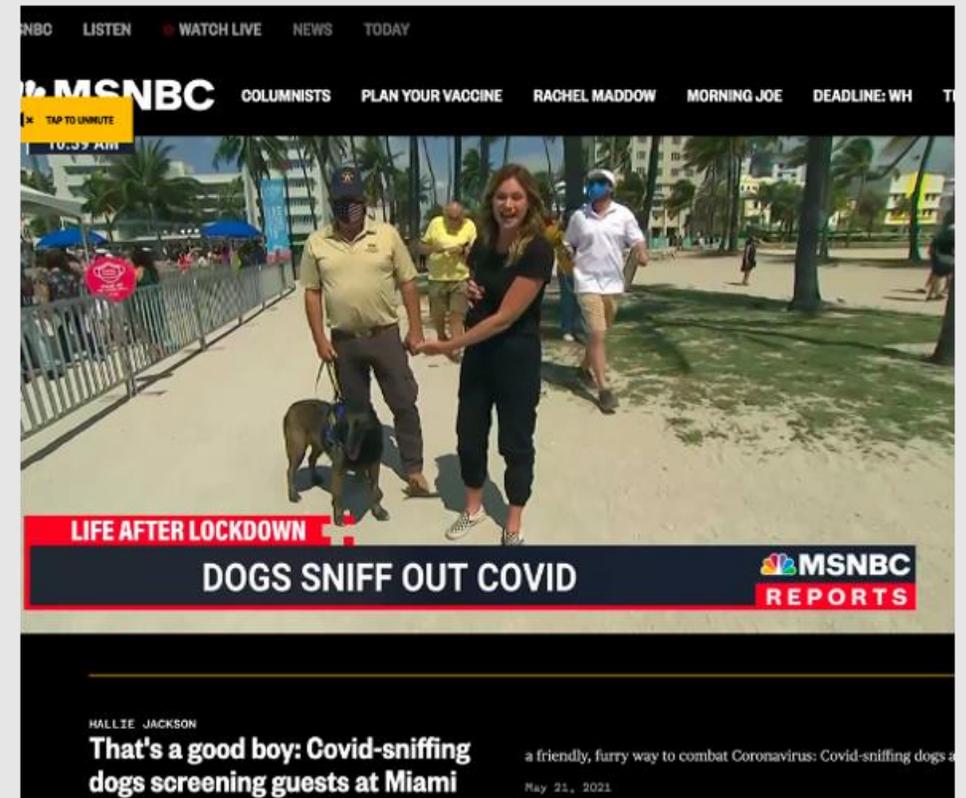
Figure 4: PLS-DA showing class separation of HS-SPME-GCMS VOCs from COVID-19 positive PPE (masks) vs COVID-19 negative PPE (masks).

Deployments

- Florida State Emergency Operations Center (SEOC)
- South Beach Wine and Food Festival (SOBEWFF)
- Miami International Airport
- BARK Box
- South Motors Jazz Series

Pending

- Port of Miami
- Steven P. Clark Government Center



Thank you

Redland Ahead

- John Mills
- Kelley Hall
- Denise Webb

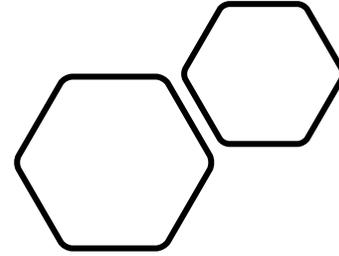
Baptist Hospital West Kendall

Global Forensic and Justice Center

- Kenneth G. Furton
- DeEtta Mills
- Kevin Lothridge
- Howard Holness
- Kelvin Frank



Supply Chain Challenges and Solutions



G. Sossaman, M.D.

E. Occhipinti, M.D.

Department of Pathology and
Laboratory Medicine

Ochsner Health System

Worldwide
disruption
with no end
in sight...

January 19, 2022 Update: The FDA expanded the [medical device shortage list](#) to include all blood specimen collection tubes. For details, see the [Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel](#).

