

SPECIMEN SUBMISSION & OUTREACH PROJECTS

ALABAMA DEPARTMENT
OF PUBLIC HEALTH

BUREAU OF CLINICAL LABORATORIES

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August 31, 2023 (updated September 29, 2023)

BCL=Bureau of Clinical Laboratories

CHD=County Health Department

CLIA=Clinical Laboratory Improvement Amendments

CMS=Centers for Medicare and Medicaid Services

DOT=Department of Transportation

FDA=U.S. Food and Drug Administration

IATA=International Air Transport Association

QM=Quality Management

SOP=Standard Operating Procedure

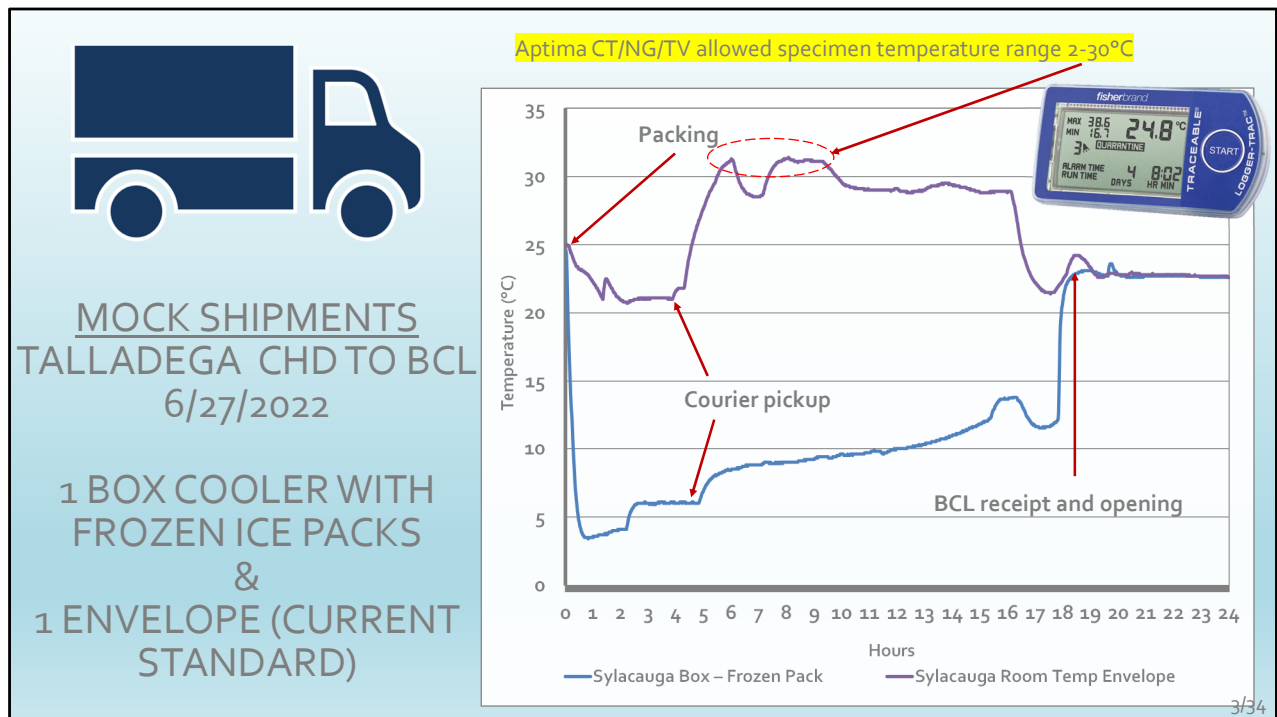
TC=Technical Consultant

RESULTS FROM THE BCL'S JULY 2021 CMS AUDIT 	▪ CMS advocated for improvement in preanalytical processes to include: ➤ Laboratory Testing Requisitions ➤ Sample Collection ➤ Processing of Samples ➤ Packaging and Shipping of Samples ➤ Receipt of Specimens by the Laboratory ▪ Laboratories across the southeast, and nation, were cited for failure to meet these improvements. ➤ Alabama was not cited but given strong recommendations as some preanalytical processes were in place, but not ideal
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Why did you choose these projects? What problem were you trying to solve?
INTRODUCTION

Ashley: In July of 2021 the BCL had its typical biannual CMS audit. During the exit interview the surveyor recommended either checking the temperature at arrival of every specimen with a specified temperature range or conduct a limited study and record the temperature of every specimen received for a designated amount of time to prove the specimens are arriving within the allowed ranges for the analytes requested.

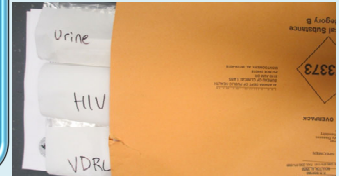


Ashley: Then, in January 2022, the BCL conducted a limited study of COVID specimen temperatures upon arrival which found that most specimens arrived too warm for testing. In the summer of 2022, Quality Management at the BCL started a study that monitored the temperature of many other specimen types during transit. This study helped us see that our recommended shipping procedures were not sufficient.

Through the “grapevine” aka APHL listserv, we heard that this cycle of CMS audits was going to be highly directed on pre-analytical processes. That the auditors were specifically targeting specimen integrity upon receipt by the laboratory. Like our auditor alluded to at our last inspection. Many state laboratories that we stay in contact with were being cited for insufficient procedures related to specimen logistics, receipt, and processing. Which told us we needed to step on it and ensure we had everything in order by our next survey.

