

The Food and Drug Administration (FDA) Issues New Zika Guidance For Blood Centers

The FDA has issued a final guidance recommending universal individual donation Zika virus (ZIKV) nucleic acid testing for all donations in all U.S. blood collection facilities.

“The FDA has critical responsibilities in outbreak situations and has been working rapidly to take important steps to respond to the emerging Zika virus outbreak,” said Luciana Borio, MD, the FDA’s acting chief scientist, in a statement Friday, August 26. “We are issuing this guidance for immediate implementation in order to better protect the U.S. blood supply.”

An abbreviated version of the guidance was released earlier to ABC member centers in an [MCN](#) and highlighted the key provisions of the final guidance for whole blood and blood components excluding source plasma.

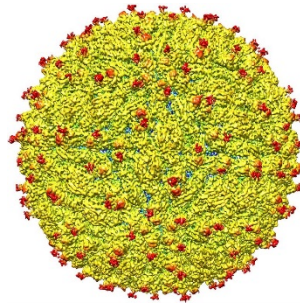
The communication also noted U.S. states and territories with one or more reported locally-acquired mosquito-borne cases of ZIKV – Florida and Puerto Rico—must implement the guidance immediately. Collections should cease in these areas until these recommendations are implemented. The following states should be in compliance no later than September 23: Alabama, Arizona, California, Georgia, Hawaii, Louisiana, Mississippi, New Mexico, New York, South Carolina and Texas. All other states and territories must be in compliance no later than November 18, 2016.

To read the full guidance, click [here](#).

When talking to the media about the topic, Louis Katz, ABC’s chief medical officer at

ABC, has been reinforcing the following messages:

- Members of ABC are committed to the safest possible blood supply and will work with the test manufacturers to comply with FDA Guidance.



- Testing is ongoing for all Florida donors—the only place where (limited) local transmission has been observed. Testing is also being conducted in the high-risk areas of Texas and will be brought online in the rest of the state in compliance with the guidance, as well as in those other areas identified in the first tier in the guidance (e.g. those areas that are to be up and running in four weeks). That effort preceded issuance of the guidance. The amount of work to do

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NEW FDA ZIKA GUIDANCE (continued from page 1)

this in short timeframes is/will be TITANIC, but see bullet 1.

- Testing labs and the test vendors are working feverishly to allow testing to start on-time in the areas subject to the 12-week timeline. If all goes smoothly that goal seems to be feasible, according to vendor contacts. For everything to go smoothly in an incredibly complex set of processes becomes critical for the implementation of this guideline within this time period.

ABC has been in contact with members of the [FDA](#) and [Assistant Secretary of Health and Human Services](#) to reinforce the constraints associated with the rapid extension of testing to all blood centers. The issues of cost and reimbursement were emphasized to the Assistant Secretary. The [FDA has responded](#) that they believe there is too much uncertainty in regards to the spread of ZIKV and risks from sexual contact.

While the guidance issued as final, ABC will be assembling the thoughts of the membership and drafting comments to FDA.



New ISBT Codes for Latest Zika Guidance Released

The ICCBBA issued new codes in relation to the new Zika guidance from the Food and Drug Administration (see this newsletter's top story, "Universal Testing for Zika Virus at All U.S. Blood Centers. The codes for "Test for Zika virus negative" and "CMV seronegative; Test for Zika virus negative" can be encoded into the ISBT 128 Special Testing General Data Structure. This was in response to several requests for an ISBT 128 coding solution. Contact ICCBBA with any questions at iccbba@iccbba.org. To read more, [click here](#).

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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LETTERS TO THE EDITOR

America's Blood Centers' API Scholarship Program, made possible by a grant from the Foundation for America's Blood Centers (FABC), provides scholarships to blood industry professionals at ABC's member blood centers to supplement costs for attendance to an ABC Specialty Workshop or Meeting. ABC recently held the ABC Summer Meeting in Honolulu, Hawaii, on August 1 to 4. Below are edited excerpts from ABC Scholarship winners who attended the ABC Summer Meeting. Thank you to all the winners and those who applied!

What an honor to receive a scholarship to the ABC Summer Meeting. I want to thank both FABC and ABC for making the scholarship available. In addition, my gratitude goes to LifeShare Blood Centers for submitting me as a nominee for the scholarship. It was a great opportunity to be part of the Summer Meeting. The topics presented are challenges all blood centers are facing. The open discussions after the presentations showed the various ways each of us can approach the same issue. They also brought us together as a community. Networking with others also opened up channels for collaboration. The ABC staff went above and beyond to make sure everyone felt welcome. I met new people from across the country and was able to reconnect with others I had talked with or met previously. It was a wonderful experience. –Anna Putnam, director of business development, LifeShare Blood Centers.