HEALTH | News

'This will have a massive impact': Blood tube shortage could limit non-essential tests



CAP Publishes Strategies to Mitigate National Shortage of 'Blue Top' Test Tubes

NHS blood test tube shortage:
Doctors 'facing difficult choices'

Laboratory Supply Shortages

Turning Crisis to Opportunity

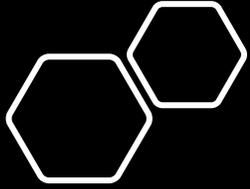
Lee H. Hilborne, MD, MPH, FASCP, DLM(ASCP)^{CM, 1, 6}

Greg Sossaman, MD, MACSP,²

Barbara Caldwell, MS, MASCP, MLS (ASCP)^{CM}, SH^{CM, 3}

and Steven Kroft, MD, MASCP⁴

From the ¹Department of Pathology and Laboratory Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA, and Medical Affairs, Quest Diagnostics, Secaucus, NJ, USA; ²Department of Pathology and Laboratory Medicine, Ochsner Health, New Orleans, LA; ³Consultant, Mount Airy, MD, USA; and ⁴Department of Pathology, Medical College of Wisconsin, Milwaukee, WI, USA.



ASCP survey 2022

- Survey of Choosing Wisely Advisory board and ASCP members
- Survey conducted twice- 12/21 and 1/22
- Focus topics:
 - How supply chain issues impacted the laboratory
 - What initiatives were undertaken in response to supply chain issues
 - Suggestions to reduce unnecessary supply consumption

Survey Results- Impact of Supply Chain Issues

Themes	Count	Percent
Laboratory supply shortage	88	63.8%
Taking away critical time from diagnosing cases	53	38.4%
Utilize alternative methods, vendors or supplies	36	26.1%
Outsourcing	18	13.0%
Stress and burnout	12	8.7%
Total number of comments:	138	100.0%

Initiatives to Address Supply Chain

Themes	Count	Percent
Using alternative test supplies/vendors/labs	73	55.3%
Testing conservation strategies	47	35.6%
Ordering additional supplies	21	15.9%
Continuing communication with vendor	10	7.6%
Educate providers	10	7.6%
Monitor inventory	9	6.8%
Not in charge	5	3.8%
Communication with hospital administration	3	2.3%
Miscellaneous	14	10.6%
Total number of comments:	132	100.0%

Suggestions to Reduce Unnecessary Supply Consumption

Themes	Count	Percent
Develop test utilization strategies	49	39.5%
Education/Awareness	25	20.2%
Other	34	27.4%
Total number of comments:	124	100.0%

What levers to pull?

- **Increase Inventory**

- Local supply chain coordination
- Daily vendor meetings/escalations
- Validation of alternate tube types
- Explore alternate vendors