PROBLEMS TO SOLVE

1. Specimens are arriving in uninsulated packaging which can not keep the specimens at the correct temperatures.



2. Most blood specimens arriving at the lab are in vacutainer tubes and not centrifuged.



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Ashley: We determined the most crucial items to address were that 1. almost all plastic specimen tubes were sent to the lab in uninsulated envelopes which could not maintain any specific temperature range and 2. we did not require that serum and plasma be aliquoted to a transport tube before arrival at the lab. Once these items were identified, the Quality Management division researched and started rewriting SOPs and looking for alternate shipping containers.

APHL TO THE RESCUE!

August 2022

Quality Improvement Funding Opportunities from APHL

- \$10,000 Sample Submission grant to improve sample submission error rates
- \$10,000 Outreach grant to strengthen relationships with clinical laboratories



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What did you do for your projects? INTRODUCTION

Ashley: In September of 2022 our Laboratory Directors encouraged the Quality Management division to apply for these APHL grants. The timing of the funding opportunity was just perfect and really helped us get the ball rolling on some ideas we had brainstormed a few months earlier regarding those two crucial sample integrity issues we needed to address: 1. Maintaining specimen temperatures during transit and 2. getting blood products to the laboratory while protecting the analytes we would be testing for which meant the providers would have to centrifuge and aliquot their serum and plasma specimens.

ASHLEY & KELLEY



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Ashley: Ashley handled the grant that helped with centrifugation and aliquoting, and Kelley was the contact for the grant that helped with transit temperatures. We work very closely and very well with each other, so we really did everything together but for the purposes of this presentation, we will go over the grant that we were “officially” over.

Stanley gave us a free cooler to try out!

**Problem 1:
Improve
specimen
packaging**

Concern:

- A different packaging method could be costly for our CHDs
- Needs to be standardized because all CHDs are under one CLIA certificate

Plan:

- Alternative packaging & shipping methods would be implemented and the supplies for this would be provided to the CHDs

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What were your project's major outcomes/findings? COOLERS

Kelley: To maintain specimen temperatures during transit to the lab, we knew our providers we were going to have to ditch the paper envelopes, so we started researching coolers. We trialed several coolers of differing types and qualities by transporting mock specimens in the different coolers with temperature data loggers to see if they could hold temperature for 24 hours.

WHAT WILL WORK BEST IN AN ALABAMA 100+°F SUMMER?



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Kelley: In the end, we found that the Stanley Adventure cooler was going to be the most affordable cooler that had the features we needed to keep the specimens within their respective ranges.

SO MANY COOLERS!



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Kelley: We ended up providing around 370 Stanley coolers in two different sizes to 81 different county health department clinics in the great state of Alabama.

SO MANY TUBE RACKS!



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Kelley: Depending on their volume and location, each clinic was given 3 to 6 coolers that each contained a plastic tube rack, plastic bags, ice packs, a “bank bag” for the requisition papers, and, of course, instructions.

DETAILED INSTRUCTIONS



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Kelley: Specimens now arrive upright in a test tube rack that is sealed in a plastic bag. As long as the clinic staff follow the instructions we provided, the specimens that arrive in the Stanley coolers have consistently maintained the allowed temperature ranges. It has been a ridiculously hot summer and we have been very impressed with the performance of these coolers.

CHALLENGES

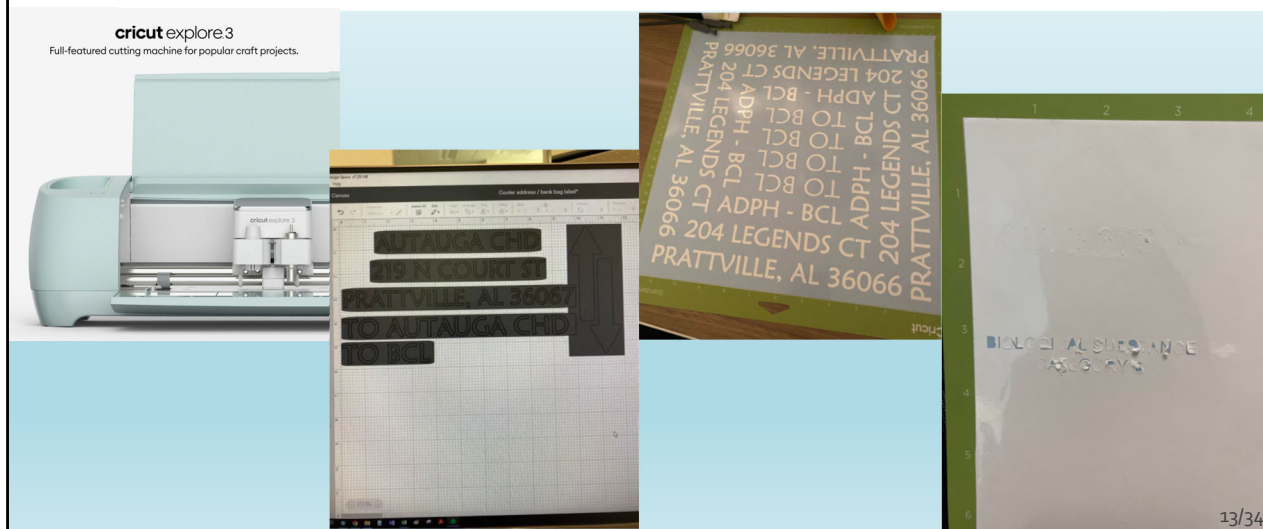


What were the challenges you encountered during your project and how did you address them? COOLERS

Kelley: Most of the issues that we encountered were centered around purchasing or logistics. I'm sure this is true of many states, but Alabama's purchasing rules are complex. As a vendor, it is complicated to sign up. As an employee, if there is not an existing contract with a vendor that sells the product you need, it's difficult and time consuming to get set up to purchase what you actually need. I know, I know the purpose of the rules is to be fair and minimize cost. But a lot of times, it ends up costing more in the long run when the rules keep you from being able to purchase the most functional product and you have to purchase an inferior product. Unfortunately, we did not have any existing contracts that allowed us to directly purchase the coolers and were required to put the coolers out for a bid request. To get the one we needed, we had to give very specific details which ended up being a locking lid, ability to maintain temperature for approximately 48 hours and a silicone seal.

