



## President's Message

Stephanie K Mabry



### We Will Celebrate

To all those in the medical laboratory profession across the state of Michigan, Happy Medical Laboratory Professionals Week (MLPW)! Originally sponsored by ASCLS (then ASMT) in 1975, MLPW offers a time for increasing public awareness and appreciation of the medical laboratory profession and for celebrating our important role in health care. While the COVID-19 pandemic has increased public discussion of laboratory testing and given our profession opportunities to highlight our impact on patient care, it feels odd to think of celebrating at this time. However, we do have things to celebrate, even though they may differ from our "normal" celebrations.



**Normally at this time**, we would be celebrating another successful ASCLS-Michigan Annual Conference in the books. We would be recording our CE credits, printing our PACE certificates, and celebrating the fun we had with old friends and new alike. Instead, duty in the laboratory calls, and we celebrate our proficiency in validating molecular and serological testing at record pace; balancing new home, work, and life schedules; and ensuring each of our patients gets the quality results they deserve.

**Normally at this time**, we would be celebrating those who won awards at that Annual Conference, and we would be celebrating in their achievements. We would be celebrating our students with poster presentations, mock exam results, and scholarship fundraising. Instead, duty in the (virtual) classroom calls, and we celebrate the perseverance of our students and educators to adapt to an entirely new format of teaching and learning; to apply new methods and new techniques to study habits and pedagogy; and ultimately, to remain dedicated to the future of our profession.

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**Normally at this time**, we would be celebrating our new Board members who have been elected into leadership positions at varying levels of our organization. We would be sharing word of their installation to the Board of Directors with coworkers and employers, and would be celebrating their enthusiasm for the profession. Instead, duty in the public realm calls, and we celebrate the participation of our leaders in weekly calls with the CDC; in holding fervent discussions with elected officials; in creating viral social media posts; and in writing and submitting informative articles to various news outlets.

**Our profession plays such a critical role that we cannot help but celebrate our successes in battling COVID-19 thus far.**

- **While the fight will not end with the ending of Lab Week, neither will the celebrations.**
- **We will celebrate** our profession all along, and when we come together August 23-25 for the rescheduled Annual Conference, we will not only formally celebrate our scholarship beneficiaries, award winners, and elected Board members, but we will celebrate our collective proficiency, perseverance, and participation in this unprecedented time of public health.

- **We will celebrate** our passion for medical laboratory science, for health, and for our patients.
- **We will celebrate** our purpose of creating a positive impact in health care by assuring excellence in the practice of laboratory medicine.
- **And most importantly, we will celebrate** our people who make up this amazing profession.
- **Our people**, who are dedicated to quality laboratory services and to safe, effective, efficient, equitable, and patient-centered healthcare, not for fame or glory, but because it is right.
- **Our people**, who make all the difference in a patient's life, often with little recognition. Our people, who put the "professionals" in Medical Laboratory Professionals Week. And we will be proud.

**Proud of who we are, what we do, and why do it.  
Proud of the pivotal role medical laboratory professionals play in health care.  
And proud to say**

**#WeAreASCLS.**



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### **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.

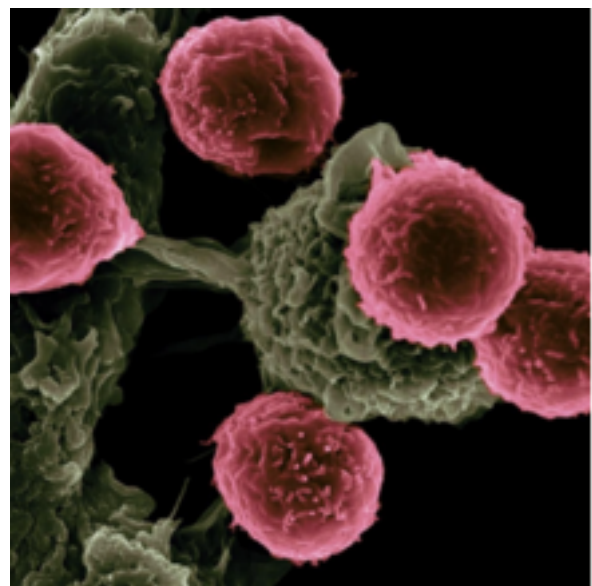
## Cancer Immunotherapy: A Revitalized Approach to Treating Malignancies

Jessica Jenkins, MLS(ASCP)<sup>CM</sup>, Scientific Assembly, Immunology

While cancer immunotherapy is not a new concept, its use has been increasingly studied and applied in recent years. Cancer immunotherapy is based around the concept of augmenting the body's own anti-tumor response. The first available therapy was a recombinant IFN- $\alpha$  for hairy cell leukemia that received FDA approval in 1986. Despite promising results, the development of immunotherapeutic agents was slow until the discovery of immune checkpoint inhibitors (ICIs) and CAR-T therapy in the 2010s. Currently, there are a variety of immunotherapies available including cancer vaccines, adoptive cell transfer, immunomodulation, monoclonal antibodies, and immune checkpoint inhibitors. Some of these therapies have been transformative in the treatment of cancers such as melanoma, refractory B-cell acute lymphoblastic leukemia, and bladder cancer. However, as the use of cancer immunotherapy increases, so does the incidence of side effects which can range from mild to severe or even fatal.

