Montana Laboratory ewswinter 2022

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What's in a Name? by Holly Weinberg

In 2020 the ASCP Board of Certification (BOC) and ASCLS collaborated and wrote a position paper titled, "Standardizing the Professional Title of Medical Laboratory Scientists." The paper was fully endorsed by both organizations. The primary purpose of the paper was to address the inconsistency of professional nomenclature and the impact this has had on the profession and the professionals' identity. Click on this link to read the complete paper (Standardizing the Professional Title). (It can also be found at the ASCLS website-Advocacy-Position Papers). At the BOC Board of Governors (BOG) meeting in October 2021, the BOG approved a plan to transition all MT(ASCP) and MT(ASCPi) credentials to MLS(ASCP) and MLS (ASCPi) (the ASCPi designation refers to international certification). This change of terminology from Medical Technologist to Medical Laboratory Scientist is a critical step in the move towards standardizing the professional title of medical laboratory professionals. BOC staff will be implementing this transition in 2022.

To provide background to this, let's look at the history of our professional designation. In 1926, ASCP appointed a Committee on the Registration of Laboratory Technicians (LT); in 1928, the committee's recommendations on rules and regulations for a registry of LT's and MT's were adopted to form the official Board of Registry (BOR). The first certificate was issued in 1931 for MT and LT. Standards were raised to require >3 years of college with prerequisite science courses in 1958 and again raised to require BS degree for MT in 1962. The first MLT certificate was issued in 1969.

In the 1970's concerned were raised regarding the professional independence of Medical Technologists and Technicians from the Pathologists and this resulted in the establishment of the independent National Credentialing Agency (NCA) by ASMT (now ASCLS) in 1977; the credentials were Clinical Laboratory Scientist (CLS) and Clinical Laboratory Technician (CLT). The NCA certification exam was developed by practicing CLS's and NCA also required recertification every 3 years by submitting proof of a minimum number of continuing education credits during each 3-year period. This was a NEW concept to our profession! The ASCP certification was a lifetime rubber stamp of certification for a profession that is rapidly growing and changing year after year. Pathologists across the country continued to promote ASCP certification as the only legitimate credential but accepted NCA certification as a secondary credential. Gradually, laboratories began to accept NCA as a primary credential, but it was still an uphill battle. Meanwhile we now had MT, MLT, CLS, and CLT designations.

In 2009, the NCA and BOR merged to form an Independent Board of Certification (BOC) and the credentials going forward would be MLS and MLT. The new BOC continued the continuing education requirement for mandatory recertification from the NCA so from 2004 forward, anyone obtaining certification was required to recertify every 3 years through certification maintenance and their credentials reflected this with MLS(ASCP)^{CM} or MLT(ASCP)^{CM}. Individuals who certified prior to 2004 grandfathered in and were not required to recertify but because of that, they were not intended to use the MLS designation, rather they were supposed to retain MT. This of course increased the confusion and credential designation became even more muddled. CLS and CLT were to be phased out due to the merger. Note that the BOC is an INDEPENDENT entity even though it is housed on the ASCP website, there is NO requirement to be a member of ASCP to maintain certification.

Who can keep this all straight? Nobody! So the announcement from the Board of Certification Board of Governors (BOC BOG) is huge. We finally have consensus across organizations that we are ALL MLS or MLT. No other primary designation should be used – no CLS, CLT, MT, or superscript CM (note that the specialty designations such as SBB, SH, etc. remain the same). This will have many implications not only in the workplace but in licensure nomenclature. Also, we will finally, hopefully, have clearer distinction in the Bureau of Labor Statistics which directly impacts our staffing and salaries. We must come to a consensus on what we call ourselves. Using terms like lab tech, med tech, lab, just muddles the picture and continues to portray us as button pushers in the basement. As stated in the above referenced position paper, What's in a Name?