Logistically, ordering such a large volume of coolers at one time meant they did not all come in at the same time. It took more than 2 months to receive all the coolers we initially ordered. Midway through our cooler project we realized that one county with multiple clinics vastly underestimated the number of coolers they needed, and we had to send out a second bid for a second order of coolers to have enough for all the clinics.

CHALLENGES CONTINUED

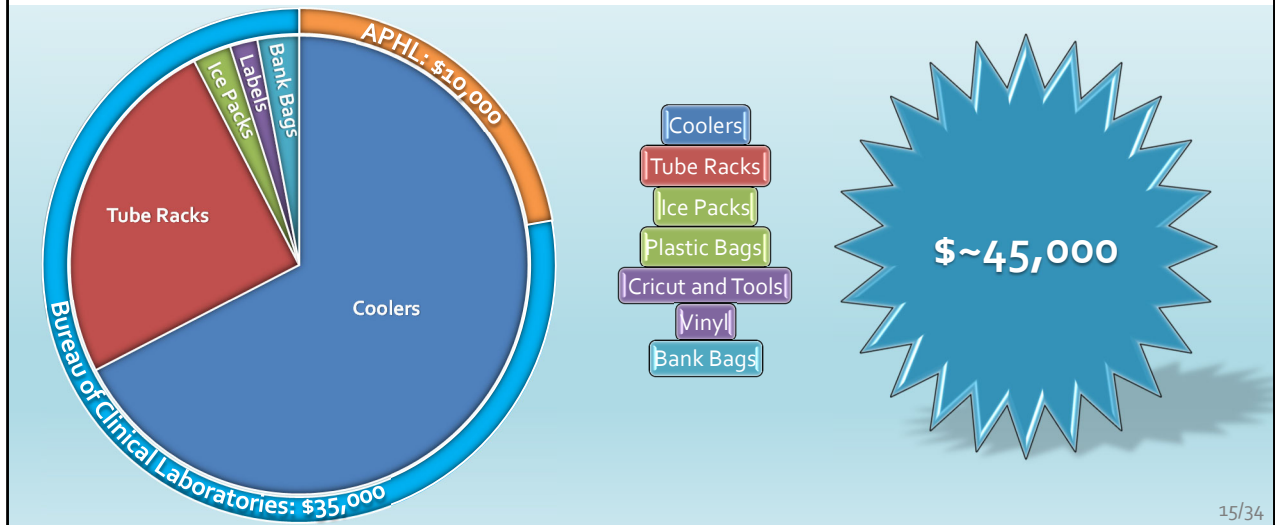


Kelley: Labeling the coolers was probably the biggest challenge and also the most time-consuming part. Because of DOT and IATA rules, shipping containers that contain Category B specimens must be specifically labeled. Since we were providing coolers to 81 different locations, each cooler would have to be labeled with different addresses. So, we purchased a Cricut machine which cuts vinyl sheets and researched vinyl types. We ended up ordering a marine grade vinyl that claims to last 10 years (this also had to go out on bid). Ashley created most of the address files in the Cricut software and the Cricut ran practically nonstop for about a month. It took a long time to cut the addresses, so our laboratory director, Dr. Massingale, bought a second Cricut with her own money that we also used to help speed up the project. Once the project was over, she took the Cricut she purchased home and has requested some lessons from Ashley on how to use it so she can make herself some awesome t-shirts. As we were cutting the vinyl, we solicited help from the whole lab. Anyone who had 10 minutes was asked to come to help weed vinyl, apply transfer tape, and/or put the labels on the coolers.



Kelley: At the end of the whole project, QM threw a big cookie party to thank everyone for their help.

TOTAL BILL – SAMPLE SUBMISSION PROJECT



Kelley: In total, we spent about \$45,000 on the cooler project which was significantly over budget if you take into consideration that APHL provided \$10,000.

LONG LONG AGO



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Why did you choose these projects? What problem were you trying to solve?
CENTRIFUGES

Ashley: Years ago, the CHDs in Alabama would centrifuge their Serum Separator Tubes (SST) before submitting the entire tube to the lab for testing. Over time, the CHD centrifuges started breaking down and the CHDs did not have the funds to replace them so SST started arriving at the lab not spun down. Eventually this became common practice and the lab compensated for it by having the Processing division centrifuge the tubes and aliquot the serum upon arrival at the lab with one exception: the Chemistry division has always required that plasma be centrifuged/aliquoted. But, without working centrifuges, the CHDs obviously couldn't centrifuge and volume of the tests that used plasma slowly reduced.

REMEMBER THIS?

The screenshot shows the FDA website with a blue header. The main title is 'UPDATE: Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel'. Below the title are social media sharing buttons for Facebook, Twitter, LinkedIn, Email, and Print. The date 'January 19, 2022' is displayed. The main text states that the FDA is aware of significant interruptions in the supply of blood specimen collection tubes due to increased demand during the COVID-19 emergency and recent vendor supply challenges. It mentions that the FDA is expanding the medical device shortage list to include all blood specimen collection tubes. A link is provided for a letter to health care and laboratory personnel dated June 10, 2021, regarding a shortage of sodium citrate blood specimen collection tubes. A 'Recommendations' section follows, advising health care providers, laboratory directors, phlebotomists, and other personnel to consider conservation strategies to minimize blood collection tube use and maintain quality and safety of patient care.