The potential side effects of immunotherapy are dependent upon the type of therapy administered. Cancer vaccines can contain either DNA or RNA, but most success has been seen with mRNA-based vaccines. These vaccines induce the uptake of mRNA into antigen presenting cells which in turn develop the mRNA into a tumor-associated antigen that it presents to T-cells. Vaccines also use mRNA that encodes pro-inflammatory cytokines to enhance the immune response. Cancer vaccines produce relatively mild side effects when compared to other cancer immunotherapies. Typically, patients experience fever, chills, fatigue, and other 'flu-like' symptoms. As these symptoms may mimic an infection, it's important to be able to rule out a pathogenic cause. In rare cases, patients may develop an autoimmune disease as a result of cancer vaccine therapy.

CAR-T cell therapy, a type of adoptive transfer, takes the patient's own T cells and manipulates them to express a 'chimeric antigen receptor' or CAR, which is specific for a tumor antigen. CAR-T therapy is associated with the development of cytokine release syndrome (CRS) which results from T-cell activation that induces a systemic inflammatory response. It is most often characterized by clinical symptoms such as fever, muscle pain, rash, and fatigue. More severe forms of CRS can lead to edema, hypotension, and multi-organ dysfunction producing aberrant lab results. Increased ferritin, ALT/AST, and CRP, and decreased fibrinogen are common in CRS. CAR-T therapy is also associated with the development of B-cell aplasia when used as a CD19-specific therapy for B cell leukemia.



*Treatment vaccines can help the immune system learn to recognize and react to antigens and destroy cancer cells that contain them.*

Credit: Victor Segura Ibarra and Rita Serda, Ph.D. [www.cancer.gov](http://www.cancer.gov)



Immunomodulation is most commonly executed using cytokines. Cytokines are small proteins involved in cellular signaling. The first approved immunotherapy, recombinant IFN- $\alpha$ , would be considered a cytokine treatment. Most cytokine treatments use interferons (IFNs) and interleukins (ILs), though other biological agents are available as well. The predominant goal of cytokine immunotherapy is to activate T-cells and other immune cells to kill tumor cells. The most common side effects of cytokine therapy are general flu-like symptoms with fever, chills, and fatigue. As with cancer vaccination, it's imperative that infection is ruled out as the cause of these symptoms. There is also the potential for the development of cytokine release syndrome and vascular leakage.

Monoclonal antibody therapies vary in their composition and purpose, but usually are lab-developed antibodies that are specific for a particular tumor marker. In the normal immune response, an antibody attached to something on the cell surface marks that cell for death. When the tumor-specific monoclonal antibodies bind to the malignant cells, they are then identified and killed by T-cells. The side effects of monoclonal antibody therapy are generally mild and flu-like, similar to cancer vaccines and cytokine therapy. More serious side effects are possible and can include allergic reaction, capillary leak syndrome, congestive heart failure, and inflammation in the lungs.

Hypoalbuminemia is common in capillary leak syndrome, and an elevated B-type natriuretic peptide is expected in congestive heart failure. Immune checkpoints regulate the immune system by maintaining the balance between protection against pathogens and self-tolerance. Some tumor cells are capable of producing proteins that bind inhibitory receptors on T-cells. Immune checkpoint inhibitors (ICIs), which are mainly aimed at PD-1/PDL-1 and CTLA-4, help T-cells to continue attacking tumors when they would otherwise be inactivated by the tumor-produced inhibitory antigens. ICIs have had a positive impact on the treatment of several different malignancies including lymphoma, lung cancer, and ovarian cancer. However, ICIs delivered systemically can produce dermatologic, gastrointestinal, hepatic, endocrine, rheumatologic, respiratory, and neurologic

side effects. Patients may present with elevated ALT/AST with or without elevated bilirubin, hypothyroidism, hyperthyroidism, elevated ACTH, electrolyte imbalance, and variable other laboratory anomalies. Rarely, patients may even develop primary adrenal insufficiency (Addison's disease) or type I diabetes.