"Everything important to our profession — our professional identity, as well as recognition from the healthcare team, administration, government agencies, and the public. In addition, it affects recruitment to, and retention in, our

<u>profession. It is time we move to one name — Medical Laboratory Scientist".</u>



Keep up to date on the latest COVID-19 case counts, hospitalizations, and active cases by county. The state laboratory has expanded hours 7 days a week. Watch for updates via email!

Montana Response-COVID-19

Call For Nominations

Hello fellow ASCLS Montana members! The time has come to find some new candidates to serve on the board. Terms will begin August 1st. 2022. There are positions available for every comfort level. You can nominate yourself or another member (with their permission) by sending the nominee's contact information to one of the committee members listed below.

Open positions for the upcoming term include:

President Elect

Board of Directors

Nominations

Awards and Scholarships

Secretary

Finance and Audit

Please see the attached Position Descriptions for requirements and duties for each position. If you have ever wondered what doing more in ASCLS looks like, this is a great opportunity to get involved and have an active role in your state society.



American Society for Clinical Laboratory Science - Montana

2022 ANNUAL COMMUNITY GATHERING

SAVE THE DATE: MAY 5TH - 7TH HOLIDAY INN, GREAT FALLS, MT

Resilience: Emerge Stronger

Mark your calendars for our Montana Annual Spring Meeting. Take this opportunity to:

- Gather with your laboratory community and recharge your bat-
- Obtain 14 valuable PACE credits
- Network with our Vendors
- Stay updated on government
- Registration and room blocks available soon, watch our website

For more information: www.ascls-mt.org E-mail: asclsmontana@gmail.com



THIS **ISSUE:**

Spotlight on

Awards and Scholarships

> **Upcoming Events**

PAC Updates

Poster Presentation courtesy of Tori Rensink, MLS(ASCP), CTBS ASCLS-MT Treasurer

A Novel Approach to Human Tissue Endotoxin Testing using a Recombinant Factor C Assay

Victoria Rensink MLS(ASCP), CTBS Xtant Medical Laboratory Manager - e-mail: vrensink@xtantmedical.com

PDA Global Microbiology Meeting 2021 - Virtual Meeting

Introduction

Xtant Medical is a certified tissue bank that designs, manufactures and distributes orthobiologic products and fixation systems for implant. Our demineralized bone matrix (DBM) Putty is a FDA registered Class II Medical device. Due to the nature of production and the use of our product, Endotoxin analysis of this device is mandated by federal regulations.

DBM Putty is a resorbable calcium salt bone void filler device. Bone is ground into powder, demineralized, and mixed with a combination of carboxymethyl cellulose (CMC) and PBS. It is manufactured in an aseptic environment and gamma irradiated before final product testing.





Historically, Xtant has used numerous contract laboratories to perform final product Endotoxin analysis using Limulus Amebocyte Lysate assays which are sourced from the hemolymph of the Horseshoe Crab. Both laboratories utilize different chromogenic LAL methods. LAL is a naturally sourced reagent that uses the Factor C enzyme and corresponding cascade to detect endotoxin. The LAL assays also has another activation pathway which utilizes the Factor G enzyme and is activated by β -Glucans. One of the drawbacks of using LAL assays for our product is β -glucan interference. Since DBM putty is manufactured with the addition of CMC, a β -glucan blocker is needed to block the enhancing effects of the cellulose which can activate the pathway. This has proven costly, time inefficient and laborious. Recombinant Factor C(IrFC) is a replacement of the endotoxin detection pathway of the LAL assay by utilizing only the Factor C enzyme made synthetically to detect endotoxin, therefore not having any β -glucan interference as it does not contain Factor G.

With the introduction of rFC methods, Xtant has found that product testing is now affordable, time efficient, and undemanding.

