

## President's Message - John Ko



Happy Summer ASCLS-Michigan members! Summer is the time for rest, relaxation, and celebration.

The overarching theme of my 2020-2021 strategic plan was: a Strong Board + a Strong Conference = a Strong Organization. Despite social distancing and virtual BOD meetings, ASCLS-Michigan continues to be a strong organization and there are many successes to celebrate this past year.

**Strong Board:** This past year, we welcomed new individuals to the BOD, while others continued their participation in a different role. The BOD adopted new policies to align with national and approved revised position descriptions and existing policies to better improve our operations. Our District Directors organized virtual gatherings

to maintain a presence with members. And our President-Elect, Meighan Sharp, successfully obtained a proclamation from Governor Whitmer acknowledging the Laboratory Profession during MLPW this past April.

**Strong Conference:** ASCLS-Michigan members and laboratory peers, under the direction of Past President and Conference Coordinator Stephanie Mabry, were still able to network and obtain CE at our annual meeting held virtually. This team made it a priority to provide the same world-class experience as our traditional conference.

**Strong Organization:** With a total of 8 delegates and several other members attending in-person or participating virtually, ASCLS-Michigan was well represented at JAM 2021.

Some of our members received recognition at the Awards Ceremony. These individuals are a testament of our strong organization and commitment to our profession:

- Barb Mannor: 50-year ASCLS Member
- Paul Guthrie, Newslinks Editor: 3rd place for Society Publication Award
- Stephanie Mabry (ASCLS PAC Chair) and Abbey Hilden (ASCLS-Michigan PAC Chair): 2nd place in PAC competition
- Kyle McCafferty: ASCLS Leadership Academy graduate
- Kristin Landis-Piowar: Hematology SA Professional Achievement Award
- Heather Alvarez (MSU graduate student): Graduate Poster Competition
- Kate Hadlich: Developing Professional Leadership Award
- Kara Daniels: AMTF Ruth M. French Memorial Scholarship
- Elizabeth Truitt: AMTF Undergraduate Scholarship
- Alicia Kuzia: Ascending Professional Leadership recognition
- Julie Hall: Constituent Society Member of the Year recognition
- Janet Brown: Lifetime Achievement recognition



*Continued on next page*

### Inside This Edition:

FDA EUA and the Novel 2019 Coronavirus

Pages 3-6

Chemistry SA Article: HS Troponin

Pages 7-8

### President's Message

2021-2022 BOD Election Results

Omicron Sigma Awardees

Pages 1-2

Page 6

Page 9

- Also, please see the extensive list on page 9 with the ASCLS-Michigan Omicron Sigma awardees in the Constituent Society, Regional and National categories

ASCLS-Michigan is centered around strong community. I am thankful to have been entrusted to lead this group and I am confident that our next president, Mariane Wolfe, will lead ASCLS-Michigan to accomplish greater things. I hope you enjoy your summer and that you get the opportunity rest, relax, and

## #LiveLoveLab #ASCLS



*Blue Water Bridge - Port Huron, Michigan*



**American  
Society for  
Clinical  
Laboratory  
Science Mi-  
chigan**

### 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.

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# Clinical Laboratory Science

A focus on what is happening in our profession

Featuring articles from Scientific Assembly Chairs.

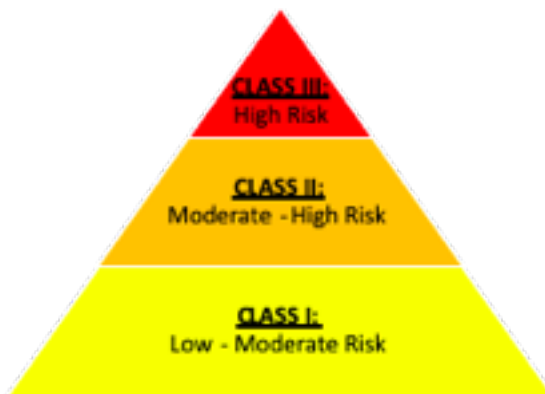
Materials from all members are also welcomed. Submit to editor. See page 2 for details.

## EUA and the 2019 Novel Coronavirus

Kristin Denzer, Scientific Assembly, FAB Five

Laboratory testing is a highly regulated diagnostic tool requiring a thorough vetting process to ensure reliable results for patients. The means to get through the regular channels of approval is time consuming, and there are emergent cases where the demand for testing cannot wait. So how does laboratory testing in the United States meet testing demand in a timely fashion during an outbreak of new disease?