Immunotherapy encompasses a myriad of different cancer treatments. If current trends continue, it is likely that immunotherapeutic treatment options will expand and continue to change and improve. The applicability, effectiveness, and potential side effects of immunotherapy vary by type. While many of these side effects are primarily clinical, laboratory evaluation is especially useful for evaluating excessive inflammatory responses, differentiating infection and inflammation, assessing endocrine function, and monitoring for the development of autoimmune reactions.

## References

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# Blood Bank Update:

## FDA Final Guidance on Platelet Bacterial Testing

Billie Ketelson, Scientific Assembly, Blood Bank



In September 2019, the FDA released their final guidance on Platelet Bacterial Testing, a guidance the Blood Bank labs have been anticipating for the last few years. With the issuance of this final guidance, changes are required for both the blood collection center and the in hospital laboratory.

At the blood center, there are two new approved tests that can be performed prior to sending the platelet to the hospital. This testing includes Pathogen Reduction technology (PR) and Large Volume Delayed Sampling (LVDS).

- **PR** technology uses a psoralen additive that is inactivated by UV light during the platelet processing. The UV inactivation process destroys many bacteria and viruses.
- **LVDS** is a culture technique that requires a larger sample of the platelet product and is removed 36-48 hours after collection for extended bacterial testing. Depending on sample conditions, the platelet product will have a shelf-life of 5-7 days.

In the blood bank proper, the options for bacterial testing is limited to a Platelet PGD (Pan Genera Detection) test on the bench, unless developing an in-house micro-culturing program is desired.

- **PGD** is a rapid cartridge test performed in-house that uses a small sample from each platelet unit prior to dispensing to patients. This testing occurs on day 4 and 5 at a minimum to ensure the platelet is not contaminated but can be extended to day 6 and 7 as long as the testing remains negative. If PGD is performed in the laboratory, PR and LVDS is not required.

No matter the testing route that is decided on within your own institution, the final guidance does require a review of workflow at both the blood center and hospital laboratory.

### References:

- FDA Guidance on Platelet Bacterial Testing LVDS, FDA <https://www.fda.gov/media/123448/download>
- Pathogen Reduction Technology, Cerus, [www.cerus.com](http://www.cerus.com)
- PGD, Verax Biomedical <https://www.veraxbiomedical.com/products/platelet-pgd-test/>

Free CE module if you are interested in learning more at [www.bloodsafetyonline.com](http://www.bloodsafetyonline.com)



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- Recognition and Mitigation of Serious Transfusion-Associated Adverse Events: TACO, TRALI and Bacterial Sepsis: Part 1
- Recognition and Mitigation of Serious Transfusion-Associated Adverse Events: Part 2

## Read this great article in Forbes Magazine from an ASCLS member

EDITORS' PICK | 40,071 views | Apr 22, 2020, 02:30pm EDT

# Beating Pandemics Like COVID-19 Requires More Medical Laboratory Professionals, This Virologist Explains



Rodney Rohde Contributor

Coronavirus Frontlines Contributor Group 

*Rodney Rohde, PhD is a Professor and Chair for the Clinical Laboratory Science (CLS) Program in the College of Health Professions at Texas State University.*

<https://www.forbes.com/sites/coronavirusfrontlines/2020/04/22/beating-pandemics-like-covid-19-requires-more-medical-laboratory-professionals-this-virologist-explains/#c4d5136e3263>

## Recognize Lab Heroes During Covid-19 Pandemic

To all the clinical laboratory professionals on the front lines, thank you for what you do every minute of every day. Each of you are saving lives and improving the quality of patient care in your community. Recognition is due for your extraordinary colleagues that exhibit professionalism and compassion while performing clinical laboratory duties. Nominate your extraordinary colleague for recognition as a Lab Hero. Selected nominees will receive a grant for use for educational or continuing education purposes. Lab Hero will receive a \$750 honorarium and each runner-up (2) will receive a \$375 honorarium.

Submit the following information by email with subject line of Lab Hero to [mlbishop5@bellsouth.net](mailto:mlbishop5@bellsouth.net) by July 15, 2020.

Nominator's name:

Nominator's email:

ZIP Code:

Nominee's name:

Nominee's credentials:

Nominee's email address:

Statement of why this nominee is a Lab Hero (maximum 500 words):

- Please make sure that submissions do not violate any patient confidentiality rules or institutional policies. Identification of where the nominee works is not required.
- All submissions will be acknowledged, shared, and reviewed by a team of healthcare professionals. Selected Lab Heroes will be notified in early August 2020.
- Honoraria are sponsored by Healthcare Consulting Division of Sheila N. Bishop, CPA, PA.
- Please share this post/email with your colleagues by social media or email.

For more information, please contact Michael L. Bishop, MS, MT(ASCP), [mlbishop5@bellsouth.net](mailto:mlbishop5@bellsouth.net),  
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**#LabHeroes #WeSaveLivesEveryday**

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