- **Decrease Utilization**

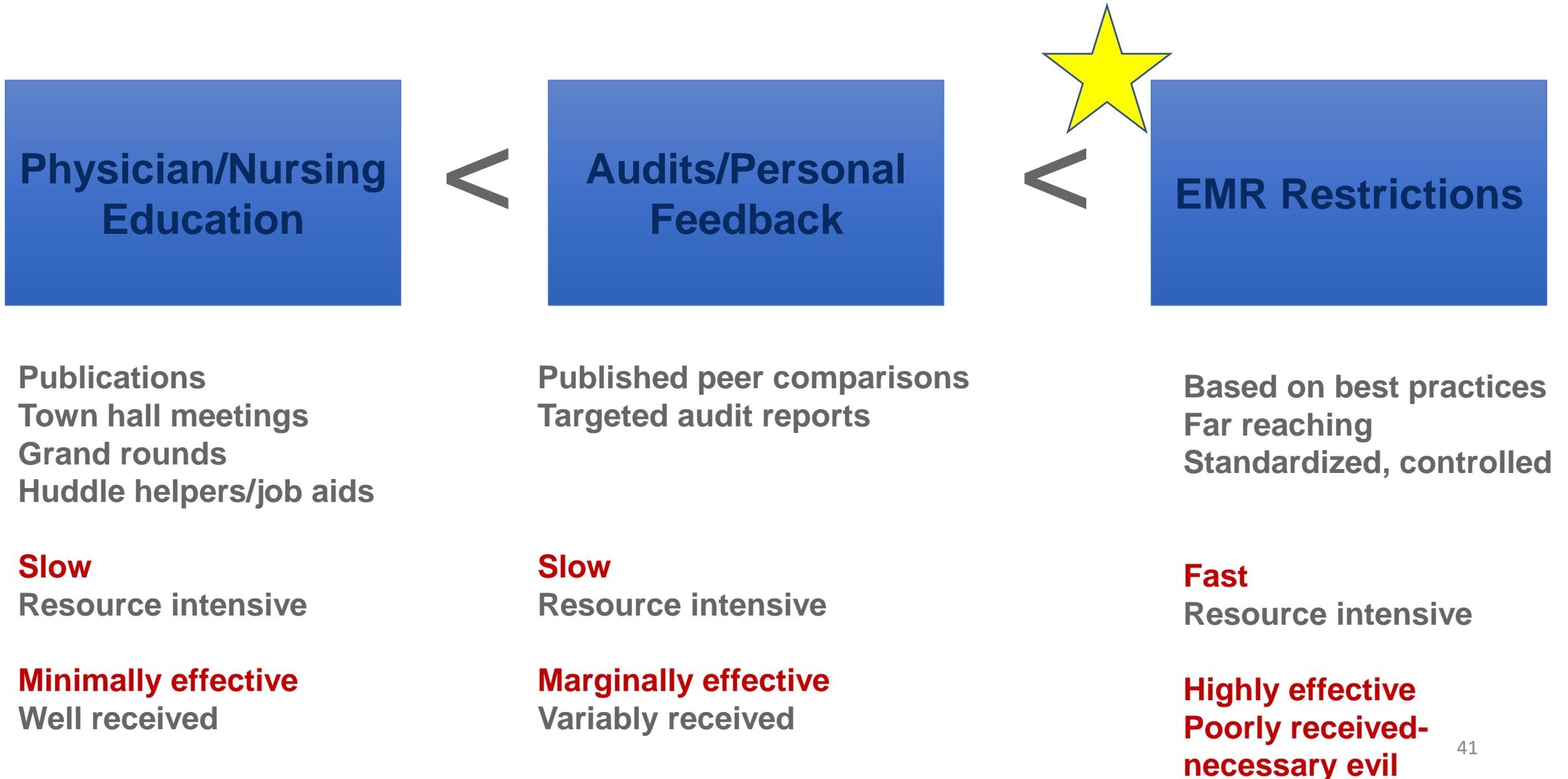
- Eliminate rainbow
- Eliminate extra tubes
- Decrease daily labs
- Decrease repeat orders
- Cease non essential orders (routine wellness, etc)



Stewardship Framework- Care Variation Committee

- **Multidisciplinary committee-** Over 25 members, all hospital locations
 - Strong IT/EMR representation
 - Finance/rev cycle
 - Population health
 - Primary care, ED and specialty involvement
 - C-Suite
 - Lab operations
- **Monthly meetings** since 2017
- Focus points
 - Reducing variation in laboratory testing
 - Appropriate utilization (over and under)
 - Vetting new test requests, vendors (formulary creation and cultivation)
 - Choosing wisely discussions, sharing best practices
 - EMR rules, modifications
- **Decisions are not made or owned solely by lab!**

Utilization Interventions- Combination Approach



Best Practices

1. Choosing Wisely
2. Society Guidelines
3. Expert Consensus
4. NHS retesting Interval Guidance

Data

1. Tubes used per day
2. Tube wastage per day (extra, rainbow, rejected)
3. Daily orders by hospitalist- weekly report
4. Outpatient test volume
5. Repeat orders

Communication and Education

1. Governance/Infrastructure
2. Transparency
3. Frequency
4. Visibility
5. Diversity (c- suite, nursing, providers, laboratory team)

EMR

1. Hard stops
2. Order set review and curation
3. Specialty Restrictions

First Step- Data Collection

- **Total tubes (avg 50,000 per day) – daily report**
 - Top 3 utilizers: ED, internal med, family med
 - Analysis of site, physician and identifier of outliers
- **Extra tubes, rejected tubes, and rainbow draws- daily report**
 - 1-2% of tube usage but approaching 20,000 per month- pure waste
 - Analysis of site and nurse/phlebotomist
 - Easiest intervention point because it was predominantly under lab control
- **Daily lab orders per hospitalist- weekly report**
 - Challenge- unable to calibrate for patient volume and complexity
 - Most difficult intervention- no organizational consensus
- **In patient order set monitoring- one time report**
 - Most frequently used order sets in institution- can any be altered for removal of daily labs?