Ashley: At the end of 2021, there was a blood tube shortage. Kelley started looking for other tube manufacturers who had stock available that were FDA approved. In doing this she read package inserts to compare products.

 BD Vacutainer®
Evacuated Blood Collection System
 For In Vitro Diagnostic Use

PRECAUTIONS

1. Storage of glass tubes containing blood at or below 0°C may result in tube breakage.
2. Do not remove conventional rubber stoppers by rolling with thumb. Remove stoppers with a twist and pull motion.
3. Do not use tubes or needles if foreign matter is present.
4. The paper label covering the connection of the needle shields will tear when the needle is opened. Do not use needle if label has been torn before venipuncture.
5. CTAD tubes must be protected from artificial and natural light during storage. Accumulated light exposure in excess of 12 hours can cause additive inactivation.
6. Separation of serum or plasma from the cells should take place within 2 hours of collection to prevent erroneous test results unless conclusive evidence indicates that longer contact times do not contribute to result error.

LIMITATIONS OF SYSTEM

The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique. Tubes with draw volume smaller than the apparent dimensions indicated (partial draw tubes), may fill more slowly than tubes of the same size with greater draw volume.

For tubes subjected to centrifugation to generate plasma or serum for testing, standard processing conditions do not necessarily completely sediment all cells, whether or not barrier gel is present. Cell-based metabolism, as well as natural degradation *ex vivo*, can continue to affect serum/plasma analyte concentrations/activities after centrifugation. Separated plasma samples in particular, will have a gradient of cells and platelets present after centrifugation. The presence of cells and platelets in the plasma may lead to increased variability and/or instability of certain analytes that are involved in cell/platelet-mediated metabolic processes and/or are present in higher concentrations in cells or platelets. Analytes that may be affected include aspartate aminotransferase, glucose, inorganic phosphorus, lactate dehydrogenase and potassium. The magnitude of such effects may vary depending on several factors, including whether the plasma is aliquoted or remains in the primary tube, sample agitation, and time. Analyte stability should be evaluated for the storage containers and conditions of each laboratory.

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Ashley: In reading these inserts, Kelley found that they state that tubes must be spun down within 2 hours of collection which meant it would have to be done by the provider. She also found that Becton Dickinson (BD) had not validated transporting already centrifuged SST tubes. This left the onus of validation to the individual laboratories. We had not done this so, we informed our Laboratory Directors that when it came to blood tubes, we were not following manufacturer's recommendations.

**Problem 2:
Blood
products not
centrifuged**

Concern:

- Centrifuges at CHDs are old, work poorly, or have been discarded
- Costly to replace
- Needs to be standardized because all CHDs are under one CLIA certificate
- Staff turnover – new staff may not have experience with centrifuges
- Stress on CHD staff

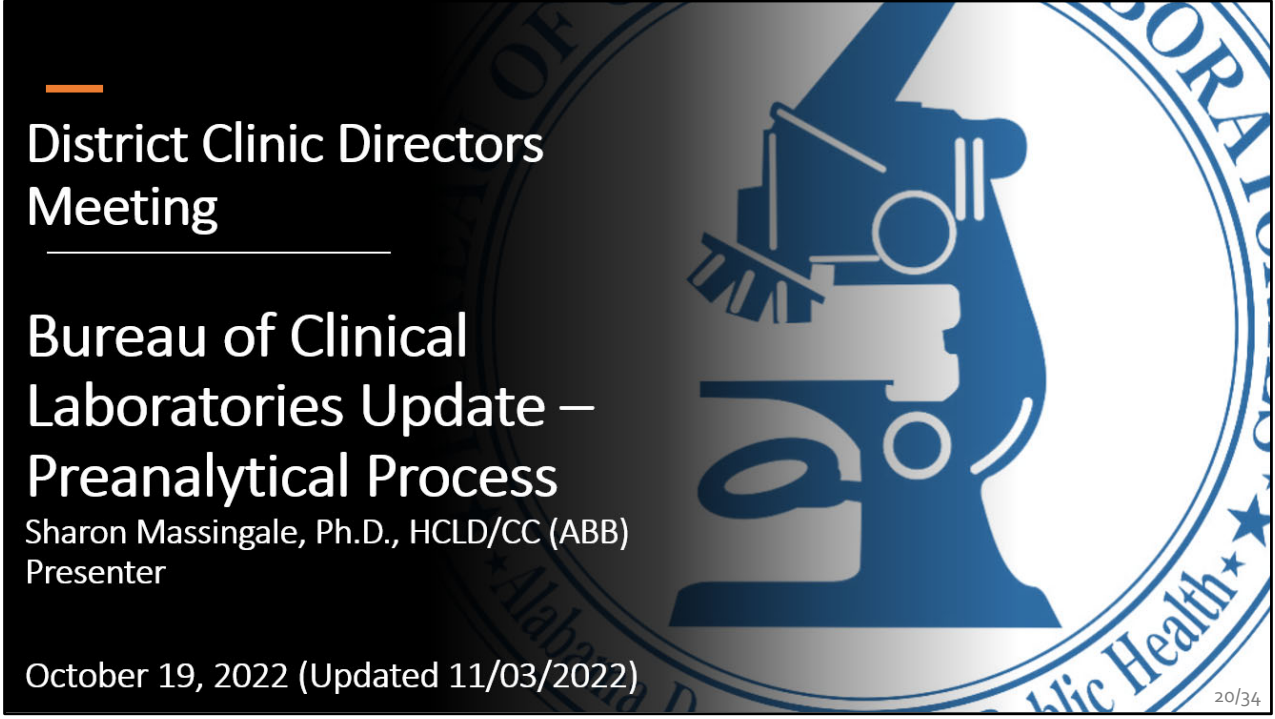
Plan:

- Alternative packaging & shipping methods would be implemented and supplies would be provided to the CHDs to improve the quality of the specimens (regarding temperatures) received at BCL.
- This plan would ease worries and improve the relationship between the lab staff and CHD staff.

