

# **NEWSLINKS**

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AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE - MICHIGAN

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# President's Message Meighan Sharp



### **Happy New Year Everyone!**

As I look back at 2022, I think of all that we have achieved as a Constituent Society in the past year. For the first time in two years, ASCLS-Michigan held an Annual Spring Meeting with attendees meeting in person. For the first time in decades, an ASCLS Annual Meeting (JAM) was held in Michigan at the Amway Grand in Grand Rapids with record attendance. As I walked the hallways of the Amway Grand, I heard nothing but praise for Michigan's June weather and warm hospitality.

With all that happened in 2022, the sky's the limit for ASCLS-Michigan in 2023! I am looking forward to our Annual Spring Meeting in Southfield April 2<sup>nd</sup>-4<sup>th</sup>. I expect Michigan to again, have strong attendance at CLEC in New Orleans in March, the Legislative Symposium in Alexandria in the fall, and a strong delegation to the Joint Annual Meeting in Providence, Rhode Island at the end of June.

Let us continue to make great strides advocating and promoting the profession in 2023. I look forward working with all members to accomplish our goals in the new year.

Dates to keep in mind (and add to your calendar) as we manage these changes and transition together during this 2022-2023 term:

- January 20-21, 2023: Emerging Laboratory Managers Collaborative Conference (ELMC<sup>2</sup>), Virtual
- March 2-4, 2023: Clinical Laboratory Educators Conference (CLEC), New Orleans, LA
- April 2-4, 2023: ASCLS-Michigan Annual Spring Conference, Westin Southfield Detroit, MI
- June 26-30, 2023: Joint Annual Meeting, Providence, RI

Inside This Edition:		President's Messsage	Pages 1
Member News - Birth Announcement	Page 2	Pandemic Supply Chain Story	Pages 3-9
Annual Meeting Save The Date	Page 10		

#### Member News - Birth Announcement!

Meighan Sharp

Kyle (our President-Elect) and his wife Taylir gave me the go ahead to announce the birth of their baby boy!

Dashiell Scott McCafferty was born at 6:16am on Saturday 1/7/23 at 8 lbs, 1 oz. and 20.5 inches long.

Everyone is doing great and settling in at home now as a family of 3! Kyle and Taylir are excited to introduce Dash to his fur brother, Bernie.

Congratulations to the McCafferty's!





Michigan

#### **ASCLS-Michigan Newslinks**

A bi-monthly publication of the American Society for Clinical Laboratory Science - Michigan. Deadlines for articles are the 20th of Feb, Apr, Jun, Aug, Oct, & Dec. Articles must have name of author. Anonymous letters will not be published. The editor reserves the right to edit all materials submitted for publication. Articles appearing in *Newslinks* represent the opinion of the author and may not represent the opinion of the society.

**Membership**: Join ASCLS-Michigan by visiting the ASCLS web site:

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# **ASCLS-MI Leadership:** Visit our web site at <a href="https://www.ascls-michigan.org">www.ascls-michigan.org</a>

for a complete listing and contact information for all ASCLS-MI board members and a wealth of other information on the Society.

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# Clinical Laboratory Science

A focus on what is happening in our profession

Featuring articles from Scientific Assembly Chairs or Board Members.

Materials from all members are also welcomed. Submit to editor. See page 2 for details



# Author in 1963 on a bike of course!

# Pandemic Supply Chain Challenge: Blood Collection Tube Shortages

Paul F Guthrie, Publications Chair

The Covid-19 pandemic has had a massive impact on many aspects of our personal and professional lives. It is likely every clinical laboratory dealt with the highly publicized shortages that were so very acute early on. At times, items like Covid-19 PCR tests, masks and other PPE were simply not available. One critical shortage that mostly flew under the public radar in this country was that of blood collection tubes. This article is a brief review of some of the guidance, both at home and abroad to manage the shortage.

In late 2021, the tube supply disruption became more acute for the laboratory system I work at. Earlier there had been sporadic but manageable issues with blue top-citrate tubes. Then suddenly the "mint" top Plasma Separator Tubes (PST®) were on a strict delivery allocation from our supplier. The PST® is a key component for meeting our STAT/ER turn around time goals. Samples drawn in those tubes don't have to wait to clot, and at our main laboratory, these gel separator tubes can be directly loaded on to the pre-analytical automation line (Roche cobas 8100).

As one often does when questions arise, I performed a Google<sup>©</sup> search for information on the tube shortage. About the only data that came up was from the National Health Service (NHS) in the United Kingdom. It appears the shortage hit the British first, perhaps because most of the BD tubes are produced in the United States. Headlines on the British Broadcasting Service (BBC) <sup>1</sup> had entries like these below, with stories from some patients having their testing postponed.