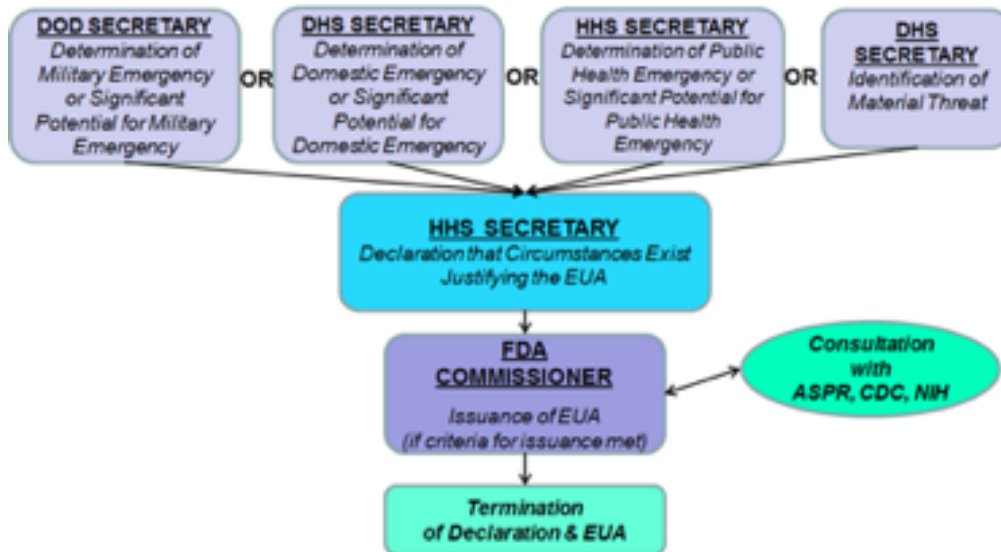
Diagnostic testing is classified as an “in vitro diagnostic product” (IVD) and is regulated by the United States Food and Drug Administration (FDA). Any reagents, instruments, or systems used in diagnosing disease or other conditions fall under the FDA’s purview. Medical devices, such as IVDs, seeking FDA approval must first determine their product’s classification. Class I, Class II, or Class III designation determines the required steps for approval. As the device’s level of risk increases so does the class rating and subsequently the regulatory control. For example, a Class I medical device such as a tongue depressor does not need as strict of approval process as a Class III atrial defibrillator. Higher class designations go through stricter approval routes, including, but not limited to, the 501(k) Pre-market notification and Pre-market Approval (PMA).



The 501(k) Pre-market notification route requires the manufacturer to submit evidence that their device is equivalent to a previously approved legal device with the same intended use and similar technology. The new device is evaluated against the predicated device, which includes comparing bias, imprecision, and analytical specificity/sensitivity for IVDs. If the FDA determines the new device is substantially equivalent (SE), the product gets clearance to be marketed in the United States as the same class level as the predicate. This route saves significant time and the product can go to market faster.

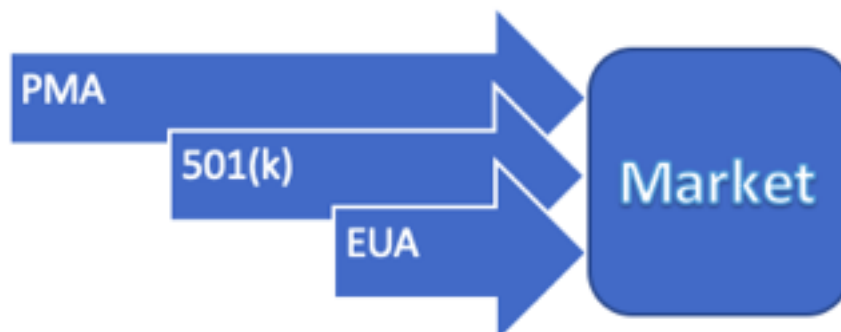
The more regulated Class III devices must go through a Pre-Market Approval (PMA) which is the most intense process and therefore more time consuming path. The PMA process requires scientific review to ensure the safety and effectiveness of Class III devices. The manufacturer must prove safety and efficacy through clinical evidence and a full FDA review of the data which takes substantial time - the entire process could take years.

In the event of an emergency due to chemical, biological, radiological, or nuclear (CBRN) threats or emerging infectious diseases, time is of the essence to respond effectively. The HHS Secretary can give the FDA commissioner the authority to allow unapproved medical products or unapproved uses of approved medical products to be used as medical countermeasures (MCMs) under Emergency Use Authorization (EUA).