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What did you do for your projects? CENTRIFUGES

Ashley: When the APHL funding opportunities became available, QM realized that the BCL providing new centrifuges to the CHDs would help the clinics transition to the new specimen requirements and that removing the burden of having to figure out how to pay for new centrifuges and train staff would likely improve relations between the CHD clinics, the TCs that cover the CHD certificate, as well as the state lab. I mean, who doesn't like new shiny things? In September of 2022 we applied for and were awarded the APHL grant for outreach.



District Clinic Directors Meeting

Bureau of Clinical Laboratories Update – Preanalytical Process

Sharon Massingale, Ph.D., HCLD/CC (ABB)
Presenter

October 19, 2022 (Updated 11/03/2022)

Ashley: In October 2022, QM met with all of the head nurses from each public health district and Dr. Massingale did a presentation that introduced the specimen submission requirements that were coming on the horizon. It is hard to be the bearer of bad news, so it was very nice to be able to end that presentation by telling them we were going to make it easier for them by providing the coolers and centrifuges....

NEW and IMPROVED

Preanalytical Processes, Guidance Documents, and Forms

- ✓ Analyte list – Collection guidance
- ✓ BCL Requisition form for Laboratory testing
- ✓ BCL Requisition for Container, Kits, and Forms
- ✓ Bureau of Clinical Laboratories Shipping Requirements for Specimens Policy
- ✓ Implementation of a standardized courier log

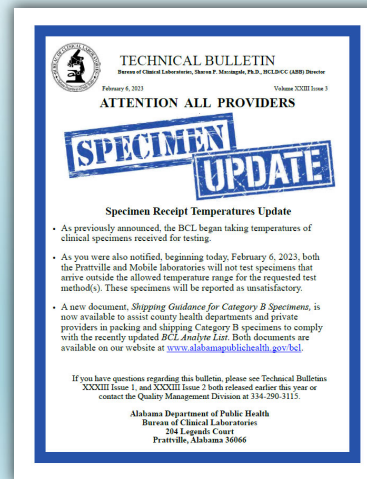
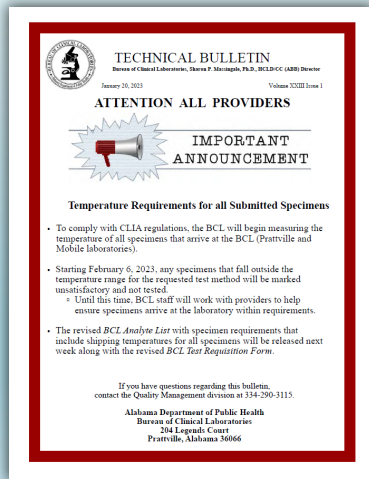
All updated documents will be placed in Lotus Notes Document Library



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Ashley: ...along with training and updated documentation. After a few months of red tape, we were finally able to order the centrifuges in January 2022.

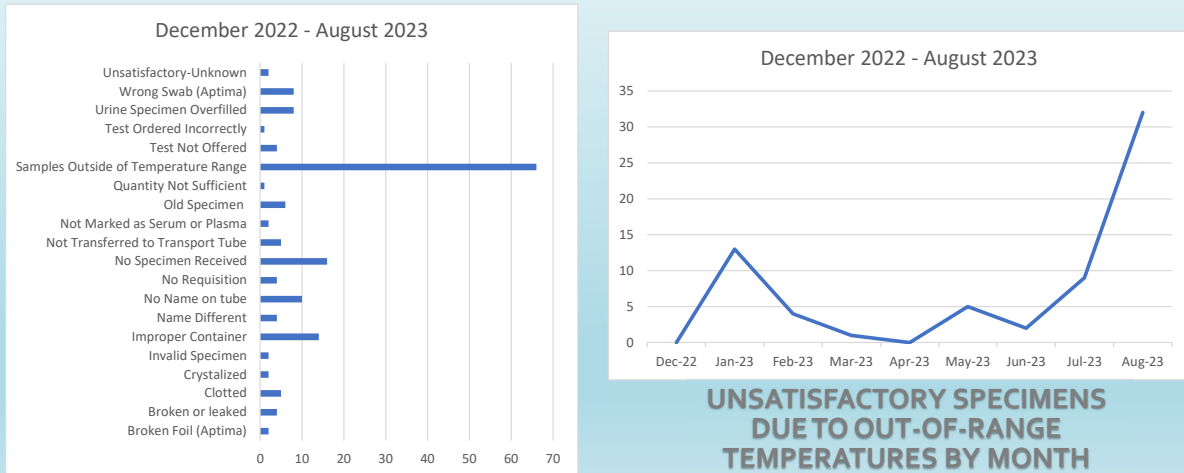
IMPLEMENTATION OF TEMPERATURE REQUIREMENTS



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Ashley: In February of this year, we implemented those specimen submission requirement changes and started requiring specimens to arrive at the laboratory within their required temperature ranges (this was after ordering the coolers but before they had been distributed).