### Doctors told to ration blood tests

25 August 2021



NHS blood test tube shortage set to worsen

26 August 2021



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

29 August 2021

On August 18<sup>th</sup>, 2021, the National Health Service (NHS) issued detailed and specific actions for the all laboratories and physicians to take. The excerpt below <sup>2</sup> offers many suggestions, some of which are efficient practices for laboratory utilization regardless of inventory supply levels.

#### Aims and objectives

In light of global shortages of blood tube products (not just those from BD), this guidance is intended to apply to every site regardless of system being used in order to balance demand. The recommendations below have been provided by clinical experts from pathology teams, primary care and acute care, including input from Royal College of Pathologists (RCPath), Institute of Biomedical Science (IBMS), the Association for Clinical Biochemistry and Laboratory Medicine (ACB), Genomics Implementation

Unit (NHSE) and the Academy of Medical Royal Colleges (AoMRC), as a guide to local optimization of resources during this time.

The following measures should be implemented now, to optimize the use of blood tubes and ensure that existing stocks are managed in a coordinated and equitable way. Each organization should have a pathology handbook which explains which tubes are used for which test. The measures set out in this guidance seek to ensure that there is no disruption to urgent care, and services for patients are able to continue as clinically appropriate. Separate actions are noted for pathology laboratories, supported by national and regional pathology teams, and medical and nursing directors.

This guidance is subject to review and may be updated.

#### Scope

The following measures should be implemented urgently by all medical directors, nursing directors, GPs, and Pathology laboratories and clinical pathology providers, working with primary care, community and acute care providers, including NHS and Public Health England.

#### **Overview and recommendations**

Senior clinical oversight is needed around the ordering of tests with a view to reducing the use of the products impacted by the supply disruption.

#### Actions for pathology laboratories, with support from national and regional pathology teams

#### Stock check, ordering and double tube practices

- Current store room and circulating levels of blood tubes in all areas to be reviewed, to assess capacity.
- Order levels should be maintained at normal levels. No stockpiling should happen.
- Stock to be ordered from NHS Supply Chain to allow UK-wide management of supplies.
- Rotation of stock to ensure optimal usage of tubes to avoid out-of-date wastage.
- Training which involves the use of these tubes should be delayed. Student training in the use of these
  tubes may be delayed until a resolution to the supply disruption has been put into place and catch up
  training will be needed.
- Double tube practices to be halted (with the exception of blood transfusion): Where possible the use of EDTA, SST and citrate tubes to be urgently reviewed to stop any 'double tube' practices, eg HbA1C and full blood count. This may entail moving tubes between laboratory areas. Staff should check if there is a historical sample/group and screen (G&S) result before automatically taking a second G & S sample.

#### Encouraging add-on testing to reduce the need for blood tube usage

- Review sample storage and stability protocols.
- Work with service users to encourage add-on testing.
- A dedicated phone service/IT solution for add-on test sent to requestors.

#### Point of care hemoglobin devices to be used where possible

• Use point of care devices that have been appropriately quality assured for hemoglobin measurement, eg in critical care and theatres, instead of using EDTA tubes.

#### Actions for medical directors, nursing directors and GPs

• Clinical leaders should ensure all staff ordering or taking bloods are informed of the following recommendations, and that these are actioned urgently to protect existing supply levels.

#### Minimum retest intervals

• All organizations should follow the <u>guidelines related to RCPath minimum retest intervals</u> to avoid overtesting for items such as B12 and thyroid disease.

#### Encouraging add-on testing to reduce the need for blood tube usage

- Encourage add-on testing by clinicians ordering tests.
- Work with pathology laboratories to communicate changes in systems, eg a dedicated phone service/IT solution for add-on test sent to requestors.

#### Optimizing inpatient and assessment unit sampling

- Only test for a clinical indication in patients and increase the testing interval
- for monitoring where it is clinically safe to do so.
- Keep testing levels under active review.
- Avoid routine group and screen testing unless patient likely to require transfusion, in line with <u>Choosing Wisely</u> guidance.

#### **Genomics testing**

• Genomics is a high priority in the testing of unwell neonates, prenatal screening and cancer diagnosis. Stock should be used for these tests and should be prioritized accordingly to allow these tests to continue uninterrupted.

#### Reducing non-essential (non-clinically urgent) testing

- Only test for a clinical indication in patients and increase the testing interval for monitoring where it is clinically safe to do so.
- Review testing levels to ensure a reduction in non-clinically urgent testing.
- Ensure clinical staff are aware of which tests may be impacted by the supply disruption. Each organization should have a pathology handbook which explains which tubes are used for which test.
- Liaise with staff to agree essential testing priorities, examples of such areas are given below:

#### Vitamin D testing

• It is recommended that Vitamin D testing (except in very exceptional circumstances set out in NICE guidance) is stopped.