Source: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance>

The FDA issues Emergency Use Authorizations (EUA) for new MCMs if there are no existing methods to meet demand, such as emergency testing for an infectious disease, allowing for a faster response. Regulations are reduced to get more products to market faster to assist in the emergency. Manufacturers submit a formal request of FDA EUA for their products with a well-organized summary of available scientific evidence and supportive data available. The FDA reviews the submissions and must take all known factors into consideration, including weighing the risk and harm against the potential benefits. The FDA will issue a formal Emergency Use Authorization document specifying the effective date if approved and the product must be labeled as "Emergency Use Authorization" when in use.





An FDA EUA can be revised or revoked when subsequent data is reviewed and changes are needed to protect public health. For example, if the FDA receives reports that the clinical performance estimates did not match with the original data submitted by the manufacturer to justify the EUA, they can send out a notice revoking their approval. All up-to-date information is kept on the FDA website so everyone can view all issuance, revisions, or revocation letters for granted EUAs. Manufacturers typically submit for premarket approval via traditional pathways concurrently with their EUA submission. EUAs are terminated when the public health emergency that prompted its approval is ended by the HHS Secretary or when the product has been approved through the traditional 501(k) or PMA pathways.

The United States has had several circumstances that led to EUAs for emerging infectious diseases that posed a threat to the public. A list of current and historical EUAs are listed on the FDA website. Testing issued for Zika, H1N1, and Ebola are listed with issued and if applicable, revocation dates. The process has been used and worked in the past for diseases that threatened public health.



<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices>

In 2020 the Health and Human Services Secretary declared a public health emergency in response to the 2019 Novel Coronavirus which has led to many FDA issued EUAs and brought challenges to all aspects of healthcare. Diagnostic testing had to be rapidly developed to help care providers determine the infection status of patients. Evaluation of treatments to address the growing number of hospitalized intensive care unit patients was needed. All the while, supply chains strained to adapt and meet demands. Vaccines were developed to gain the upper hand against the new threat. The scale at which EUA has been used for the pandemic of our time is significantly increased compared to historical cases.

Laboratories have certainly been at the forefront of this battle, trying to give care providers tools to fight back. Laboratories must follow their accreditation body's requirements for validating EUA tests, which follow FDA, CDC, and CLIA guidelines. Per CAP, the validation of EUA testing requires:

- Employees trained and qualified
- for the testing per the specific FDA EUA letter of authorization
- Labs follow FDA approved manufacturers protocol with no modifications
- Labs verify test method performance specifications, using both positive and negative controls

All of this is in relation to EUA authorized tests, as Laboratory Developed Tests (LDTs) have their own set of challenges and regulations.

Striking a balance between ensuring products, such as medical testing, is safe and reliable for the public while ensuring enough flexibility to meet the demand at hand is a fine balance. Regulatory requirements slow processes down, but they exist to protect the public's health. Fortunately, alternative processes exist to bypass when circumstances demand.

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## 2021-2022 ASCLS-Michigan BOD Election Results

Kristin Landis-Piowar, Nominations Chair

The 2021/2022 Board of Director elections are complete, and the results are in! Thank you to everyone who took the time to vote for your new leadership and representatives on the board. We had a ballot return of about 30%, which is higher than for most years. Let's continue the voting streak next year by remaining engaged and encouraging your fellow members to vote!

I'm so thankful to the Nominations Committee members this past year (Stephanie Mabry, Lindsey Haveman, and Sharon Ziemba) for recruiting candidates and to all the candidates who selflessly decided to run. I hope you all continue to be involved in our great society in the future.

Here are the new members for the 2021/2022 ASCLS-MI Board of Directors:

President Elect: Meighan Sharp

Secretary: Sarah Barnes

Ascending Professional Director: Kate Hadlich

Government Affairs Committee: Michelle Russell

Nominations Committee: Alicia Kuzia (Chair-Elect) and Sandy Cook

District 1 Representatives: Mattie Brechbiel, Lindsey Haveman, Kathleen Hoag

District 2 Representatives: Roslyn McQueen, Allison Young, Shawn Videan

District 3 Representatives: Billie Ketelsen, Christina Lim, Kyle McCafferty

## Congratulations to the Newly Elected Board!

## High-Sensitivity Cardiac Troponin: A High-Level Overview

Chemistry Scientific Assembly: Chelsea McIntyre-Roe, MLS(ASCP)<sup>CM</sup>

One of the leading causes of death for men and women in the United States is heart disease. More than 800,000 Americans suffer from heart attacks every year. Assays used to detect circulating cardiac biomarkers are just one of the tools used by clinicians to evaluate and diagnose acute coronary syndrome (ACS). ACS is the umbrella term used to define a variety of conditions associated with a sudden decrease in blood flow to the heart including myocardial infarction (MI). Cardiac biomarkers release into the bloodstream when injury to the heart muscle occurs. Troponin I (TnI) and Troponin (TnT) are the cardiac biomarkers most often used as they are specific indicators of damage to the myocardium. Conventional troponin assays are widely renowned as the gold standard for diagnosing acute myocardial infarction (AMI) in patients presenting with classic MI symptoms including chest pain.