REASONS FOR UNSATISFACTORY SPECIMENS



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Ashley: Once implemented, we had an immediate increase in samples deemed unsatisfactory for not meeting temperature requirements but shortly after that we had a significant increase in specimens being deemed unsatisfactory due to hemolysis. Research told us that rapid cooling before centrifugation was likely the cause of the hemolysis which meant the clinics needed their centrifuges ASAP. Having so many unsatisfactory specimens and requesting that patients return to the clinic to be restuck was very frustrating for our clinics.

MEET THE DRUCKER 642B



Ashley: We ordered a single-speed, horizontal head centrifuge with an adjustable mechanical (dial) timer. Made in the USA! Because we ordered 70, we managed to get a bulk deal that lowered the price under the threshold amount that would require an item to be inventoried yearly!

The centrifuges arrived, function checks performed, and were distributed on March 10-13.

TRAINING



County Health Department Centrifugation Introduction Series Course Landing Page

On this page you will find information on centrifugation of blood products. All staff that will operate a centrifuge in a county health department clinic must complete this course designed to familiarize the user on use of the centrifuge and how to aliquot samples to send the serum or plasma portion of the patient's blood sample to the laboratory. The course is divided into two parts:

1. Two required videos on the operation and maintenance of the specific centrifuge in use at every CHD in Alabama, the Drucker 642B.
2. A PowerPoint training module with a step by step procedure that covers centrifuging and aliquoting serum and plasma samples.

After completing the two videos in Part 1, there will be a link at the bottom of the Part 1 page that will bring you back to this landing page to complete Part 2.

After completing both parts, click the link below to complete the acknowledgement form. Let's get started!

Part 1: [Use and Care of the Drucker 642B Centrifuge](#)

Part 2: [After the Spin: Centrifuge and Aliquot](#)

After completing both parts of this course, click [here](#) to sign the acknowledgement form.

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- Laboratory Safety
- Centrifuge? Why?
- Before the Spin
- Centrifuge Information
- Centrifugation
- Aliquoting
- Final Steps
- Tube Labeling – Dos and Don'ts
- Extra Information

Why did the two test tubes spin around?
Their centrifuge was all in with.



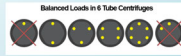
BEFORE THE SPIN – COAGULATE GOLD OR TIGER TOP – GEL BARRIER

After inversion, SST gold or tiger top tubes with gel barrier used for serum separation must be allowed to fully clot before centrifugation. Stand the tubes upright and allow them to sit at room temperature for approximately 30 minutes or until the clot has settled in the tube. If clotting fails to occur within 60 minutes, recollect the specimen.



CENTRIFUGATION – BALANCE

Open the centrifuge lid and place the specimen tube(s) into the centrifuge carrier tubes. Ensure the load will be balanced by placing tubes opposite from one another.



If only one tube needs to be centrifuged, a "balance tube" will need to be used. Simply fill a new blood tube of the same size and type with an amount of water equal to the amount of blood in the tube to be spun. Place it in the centrifuge opposite the blood tube to balance the load.

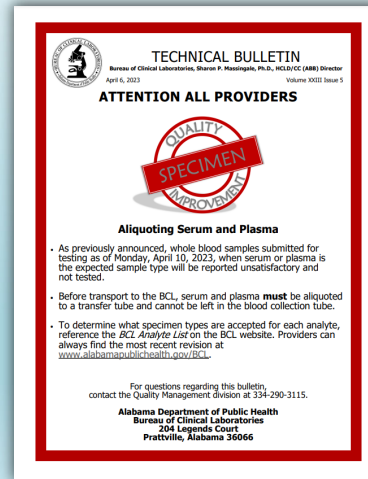
Worst Dressed Tubes



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Ashley: It had been a while since the clinics had working centrifuges and there had been significant staff turnover during COVID; so, I prepared a training course on centrifugation and aliquoting that included manufacturer's videos and a PowerPoint that I created. They were required to go through the course and sign an acknowledgement form before they could use the new centrifuges.

IMPLEMENTATION OF REQUIRED CENTRIFUGATION



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Ashley: Then, in April of this year, the lab implemented requiring that serum be centrifuged and aliquoted to a transfer tube prior to arrival at the laboratory. With any new process, there have been some bumps in the road but overall, it's going really well.