#### Routine wellness screening

- Routine wellness screening is not a priority.
- In the acute setting routine wellness screening is not a priority, for example screening for pre-diabetes, dyslipidemia, and so forth, especially if patients are in the acute phase of illness. However, certain acute tests should be assessed as appropriate. Patients should be assessed appropriately when recovered.

#### Allergy testing

Allergy testing is not a priority at this time unless there are overriding clinical indications.

#### Routine infertility testing

• Routine infertility testing should be deferred until a resolution to the supply disruption is in place, with the exception of patients over 35 years of age in consultation with the individual patient.

Through the NHS documents, I also found recommendations from the main supplier of tubes, Becton, Dickinson and Company (BD).<sup>3</sup>





We take our responsibility to be ready to support health care providers with patient care very seriously. Since the onset of COVID, the healthcare industry has been facing multiple challenges. Currently, BD's specimen management business is confronted with a surge in demand for blood collection tubes, urine products and wingsets, challenging our ability to supply our customers and obtain required raw materials for our plants.

We recommend you consider the following options for continuity of care, in consultation with your clinical staff and according to your institution's policies and procedures:

- 1. Evaluate potentially unnecessary collection of tubes, such as "rainbow" tube arrays of extra tubes and standing orders for tests.
- 2. Review test request patterns within your institution to help identify potential opportunities to reduce testing frequency and avoid duplicate test orders.
- 3. Avoid the use of additive tubes as discard tubes.
- 4. Review testing volume requirements and consider potential consolidation of testing with one tube (e.g., one chemistry tube instead of two), where testing needs may be addressed using aliquots or add-on testing.
- 5. Consider the use of point of care devices that allow use of blood specimens not collected in evacuated blood collection tubes (e.g., collection via syringe or capillary blood collection).
- 6. Consider the use of capillary blood specimens instead of venous blood.
- 7. Consider the use of alternate products with the same intended use based on product availability (e.g., use of serum tube without separator vs. serum separator tube).
- 8. Consider evaluating sample stability to extend allowed timeframes for add-on testing.

And in the United States, the FDA issued a letter on June  $10^{th}$ , 2021 concerning citrate-blue top tubes, that was later expanded to all tubes in January of 2022.4



- Hunte / Medical Devices / Medical Device Safety / Letters to Health Care Provides / WESATE Blood Sommer Collection Tube Commendion Strategies: Letter to Health Care and Laborators Personnel

UPDATE: Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel The U.S. Food and Drug Administration (FDA) is aware the United States is experiencing significant interruptions in the supply of several blood specimen collection (blood draw) tubes because of an increase in demand during the COVID-19 public health emergency and recent vendor supply challenges. The FDA is expanding the <u>medical device shortage list</u> to include **all** blood specimen collection tubes. The FDA previously issued a letter to health care and laboratory personnel on June 10, about a shortage of sodium citrate blood specimen collection (light blue top) tubes.

#### Recommendations

The FDA recommends health care providers, laboratory directors, phlebotomists, and other personnel consider the following conservation strategies to minimize blood collection tube use and maintain quality and safety of patient care:

- Only perform blood draws considered medically necessary.
- Remove duplicate test orders to avoid unnecessary blood draws.
- Avoid testing too frequently or extend time intervals between tests whenever possible.
- Reduce tests at routine wellness visits and allergy testing only to those that target specific disease states or where it will change patient treatment.
- Consider add-on testing or sharing samples between laboratory departments if previously collected specimens are available.
- If you need a discard tube, use a tube type that has a greater quantity available at your facility.
- Consider point of care testing that does not require using blood specimen collection tubes (lateral flow tests).

In November of 2021, we had to take prompt action to deal with the dwindling supply of PST<sup>©</sup>. Our first activity was to find a way to assess how many we were using and where they were being used. We also wanted to find the number of "extra" tubes being drawn. We have discouraged drawing a "rainbow" of extra tubes for many years. However, this seems to be a practice that tends to creeps back into practice if attention does not remain focused on it. We found a way to develop a daily report from our LIS that gave the volumes of each tube type used per laboratory. Knowing we had a good supply of "plain" (non gel) green top tubes, we decided to divert all of our PST<sup>©</sup> tubes to the main lab. The reason being we could not use the non-gel green top tubes on the automation line.