The ABC Summer Meeting was an outstanding experience from start to finish. The speakers were excellent and the material was focused enough to have a theme, while broad enough to keep me engaged with interest. Highlights included hearing from industry outsiders about leadership practices and specifically millennials. Succession planning was an area which I've identified as high risk in our current environment. Some of the speakers really helped me derive talking points which I'll discuss with my leadership team. Having been in the industry for nine years in both IT and Operations, it was excellent to network with peers and hear insights about where the industry was headed and potential opportunities. Receiving this scholarship enabled me to attend this wonderful event, which would've been prevented due to financial constraints otherwise. As a smaller blood center hearing how those on a larger scale operate was invaluable. I'm more excited about the industry as ever after attending the ABC Summer Meeting. –Paul Ruddy, director of IT & operations, Central Jersey Blood Center.

I sincerely thank ABC's API Scholarship Program for granting me a scholarship to this year's ABC Summer Meeting. The many presentations gave me valuable knowledge on the current issues facing blood banking today. This knowledge is very timely and directly applicable to the teams and workgroups on which I participate at my blood center. Of particular interest to me was Dr. Katz' discussion of the New Common Rule and Protection of Human Research Subjects. I also enjoyed Dr. Armitage's talk, Patient-Centric Transfusion - Spreading the News. We are all in the business of saving lives, and that intrinsic value draws and maintains many dedicated staff. Succession Planning for your Aging Donor Base, Vanessa Merina, left me with several ideas that will help me lead, and contribute to these critical ongoing discussions. Hearing these issues discussed by so many experts in our industry has provided me with a broader understanding of the issues' impacts and implementation strategies' risks and benefits. Many wonderful memories of the venue and corporate evening adventure—luau is now checked off my bucket list. I am very grateful for the foundation grant and being selected to attend the ABC Summer Meeting - it was a wonderful experience, and I would not have been afforded this opportunity without the scholarship. –Linda White, director of clinical service, Indiana Blood Center. ♦

Ready for download

Presentations and materials from ABC's Summer Meeting are now ready for download on the ABC Member Site.

Click [here to view and download](#).



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It's About *Life.*

INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.



America's Blood Centers Professional Institute (API) is One Step Closer to Launch

API hit a significant milestone this week as ABC launched the new infrastructure that will support integrating our [member](#) and [public](#) websites with our new learning management system. In a few short weeks, webinars and the new eLearning courses can be accessed through the API Learning Portal on the Education pages of those sites. The API Learning Portal and our initial course offerings were made possible through the generosity of many ABC member centers and blood industry contributors to the Foundation for America's Blood Centers (FABC) capital campaign, and we sincerely thank you for making this possible.

At the request of ABC members, the very first eLearning courses will include "Introduction to the Blood Banking Industry" and courses in leadership development and customer service. Some key information for ABC Members on these courses are as follows:

- The leadership development program and customer service program will include core courses that cross industries and custom-built courses for the blood banking industry. The custom-built leadership and customer service course development will begin later this year.
- A survey will go out next week to all members to identify what training topics in these areas are the most meaningful to you.
- The API Learning Portal will launch as a pilot program. HR leaders will be asked to identify four pilot participants at their member blood centers in a separate survey next week. These individuals will play an essential role in evaluating the course offerings.

ABC members get access to the webinars as part of their member benefits. There is no charge for members to access "Introduction to the Blood Banking Industry," and pilot participants can access all eLearning courses without a charge. Blood centers may register additional employees for an annual fee of \$100 for full access to all eLearning courses. Non-members may register for \$250 per individual program, e.g., leadership development; customer service.

ABC wishes to thank the members of the API Curriculum Development Committee for their enthusiasm, intellect, and imagination in developing the strategy and curriculums for the launch. ABC members should watch for a survey asking for your input on additional training topics.

Additional details about accessing the API Learning Portal will be forthcoming via MCN. Meanwhile, please contact [Rachelle Fondaw](#) with any questions about the API. ♦



RESEARCH IN BRIEF



Two probable Zika virus (ZIKV) transmission by transfusion cases were reported in Brazil. Both transfusion recipients received platelets from a single apheresis donor in January. The donor called back five days after donating and self-reported symptoms consistent with Zika infection: rash, and joint and eye pain. An investigation by the hospital that transfused both patients—one a patient with primary myelofibrosis syndrome and the second a leukemia patient who had undergone bone marrow transplantation—showed that while pre-transfusion samples were negative for ZIKV, samples post-transfusion (6 and 51 days in patients 1 and 2 respectively) were positive for ZIKV by PCR assay. Further, molecular sequencing and phylogenetic analysis of the ZIKV RNA strongly suggest the identity of the donor and two patients' ZIKV strains. Both recipients remained asymptomatic.

Citation: Motta I., Spencer B., Cordeiro da Silva S., *et al.* Evidence for Transmission of Zika Virus by Platelet Transfusion. *NEJM*. August 17, 2016. DOI: 10.1056/NEJMc1607262.

Compensation could encourage living kidney donations. Patients needing renal transplants often die while on waiting lists for organs due to the shortage of kidneys under current policies. Telephone survey research among U.S. voters explored their willingness to donate a kidney and the impact of financial compensation on that willingness. Of the 1,011 respondents, 68 percent said they would donate the organ to anyone, 23 percent only to certain people, and 8 percent would not donate for no compensation. Fifty-nine percent indicated \$50,000 would make them more likely to donate, 32 percent said it would have no influence on their likelihood of donating, and 9 percent would be negatively influenced by compensation. The authors concluded that “Because most registered voters favor such payments, and because thousands of lives might be saved should compensation increase the number of transplantable kidneys, laws and regulations prohibiting donor compensation should be modified to allow pilot studies of financial incentives for living kidney donors. Such studies could “result in promulgation of evidence-based policies.”