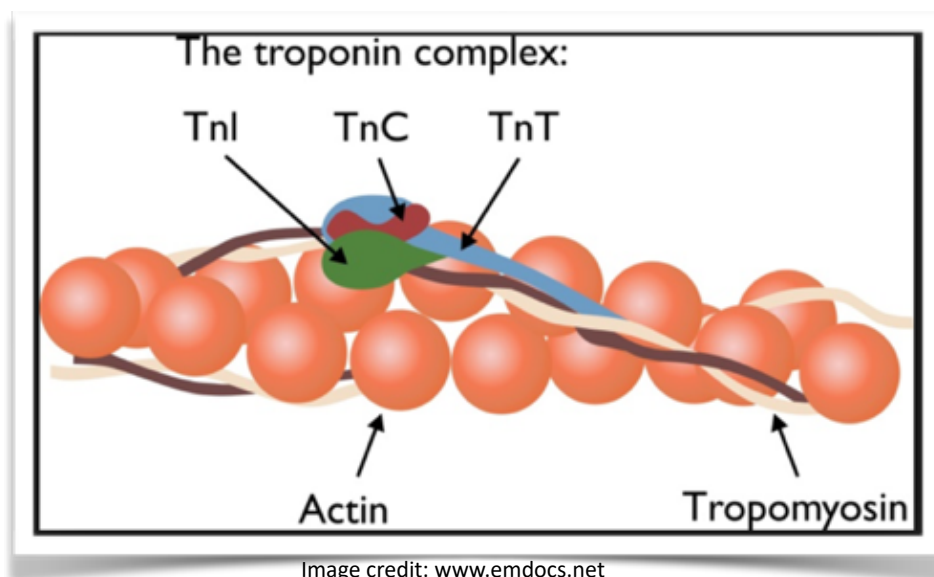
Due to the significant clinical importance of measuring circulating troponins, continual research has gone into improving the specificity and sensitivity of these tests. The most recent advancement is the production of high-sensitivity cardiac troponin assays (hs-cTn). The US Federal Drug Administration (FDA) approved the first hs-cTn assay for use in the United States in 2017. Hs-cTn assays offer precise measurements of lower levels of circulating troponin detecting concentrations 5- to 100-fold lower than conventional troponin assays. The International Federation of Clinical Chemistry (IFCC) defines an assay as high sensitivity when the assay has a  $\leq 10\%$  coefficient of variance at the 99th percentile value of the reference healthy population and can measure troponin concentrations below the 99th percentile in at least 50% of healthy individuals.

The advancement of hs-cTn assays has indicated numerous benefits. Studies indicate the increased sensitivity of hs-cTn assays contributes to the more rapid detection of myocardial injury and can support the early rule-out of acute myocardial infarction. General guidelines for integrating hs-cTn into cardiac evaluation algorithms lend to AMI rule-in or rule-out in 1 to 3 hours over the 6 to 12 hours used with conventional cTn assays. Early exclusion of AMI can allow patients to be discharged sooner, thereby freeing up beds in the emergency room. The use of hs-cTn assays also presents the opportunity to utilize sex-specific cutoffs. Women have lower, normal cTn values and often have lower levels of circulating troponins when experiencing AMI. Sex-specific cutoffs can better assist providers in accurately diagnosing AMI in women. Other benefits may include fewer subsequent blood draws on patients under observation as well as economic benefits for the organization.

Though the use of hs-cTn assays can be beneficial, there is still much to take into consideration. The population used to determine the 99th percentile is crucial to developing a successful algorithm. If the healthy population used does not reflect the patient population, or appropriately consider age, sex, or race, the 99th percentile cutoff may be too low leading to decreased specificity. In addition, the sensitivity of hs-cTn assays allows for the detection of extremely small levels of circulating troponin not necessarily associated with conditions of ACS. For example, patients with heart failure, diabetes, or chronic kidney disease can have higher levels of circulating troponin. Furthermore, otherwise healthy individuals can have detectable troponin levels due to other etiologies further complicating clinical interpretation. It is equally important to note that troponin levels above the 99th percentile are indicative of myocardial injury and do not specifically indicate AMI. In 2018, the American College of Cardiology, the American Heart Association, the European College of Cardiology, and the World Heart Federation worked together to update the Universal Definition of Myocardial Infarction. This update accounted for the increased use of hs-cTn. The fourth definition outlines the criteria for identifying type 1 and type 2 MI as including "...the detection of a rise and/or fall of cTn with at least one value above the 99th percentile..." with other clinical symptoms and imaging present in the patient (Mukherjee, D.). Universal definitions and guidelines are important for understanding the clinical utility of hs-cTn assays.