Reduction of daily orders

Society of Hospital Medicine – Adult Hospital Medicine

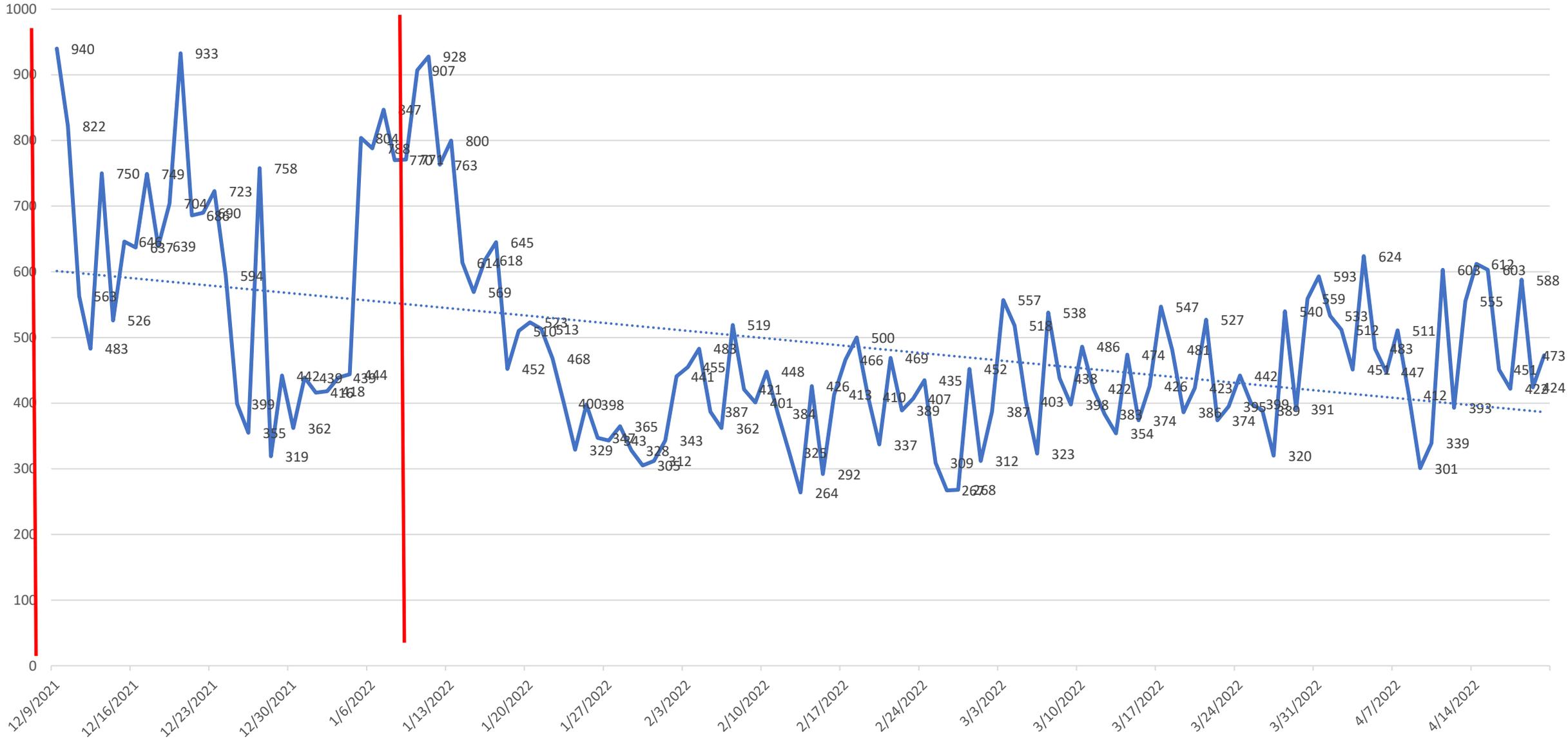
[View all recommendations from this society](#)

Released February 21, 2013

Don't perform repetitive CBC and chemistry testing in the face of clinical and lab stability.