Objectives

Reduce the time to results and costs associated with Endotoxin Testing

- Bring Endotoxin testing in-house (\$\$\$)
- Reduce sample interference (β -glucan)
- · Replace the use of animal materials (3R)

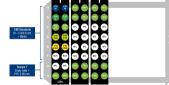
Materials

Samples

Demineralized Bone Matrix (DBM) Putty
 OsteoSelect*

Assays

- ENDOZYME II GO
 - GOPLATE Pre-coated CSE microplate
 - rFC (enzyme, substrate , assay buffer)



Accessories

- Water Endotoxin Free
- EMD Millipore Endotoxin-Free Dulbecco's Phosphate Buffered Saline w/out Calcium or Magnesium
- ENDOGRADE® glass test tubes

Methods

The DBM product samples were prepared for analysis by adding 1 cc of the putty to 4 mL of water endotoxin free (WEF) or Phosphate buffered saline (PBS) and allowed to extract at 37° C for 1 hour with gentle mixing at 15-minute intervals. Sample extraction was then run undiluted and 1/10 diluted. Assays were ran as per reagent instructions at a sensitivity level of 0.005EU/mL.

Results

All assays using rFC were compliant with valid CVs and very consistent PPCs. None of the samples were effected by β -glucan false activity. All samples were within limits for final endotoxin levels

Sample	Batch	CV	PPC	Dilution	Final Result
SPL1	B180371	4.24%	N/A	1/10 mL	0.088
PPC1	B180371	1.26%	120.17%		EU/mL
SPL2	B180371	6.04%	N/A	1/10 mL	0.103
PPC2	B180371	3.24%	124.27%		EU/mL
SPL3	B200710	6.93%	N/A	1/10 mL	0.134
PPC3	B200710	3.22%	121.34%		EU/mL
SPL4	B200710	3.97%	N/A	1/10 mL	0.125
PPC4	B200710	3.72%	121.34%		EU/mL
SPL5	B200710	4.61%	N/A	1/10 mL	0.148
PPC5	B200710	1.49%	131.64%		EU/mL
SPL14	B180485	0.87%	N/A	1/10 mL	0.071
PPC14	B180485	5.61%	115.97%		EU/mL
SPL15	B180485	3.14%	N/A	1/10 mL	0.079
PPC15	B180485	4.40%	113.66%		EU/mL
SPL16	B180485	5.49%	N/A	1/10 mL	0.068
PPC16	B180485	3.38%	116.26%		EU/mL
SPL17	B180556	0.00%	N/A	1/10 mL	0.06
PPC17	B180556	0.66%	113.10%		EU/mL
SPL18	B180556	16.26%	N/A	1/10 mL	0.057
PPC18	B180556	2.42%	119.18%		EU/mL
SPL19	B180556	7.21%	N/A	1/10 mL	0.052
PPC19	B180556	2.12%	115.05%		EU/mL

Conclusions

By using ENDOZYME II GO rFC assays for our Endotoxin testing, we were able to bring our Endotoxin testing in-house. This allowed us to significantly reduce the turn around times and save costs on testing. The pre-coated GOPLATE allowed us to reduce the time needed to set-up the assay and make the assay easier to run for the analysts.



Stay in touch virtually!

As members of ASCLS one of your most valuable resources is the ASCLS Connect Community! Each year you can customize your member community to receive email updates regarding our state society news/updates, any laboratory specialty of interest, and hot topics in the laboratory world. Stay connected to our membership across the US and across our big sky state. The most resources are at our fingertips via the Connect Community, download the app today.

■ ASCLS Connect Community and Mobile App

Connect through the Online Community

at connect.ascls.org

Download a New App to Access the Connect Community on Your Mobile Device

Convenient. The app keeps you logged in, making the entire Connect Community (and all its functions) just an icon away.

Accessible. Look up other members in the directory, send and respond to messages, and monitor community discussions in real time.

Fun!



To download the app:

 Go to the Google Play store or the Apple App Store and download the MemberCentric app.