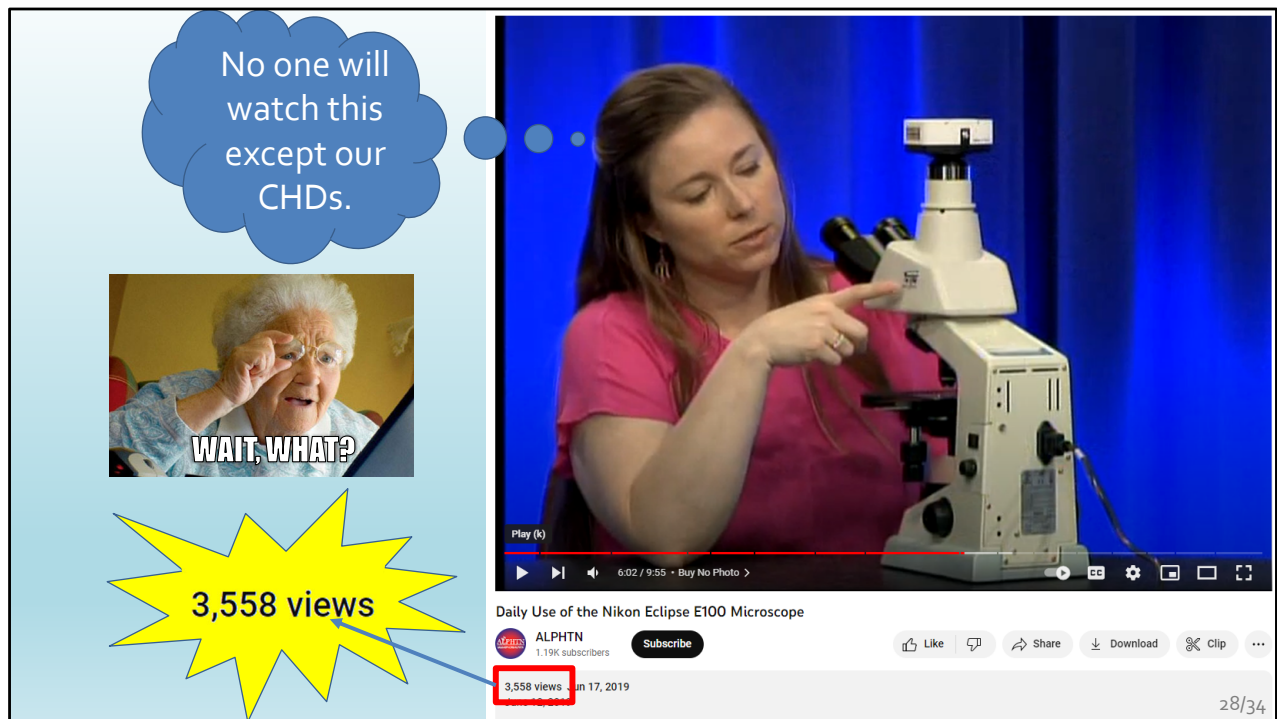
CHALLENGES



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Ashley: Procurement and logistics issues were similar to the coolers, but we also had difficulties with distribution since we did not have the staff to devote to delivering every centrifuge to its intended clinic. We ended up delivering batches of centrifuges to the central office in each of the 6 different public health districts. Individual district administration was responsible for ensuring each centrifuge reached its final destination. Unfortunately, one centrifuge was actually stolen out of an administrator's vehicle in the parking lot of one of our CHDs.

Also, when preparing to order the centrifuges, we realized that the model we had budgeted for was not going to meet the clinic's needs so we ended up ordering a more expensive model of centrifuge. It actually worked out to our advantage because the manufacturer of the model we ordered had recently redesigned most of their product lines and had recorded new education videos that they posted on YouTube.

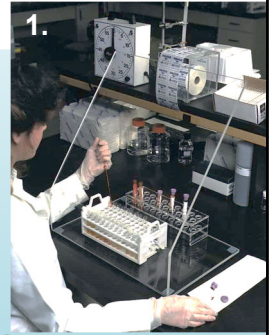
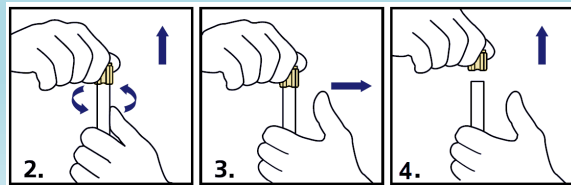


Ashley: This meant I didn't have to go on camera like I did when we provided new microscopes through a different grant in 2019.

ALIUQUOTING – UNCAPPING

Note: Forcefully removing the cap from a blood tube can create blood aerosols which are an infection hazard. Always remove caps gently and while properly using a splash shield.

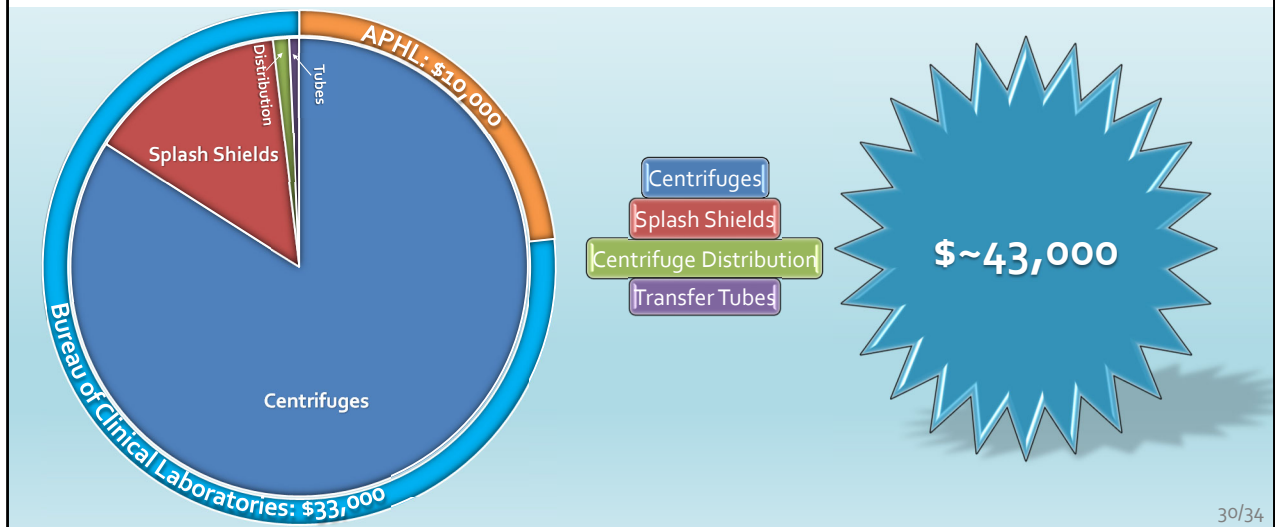
1. With a splash shield between you and the blood tube, hold the tube with one hand and place your thumb under the cap.
2. With the other hand, twist the cap while simultaneously pushing up with the thumb of the other hand only until the tube stopper is loosened.
3. Move thumb away from tube.
4. Lift cap off tube.