Hospitalized patients frequently have considerable volumes of blood drawn (phlebotomy) for diagnostic testing during short periods of time. Phlebotomy is highly associated with changes in hemoglobin and hematocrit levels for patients and can contribute to anemia. This anemia, in turn, may have significant consequences, especially for patients with cardiorespiratory diseases. Additionally, reducing the frequency of daily unnecessary phlebotomy can result in significant cost savings for hospitals.

OMC Total Morning Draws Hospital Medicine



Huddle Helper

Blood Collection Guidelines to prevent Recollection/Wasted tubes

Your help is needed to conserve blood collection tubes during this national shortage. To avoid recollections and tube wastage, read below to guide your blood collection technique.

Top Reasons for Rejected Specimens

Venipuncture Technique (Preventable Errors)

- Hemolysis
- Clotting
- Contamination
- Quantity Not Sufficient (QNS): not enough sample to process the test

Causes of Hemolysis

- Prolonged tourniquet time
- Cleansing with alcohol/CHG and not allowing to dry
- Probing and/or traumatic venipuncture
- Drawing through IV catheter or small needle
- Excessive force on syringe plunger
- Forcing blood from syringe to evacuated tube
- Vigorous mixing or shaking

Causes of Clotted Specimens

- Leaving blood in syringe too long before putting in tube
- Slow draw using a syringe
- Improper mixing of anti-coagulated tubes

Causes of Contaminated Specimens

Presence of IV Fluids

- Venipuncture directly above the site of infusion
- Drawing from an existing IV line or existing EMS line
- Inappropriate discard volume from central line or midline

Additives from blood tubes

- Incorrect order of draw
- Did not use waste tube
- Transfer syringe makes contact with anticoagulant

Date of Distribution: 12/28/21
 Intended Audience: Nursing and Phlebotomists
 Direct Questions to: Local Laboratory



Huddle Helper

Blood Collection Guidelines to prevent Recollection/Wasted tubes

Improving Venipuncture Technique

Correct Order of Draw can prevent: *hemolysis, clotting and contamination*

One Inversion = top, bottom, top →

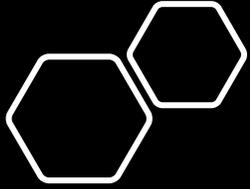


- Draw a 5 mL waste tube if using a butterfly set-up for venipuncture, and no blood culture is drawn + 1st tube is a blue top (*air in butterfly tubing prevents blue top from filling completely and can result in a QNS specimen*)
- Follow **your facility's labeling requirements** for all Blood Bank specimens
- Fill blue top tube completely to **minimum "fill line"**
- Remove **tourniquet** before drawing Lactic Acids
- Transport to lab in sealed biohazard bag (*place requisition in outer pocket during downtime / from non-LSID unit*)

Phlebotomists: Please refer to MediaLab for a more extensive Order of Draw job aid.
 Nursing: Order of Draw for Adults (left) ↓ and Neonatal-Pediatrics (right) below ↓

ORDER OF DRAW BADGE BUDDY			
Lab Label Tube Code	Tube Color	Tube Contents/ Tube Type	Inversions
MICBLCLT		Blood Cultures	8-10 Times
RYLBLUE RYLBETA		Metal Free No Additive Tube	8-10 Times
BLUE		Citrate Tube	3-4 Times
GOLD		Gel Separator Tube	5 Times
RED		Clot Activator Serum Tube	5 Times
DKGNLITH DKGNNA		Heparin No Gel Tube	8-10 Times
GREEN		Heparin With Gel	8-10 Times
LAVENDER LAVCHEM PINK		EDTA Tube	8-10 Times
GRAY		Fluoride (Glucose) Tube	8-10 Times
ACD		ACD Tube	8-10 Times

BD Microtainer™ Tubes with Microgard™ Closure Tube Guide and Order of Draw			
Catalog #/ Closure Color	Additive	Mix by Inverting	Laboratory Use
Lavender	K ₂ EDTA	10x	For whole blood hematology determinations. Tube inversions prevent clotting.
Green	Lithium Heparin	10x	For plasma determinations in chemistry. Tube inversions prevent clotting.
Mint Green Gel	Lithium Heparin and Gel for plasma separation	10x	For plasma determinations in chemistry. Tube inversions prevent clotting.
Grey	Gel NaF/Na ₂ EDTA	10x	For glucose determinations. Tube inversions ensure proper mixing of additive and blood.
Gold Gel	Gel Clot Activator and Gel for serum separation	5x	For serum determinations in chemistry.
Red	No additive	0x	For serum determinations in chemistry, serology and blood banking.
	= 1 inversion		BD Microtainer™ Tube Extender BD Microtainer™ with 46 Extender