INSTALL

2. Search for ASCLS when prompted to "Find your organization."

3. Log in using your credentials for your ASCLS member account.



Training is most effective before an incident occurs-Lab Manager Nov 30, 2021

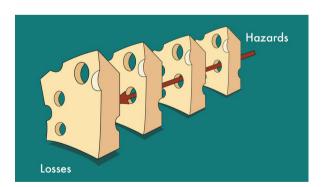
TABI THOMPSON

The goal is zero incidents in the workplace. However, employees are imperfect, and incidents will happen. We can only hope that when they occur, they are minor.

No one wants an incident to happen. Not only because someone could be injured or killed, but also because incidents mean that paperwork is filed, work is slowed, morale decreases, and money is lost. However, safety incidents have the potential to be a significant learning opportunity. When a company has a healthy safety culture, a root cause analysis will help highlight the areas for improvement and increase safety. Management has a responsibility to their employees to not just gather the low-hanging fruit during incident investigations, but to dig deeper to find the best solution or improvement to keep their employees safe. A lack of training is often blamed for an incident occurring; this is low-hanging fruit. Safety training is incredibly important, but when used as the primary resolution for an incident investigation, it is largely unhelpful and unlikely to prevent similar future incidents.

Getting to the root of the problem

Incident investigations are time-consuming and involve asking difficult questions about an uncomfortable situation. However, when they are done well, they have the power to prevent injuries and save lives. There are three common obstacles that lab managers fall prey to when performing an incident investigation: playing the blame game, assuming that there is only one cause, and seeking easy or weak remedies.



The Swiss cheese model shows that multiple, smaller solutions working together can be just as effective as a single, larger, and likely more expensive, solution.

ADAPTED FROM IMAGE BY JAMES

REASON, <u>WWW.NCBI.NLM.NIH.GOV/PMC/ARTICLES/</u> <u>PMC1117770</u>

Cont....

ARE YOU READY FOR MEDICAL LABORATORY PROFESSIONALS WEEK?



PAC Updates!

2022 Quarterly PAC Update

The Nitty Gritty of PAMA Cuts

What are the imposed CMS PAMA Cuts? What does it all mean?

Protecting Access to Medicare Act



As part of PAMA implementation, Congress directed the HHS Secretary to establish market based rates for clinical laboratories; however, the Secretary disregarded Congress' instruction and gathered private market rate information from an unrepresentative sample of less than one percent of laboratories nationwide. The data was dominated by the private market prices of the largest independent labs with the greatest economies of scale and the lowest prices, while data from market segments with higher private market pricing were underrepresented. For example, hospital labs contributed just 1 percent of data in the first reporting period but account for approximately 26 percent of Medicare spending. Physician office labs represented just 7.5 percent of data submitted, despite making up 20 percent of Medicare spending. This incomplete and skewed data collection ignores the fundamentals of a market based system. By ignoring the payment data from more than 99 percent of the nation's laboratories, HHS' actions have already had an adverse impact on patient care. Already, nursing home residents are bearing the brunt of these cuts. Specialized labs that serve nursing homes, skilled nursing facilities and long-term care facilities have already been forced to shut down operations, reduce services and lay off employees. If the PAMA cuts continue, these labs, which send personnel to nursing homes to collect specimens and turnaround results quickly, will have no choice but to limit the number and frequency of facilities they serve. Without their services, nursing home residents will have to be transported to hospitals by ambulance for specimen collection and testing – negatively impacting patient care and driving up Medicare costs.

The somewhat comforting update to all of this is that these cuts were delayed through to January 2023. Some of you may be wondering, ok, but what do we do now to permanently delay these cuts?

From the ASCLS Labvocate Action Center:

Labvocacy efforts to prevent PAMA cuts have generated a new bill to address the issue. Among other provisions, the "Protecting Medicare and American Farmers from Sequester Cuts Act" would delay any cuts under PAMA for one year until January of 2023. This will give the laboratory community time to work on a permanent solution to the problem.

Cont...