As hs-cTn assays become more widely used, a strong validation and implementation of the assay will be critical in its success. Laboratories will benefit from working with key stakeholders including but not limited to the Laboratory and ER Medical Directors, Cardiology teams, Hospitalists and nursing staff. Allowing ample time for education about the assay and creating a platform encouraging questions and feedback can create the buy-in from providers. High sensitivity troponin assays signify a breakthrough in evaluating ACS including AMI and can contribute to prompt diagnosis as well as have organizational and economic benefits. How-

ever, aspects spanning the entire healthcare system must be considered when implementing hs-cTn. The assay is only beneficial if those interpreting the results understand their clinical value. Care teams must work together and develop algorithms specific to their patient population to maintain the highest standards of patient safety and prevent unnecessary treatment or prolonged patient care.



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# Omicron Sigma Awardees at National Meeting

List submitted by Kathy Doig



First awarded in 1977, Omicron Sigma is the ASCLS President's Honor Roll for Outstanding Service. It provides lasting recognition of those dedicated members who volunteer their personal resources, time and energy to ASCLS. Recognition is at three levels: national, regional, and constituent society. This allows constituent society presidents, regional directors, and the ASCLS President to recognize members for outstanding service.

Name	State Society	Category
Abbey Hilden	Michigan	Constituent Society
Alicia Kuzia	Michigan	Constituent Society
Allison Young	Michigan	Constituent Society
Andrea Hickey	Michigan	Constituent Society
Christina Lim	Michigan	Constituent Society
Julie Hall	Michigan	Constituent Society
Kristina Martin	Michigan	Constituent Society
Mattie Brechbiel	Michigan	Constituent Society
Meighan Sharp	Michigan	Constituent Society
Michelle Russell	Michigan	Constituent Society
Paul Guthrie	Michigan	Constituent Society
Richard Benson	Michigan	Constituent Society
Sarah Lewis	Michigan	Constituent Society
Kate Hadlich	Michigan	National & Regional
Lynn Williams	Michigan	National & Regional
Rachel Morris	Michigan	National & Regional
Roslyn McQueen	Michigan	National & Regional
Suzanne Butch	Michigan	National & Regional
Kathy Doig	Michigan	National
Daniel deRegnier	Michigan	National, Regional & Constituent Society
Stephanie Mabry	Michigan	National, Regional & Constituent Society
Barbara Mannor	Michigan	Regional & Constituent Society
Billie Ketelsen	Michigan	Regional & Constituent Society
Kyle McCafferty	Michigan	Regional & Constituent Society
Carey Loveland	Michigan	Regional
John Gerlach	Michigan	Regional
John Ko	Michigan	Regional
Kathleen Hoag	Michigan	Regional
Lea Schebil	Michigan	Regional
Nineve Costa	Michigan	Regional
Romina Selzer	Michigan	Regional

## Save the Date! Attend the ASCLS Legislative Symposium and Labvocate!

Meighan Sharp, MLS(ASCP)<sup>CM</sup>. - Government Affairs Committee Chair, ASCLS-Michigan

The ASCLS Legislative Symposium will take place this fall! Mark your calendars for October 25 and 26, 2021 at the Hilton Alexandria Old Town in Alexandria, Virginia. Some of legislative issues that will be discussed will include:

- Laboratory workforce shortages
- Laboratory developed tests (LDTs)
- The effects of the Protecting Access to Medicare Act (PAMA) relating to the laboratory
- Laboratory's role in the COVID-19 pandemic.

It is never too late to become a Labvocate! There are several ways to raise awareness to our Congressional leaders. Don't hesitate to reach out to your member of Congress. To discover who your Representative and Senators are, visit [www.house.gov/representatives/find-your-representative](http://www.house.gov/representatives/find-your-representative) and [www.senate.gov](http://www.senate.gov). Call their offices and ask for the contact information for their congressional aide who handles health care issues. Someone in the office will be more than happy to give out an e-mail address. From there, start a conversation. Introduce yourself as a laboratory professional and let them know the issues you face daily and how decisions in Congress effect this profession.

To keep up on the issues, sign up for alerts on the Labvocate Action Center at [www.ascls.org](http://www.ascls.org)

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