We also sent out communications those who were collecting "extra" tubes to request they cease that activity. In addition physicians were requested to reduce routine orders as well as frequency of repeat testing. Below, you can see a comparison between the data from a report early in this process to one at a later date.

Sunquest Tube Typ	oes Routed							
Lab - Date	XTRA	Lav	Blue	Green	PST	Red	SST	Lab Total
Mon 11/22/21								
ввс	12	249	38	5	240	0	90	634
BLH	9	148	13	6	40	0	124	340
вмн	77	1,197	163	51	408	7	1,346	3,249
BSH	3	67	12	0	3	0	42	127
Day Total	101	1,661	226	62	691	7	1,602	4,350

Sunquest Tube Typ	pes Routed	i						
Lab - Date	XTRA	Lav	Blue	Green	PST	Red	SST	Lab Total
Mon 2/14/22								
ввс	4	264	33	240	6	3	126	672
BLH		150	7	50	2	2	133	344
вмн	24	1,144	135	85	503	23	1,065	2,955
BSH		81	9	22	9		50	171
Day Total	28	1,639	184	397	520	28	1,374	4,142

- The volume and distribution of PST<sup>©</sup> and green tops changed. We used more green tops overall, and almost all PST<sup>©</sup> were in use at the main lab (BMH)
- The number of extra tubes was reduced.
- Lavender tops were not as affected by the supply disruption. The only change was to run Hgb A1c and CBC on the same tube.
- The SST® tube is the primary sample for routine chemistry testing. The reduction seen here likely represents reduction in routine orders and test frequency.

Several other changes and interventions had to be taken as the months went by to avoid service disruptions. For Serum Separator Tubes (SST®) a variety of tube and draw sizes were utilized. Those sizes that did not work well on our automation line were sent to satellite labs that did not have automation lines, and the "regular" SST® tubes were sent to the main lab.

A few months after the topic was raised overseas, suggestions for how to address the blood collection tube issue in the United States began to appear. In addition to the FDA letter in June of 2021 (updated in January 2022), laboratory organizations like the AACC began to offer webinars like those listed below.

AACC.org // Clinical Laboratory News // All Articles // Supply Chain Meltdown? Laboratory Stewardship to the Rescur

## Supply Chain Meltdown? Laboratory Stewardship to the Rescue

Special Section: April 2022

Author: Elise Occhipinti, MD // Date: APR.1.2022 // Source: Clinical Laboratory News

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AACC.org // Clinical Laboratory News // All Articles // Blood, Sweat, and Tubes

# Blood, Sweat, and Tubes

Hospitals went from struggling with testing supply shortages to running out of blood itself Unrelenting shortages are forcing laboratories to rethink protocols and processes.

Author: Karen Blum // Date: MAY.1.2022 // Source: Clinical Laboratory News

AACC org // Education // Watch a Webinar // Best Practices for Optimizing Laboratory Resource

### Best Practices for Optimizing Laboratory Resources and Utilization During a Global Supply Shortage

 Credit:
 1.0 ACCENT

 Duration:
 1 hour

 Date:
 MAY.17.2022 11:30 a.m. - 12:30 p.m.

 Level:
 Basic

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At present, three years into the pandemic, the supply shortages are lessened but not entirely gone. Some lessons learned include a reconsidering of "just in time" (low onsite inventory) practices as well as an appreciation for the ongoing value for efficient laboratory utilization practices. These practices include many of the suggestions listed by NHS, BD and FDA as well as recommendations from the <a href="Choosing Wisely">Choosing Wisely</a> campaign which ASCLS is a part of. Unnecessary testing wastes more than collection tubes.



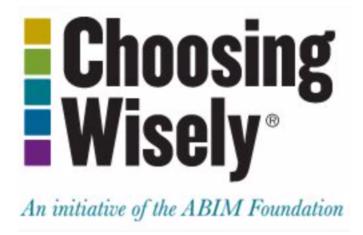
MEMBERSHIP

EDUCATION

COMMUNICATION

PARTICIPATE

ASCLS Publishes Second Set of Choosing Wisely Recommendations



#### References

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- 3. BD web site <a href="https://go.bd.com/vacutainer-supply-update.html">https://go.bd.com/vacutainer-supply-update.html</a> accessed 1/12/23
- 4. FDA web site <u>UPDATE</u>: <u>Blood Specimen Collection Tube Conservation Strategies Letter to Health Care and Laboratory Personnel | FDA accessed 1/12/23</u>





## SAVE THE DATE!

ASCLS-Michigan 2023 Annual Conference

April 2-4, 2023 The Westin Southfield Detroit Southfield, MI

www.asclsmi-conference.org

American Society for Clinical Laboratory Science



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