SPOTLIGHT ON SAFETY...cont

Incidents are a thorn in the side even when no one is hurt. It's extremely easy to try to pin the blame on someone instead of asking one very important question: "What could we have done differently to prevent this from happening?" Instead of looking for who to blame, try approaching the problem with the same curiosity you would when facing another problem in the lab. Just like problems in the lab, there is rarely one solution. There can be many corrective actions to an incident investigation. As we have seen during the pandemic, the Swiss cheese model of risk management proves that many small remedies can make up for the lack of a single large, and likely expensive, cure-all. Finally, lab managers must avoid the weaker or easier solutions. If the investigation ends by claiming that human error is at fault, and the corrective action is simply more training, it's only a matter of time before the incident happens again.

Training cannot solve human error

"The most effective risk-reduction strategies involve redesigning systems to make them more resistant to human error," says ISMP, an organization devoted to preventing medication errors in the health care community. 1 A hierarchy of controls of occupational hazards illustrates this concept perfectly. The most effective methods of preventing incidents focus on the hazards, while the least effective methods focus on people. Human error is inevitable, so "strategies that rely heavily on human memory and vigilance are much weaker" than finding ways to eliminate, reduce, or isolate the hazards. If a hazard can't hurt a person even when they make a mistake, then the method of prevention is substantially more successful. NIOSH's Prevention through Design initiative encourages companies to consider ways to design labs or processes to eliminate or reduce hazards. Keep in mind that it is easier, and cheaper, to make design decisions before a lab or process is in place rather than making changes later. While training employees is incredibly useful and important, when it comes to preventing incidents, training isn't an effective solution to a safety incident.

What does effective safety training look like?

OSHA dictates that the "best training programs are accurate, credible, clear, and practical." Ironically, the characteristic that is the least straightforward is that training programs should be clear. What's clear to one person isn't necessarily going to make much sense to another, so how do you ensure that your training is effective? Here are some tips to build a more effective training program.

Training should be easy to understand

True clarity can be extremely challenging, but there are ways to make it easier. Training material should be written in plain English (or the everyday language of the majority of employees), and lack complicated jargon. If the training will be taken by employees of a wide range of educational backgrounds, ensure the training is written so that even the employee with the least education will understand it. Furthermore, don't assume that the only barrier to understanding is strictly literacy of the language. Language barriers exist in many forms, such as regional or country dialects, uncommon references, or learning disorders, like dyslexia.

SPOTLIGHT ON SAFETY...cont

Use a variety of training techniques

"The most effective methods of preventing incidents focus on the hazards while the least effective methods focus on people."

Variety isn't only the spice of life, it's crucial for training a diverse workforce. Perform a simple Google search, and you'll find a generous selection of training options. Slide decks may be easier, but they also tend to be more boring, don't allow for employee questions, and require readers to not only understand but also read the writing. Other options include training videos, instructor-led training, hands-on training, group activities, game-based learning, and more. Try not to get into the habit of repeating the same training the same way multiple times in a row, especially if you have an experienced workforce. By providing the same training in a multitude of ways, employees are more likely to pay attention and retain the information, which inherently makes the training more effective.

Devote time for training

Time is money. While safety training may seem like a waste of time when you are under a deadline for a project, remember that devoting time toward safety training takes far less time than dealing with an incident, especially if the incident involves an injured employee. "No one gets paid for not having accidents; they get paid for producing goods," says Steve Ludwig of Rockwell Automation. While harsh, it's true. Employers don't pay their employees to be safe; employees are paid to be productive. As such, the only way for lab managers to ensure their employees take safety activities—and especially safety training—seriously is for lab managers to give safety the same priority as other things, like meeting deadlines and quotas. Lab managers can't just care about safety when something goes wrong; they must show constant vigilance to ensure safety incidents don't occur.