Summary

- Managing supply chain disruption requires decisive **process change** and strong **infrastructure** that fosters:
 - Data collection
 - Standardization of processes and interventions
 - Communication/transparency/flexibility
 - Interdepartmental collaboration- guidance is not solely lab driven
- Education alone is insufficient
- Change is ongoing

CDC Social Media

<https://www.facebook.com/CDC>



<https://twitter.com/cdcgov>

<https://www.instagram.com/cdcgov>



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

Thank You For Your Time!

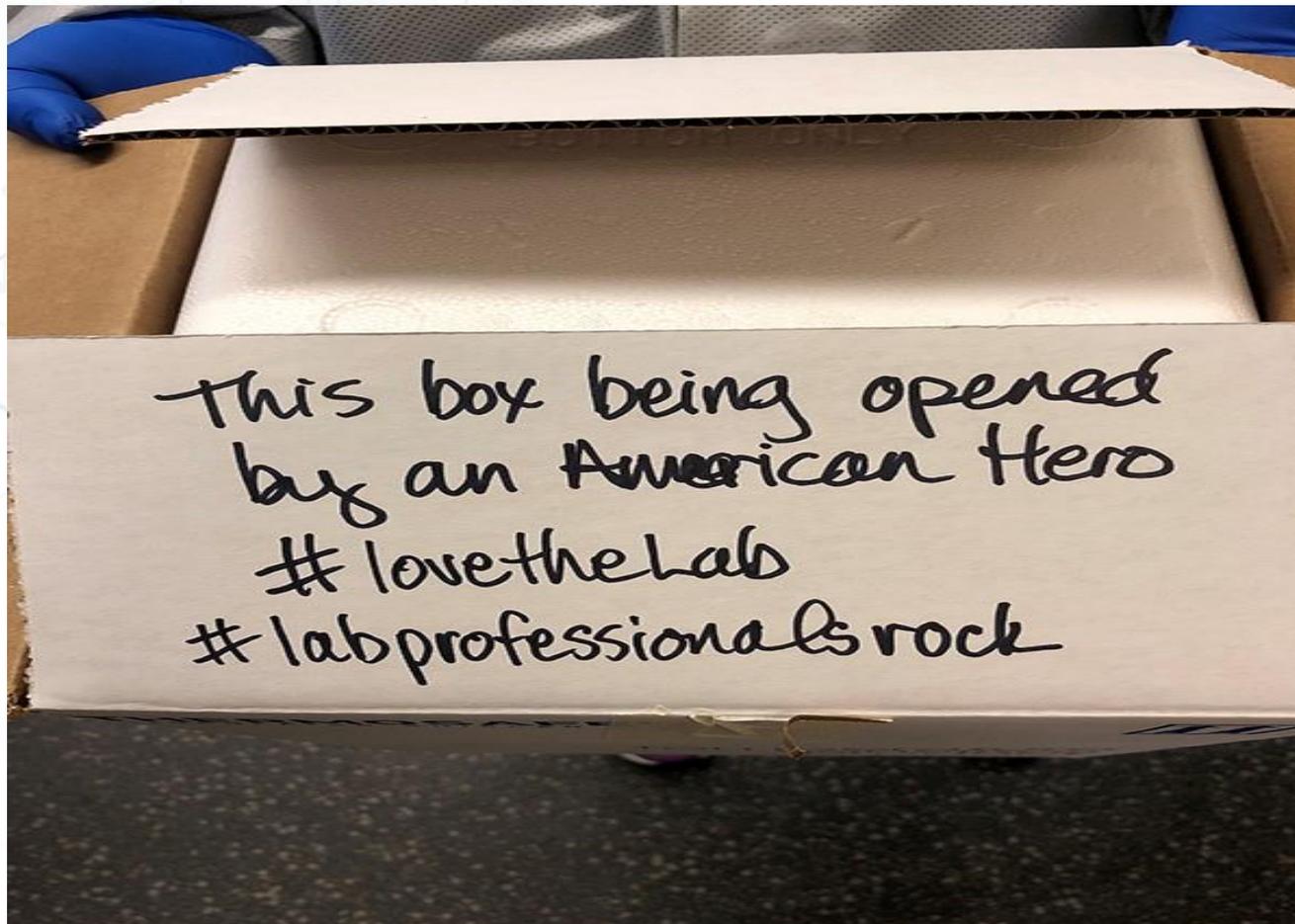
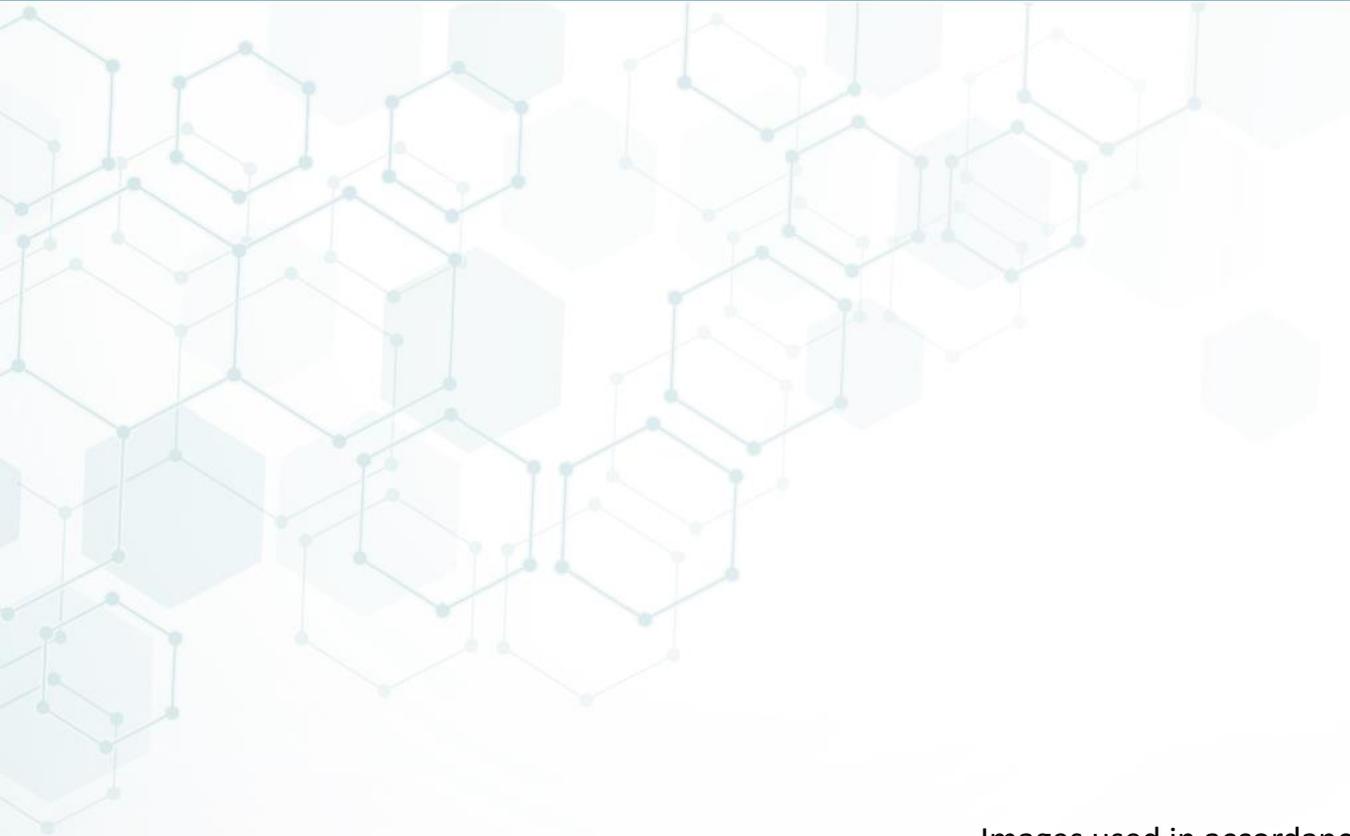


Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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