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Ashley: Splash shields: To safely aliquot the blood products, we instructed the clinic staff to remove the vacutainer caps behind a splash shield because popping off the tops can cause aerosolization which is a safety hazard. Now, during COVID, the BCL provided splash shields to each of the CHD clinics for use with the point of care COVID machines and with COVID testing winding down, the clinics were asked to repurpose the previously provided shields for aliquoting these blood specimens. After the centrifuges were delivered, most CHD clinics requested additional splash shields stating they were still regularly performing COVID testing and would need more than one shield. QM then ordered and distributed an additional unbudgeted 61 shields at around \$100 each.

TOTAL BILL – OUTREACH PROJECT



Ashley: One more challenge was that larger clinics wanted more than one centrifuge but because we had to order a more expensive model, we ended up going significantly over budget just like we did with the coolers which meant we were unable to accommodate those requests. When we went over budget our director, Dr. Massingale, decided that instead of only providing centrifuges to the locations that didn't have one, we would just replace them all and take the additional funds out of our general budget. We ended up spending around \$43k for the whole project.

LESSONS LEARNED – COOLERS



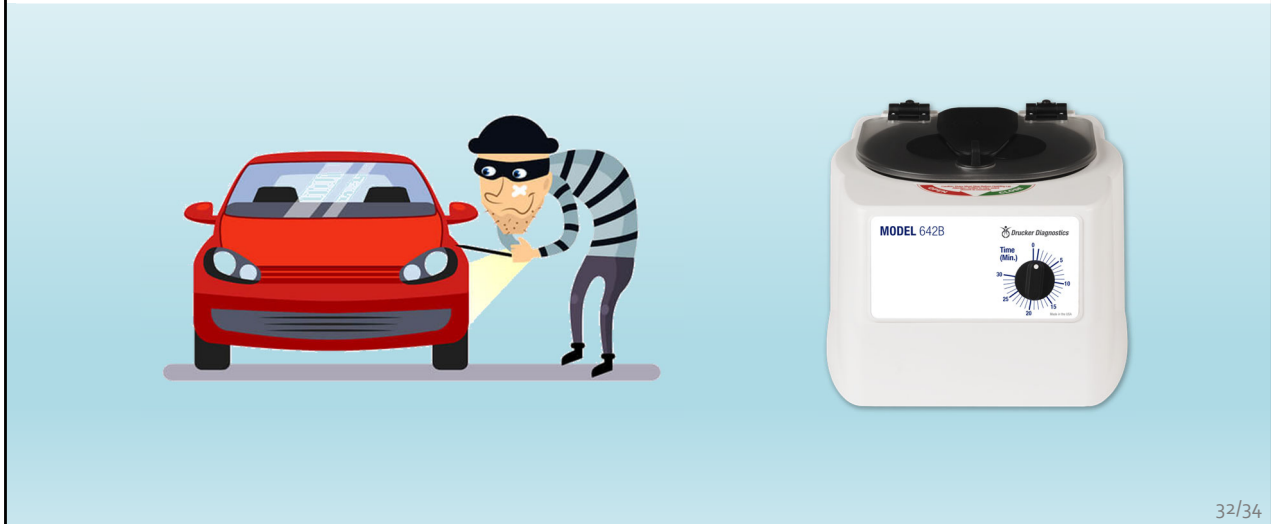
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Lessons learned: COOLERS

Kelley: What did we learn? You will need more than you think. Coolers, vinyl, test tube racks, icepacks, time, and of course MONEY. Nothing went as far as we expected or as smoothly as we expected. We put in a lot of hours to get this project done and we spent about 4 times more than the grant provided. It was a project we were going to have to undertake anyway but this grant really got us moving and helped fund a portion of it.

Also, we are pretty green when it comes to managing grants. The timetables and deliverable dates we set for ourselves when we applied for the grant were not realistic when given our other job duties that still had to be done. Also, the procurement issues we faced delayed the project SIGNIFICANTLY on top of the fact that we are experiencing staff shortages which meant less help from other lab employees.

LESSONS LEARNED – CENTRIFUGES



Lessons learned: CENTRIFUGES

Ashley: Well, that district administrator learned to not leave the car unlocked in a CHD parking lot... not even to run in to use the bathroom.

The rest of it was very similar to what was learned with the coolers, money doesn't go as far as you need it to. Procurement rules are complex and should be factored into projects and timelines to ensure you can order what you need.

While it is not something we could have predicted, when TCs visit clinics, we are finding that the onboard timer of this model is already failing. This was a problem with the older centrifuges, but I naïvely thought that this would not have been a problem across multiple brands nor would it still be an issue as there had been a few DECADES for the technology to improve. When contacted, Drucker is providing a replacement timer mechanism but that means someone at the clinic has to take the centrifuge apart to replace the timer. Most locations don't have an on-site maintenance person so it's up to the nurses or clinic aides to make the repairs and they would rather use an external digital timer to let them know the cycle is done. (beep beep)

Also, offering new equipment to our CHDs really DOES help relations! TCs communication with clinics has improved.

NEXT STEPS

Continue to monitor the arrival temperature of specimens to ensure trends are remaining stable.

Clinics will use their centrifuges daily and TCs will check the speed and timer annually.

QM will provide updated trainings as needed.



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Next steps: COOLERS

Kelley: The BCL will continue to monitor the arrival temperature of specimens to ensure temperature trends are remaining stable and we do not need to add more icepacks or start prechilling coolers to meet temperature.

Next steps: CENTRIFUGES

Ashley: Clinics will make good use of the centrifuges and TCs will check the speed and timer annually during on-site visits. QM will provide updated trainings as needed.

QUESTIONS?



Contact the Bureau of Clinical
Laboratories

Quality Management Division

334-290-3115

Thank you!

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Thank you!