Invest in your employees' continued education

Even before the pandemic, employees felt expendable. "Most individuals desire a level of satisfaction with what they are doing," writes Kyle Shobe from Missouri State University. People spend too much time at work for it to not be fulfilling and/or enjoyable. Management that invests in an employee's continued education not only contributes to job satisfaction for their employees, but that investment can also lead to in-house job expertise and safety for the company. Send an employee to an instrument manufacturer's site for hands-on training and your employee will likely come back with information about how to use the instrument more effectively, how to correct common problems, and how to use the instrument more safely. That same employee will feel valued because they know their new knowledge is now an asset to the company. The return on investing in your employees is well worth it.

Henry Ford once said that "the only thing worse than training your employees and having them leave is not training them and having them stay." Safety training and continued, job-specific education are tools that can help show employees their safety and career development are valued by lab managers and the company. However, training and education programs are most useful as preventive tools rather than as corrective actions. Instead, the best corrective actions are focused on eliminating or reducing hazards. A company that eliminates hazards doesn't have to simply hope its employees remember the safety training in order to remain safe. Likewise, employees who have fewer concerns can focus more of their attention on their job and can be more productive.





Be a winner

On Behalf of the ASCLS-MT Board, we would like to inform you of some upcoming awards deadlines. Please consider nominating your fellow ASCLS members for one of these awards! More information and the online submission form can be found at ascls.org, under the "ABOUT US" tab, and "Awards and Scholarships".

Ascending Professional Leadership Award: Due February 15, 2022

Recognizes a member who has contributed significantly to the field of Medical Laboratory Science and to ASCLS in their first 5 years in the profession. Submit online at ascls.org.

Developing Professional Leadership Award: Due February 15, 2022

Recognizes a student member of ASCLS who has demonstrated outstanding leadership and contributed to the growth and development of the ASCLS developing professionals forum. Submit online at ascls.org

Lifetime Achievement Award: Due February 15, 2022

Honors and recognizes an ASCLS member who has "made a difference" in ASCLS and the profession of Medical laboratory science. The individual should have demonstrated dedicated and outstanding service at all levels of the organization over a sustained period of time. In addition this individual should have demonstrated outstanding career achievements in MLS and has promoted the profession to the public and other health professionals. Forms for submission are available at ascls.org.

Society Website Award: Due February 15, 2022

Recognizes excellence in a constituent society's website. Submit online at ascls.org.

Society Publication Award: Due February 15, 2022

Recognizes excellence in a constituent society's publication/newsletter. Awards are given in 2 categories: traditional paper format and truly web based. Submit online at ascls.org.

Scientific Research Award: Due February 15, 2022

Recognizes and encourages development of scientific research in the field of medical laboratory science in the past 2 years. Submit online at ascls.org

Scientific Assembly Professional Achievement Award: Due February 15, 2022

Recognizes outstanding professional achievement of an individual ASCLS member within his or her chosen area of academic, scientific or vocational interest. Submit online at ascls.org

AWARDS & SCHOLARSHIPS Apply or Nominate Here!

ASCLS-Montana

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Advocacy Audit Bylaws Emeritus MLS President Treasurer Ascending
Awards
Developing
Leadership
MLT
Professional
Webmaster

ASCLS BOC Editor Membership Nominations Secretary

ASCLS UPCOMING EVENTS:

1. 2022 Clinical Laboratory Educators Conference

March 14, 2022 Denver, CO

2. ASCLS-MT Spring Meeting

May 5-7 Great Falls, MT

3. Lab Week

April 24-30, 2022

4. Joint Annual Meeting (JAM)

June 26-30 Grand Rapids, MI

ASCLS-MT is on social media...be sure to check us out!



Follow us to stay up on the latest news affecting our profession, conference updates, technology, government affairs and society updates.

If you have haven't already, follow us, like us and show us some love! You can also stay connected with us and other laboratorians with:

#WeSaveLivesEverday #IAmASCLS #UnitedAgainstCOVID19 #ASCLSMT #ASCLS #Lab4Life #EveryTestIsOurPatient #IMSS #AintItGreatInRegionEight