Citation: Peters T.G., Fisher J., Gish R.G., *et al.* Views of U.S. voters on compensating living kidney donors. *JAMA Surgery*. August 2016;151(8):710-716. DOI:10.1001/jamasurg.2016.0065.

Zika infects neural stem cells in adult mice. Much of the focus on Zika virus has been on its impact in fetuses infected *in utero*, with the resulting congenital Zika syndrome initially recognized as microcephaly. A study in *Cell Stem Cell* demonstrates that neural stem cells in adult mice are susceptible to the virus leading to cell death and reduced proliferative capacity. The findings argue for close, long-term follow-up of adults after infection to assess its impact on central nervous system/neurological functions.



Citation: Li H., Saucedo-Cuevas L., Regla-Nava J.A., *et al.* Zika virus infects neural progenitors in the adult mouse brain and alters proliferation. *Cell Stem Cell*. August 18, 2016. DOI: <http://dx.doi.org/10.1016/j.stem.2016.08.005>. ♦

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Lisa Spinelli at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.



RECENT REVIEWS

Platelet function testing in cardiovascular surgery (CVS). Bleeding during and after CVS is common and increases patient morbidity and mortality. Large populations are receiving anti-platelet drugs before or at the time of these operations and are at an increased risk for bleeding. This review discusses the most common methods in use for assessing platelet function, their use in CVS, and their impact on blood loss. Key unanswered questions from the review are whether platelet function testing or transfusion for platelet dysfunction improves clinical outcomes.

Citation: Agarwal S. Platelet function in cardiac surgery. *Transfusion Medicine*. August 18, 2016. DOI: 10.1111/tme.12335. ♦

BRIEFLY NOTED

Clinical decision support (CDS) in an electronic medical record (EMR) for transfusion at Stanford is temporally associated with 42 percent decrease in rate of red blood cell (RBC) use and improved clinical outcomes. Investigators at Stanford have used CDS integrated into physician order entry in their EMR (Epic Systems) in an effort to improve RBC transfusion practices in accordance with multiple published guidelines. A “best practices alert” is provided at the time RBCs are ordered, based on consensus criteria developed after an interdisciplinary literature review and process. Orders outside the criteria are met with a real-time message emphasizing appropriate practices that requires acknowledgment and either rescission of the order or provision of a clinical rationale for transfusion outside them. Comparing 24 months before and 60 months after implementing the CDS in 2010, RBC transfusion rates fell from 18.3 to 10.7 RBC units/100 patient days. During those intervals, hospital mortality fell, and 30-day readmission rates and lengths of stay were stable. The authors conclude “While the improvement in patient outcomes concurrent with reduction in blood transfusions cannot be stated to be causal, it is reassuring that there have been no demonstrable adverse patient outcomes after hospital-wide adoption of restrictive transfusion practices, as also reported by others.” Quality of life outcomes related to restrictive transfusion were not reported.

Citation: Goodnough LT, *et al.* How I use clinical decision support to improve red blood cell utilization. *Transfusion*. August 12, 2016. DOI: 10.1111/trf.13767.

The Centers for Disease Control and Prevention released an updated interim recommendation for initial laboratory testing and evaluation of infants with possible congenital Zika virus (ZIKV) infection. The new recommendation is that all infants born to mothers with laboratory evidence of ZIKV infections should have physical and neurological assessment as well as hearing screenings, head ultrasounds and lab work—both molecular (real-time reverse transcription–polymerase chain reaction) and serologic (immunoglobulin M [IgM]) testing—to assess if the baby has congenital ZIKV infection. Cord blood is not recommended for use in testing.

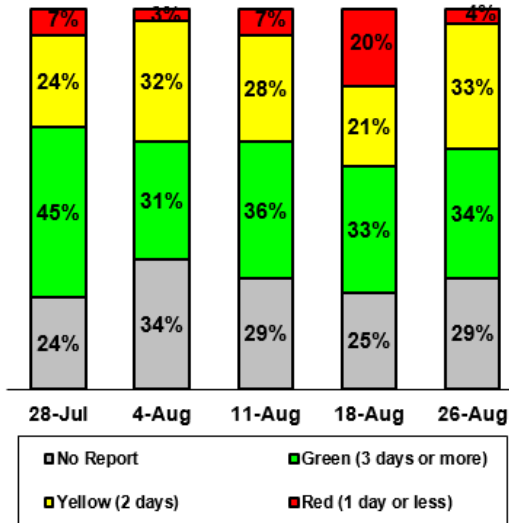
Citation: Russell K., Oliver S.E., Lewis L., *et al.* Update: Interim Guidance for the Evaluation and Management of Infants with Possible Congenital Zika Virus Infection — United States, August 2016. *MMWR Morb Mortal Wkly Rep*. ePub: August 19, 2016. DOI: <http://dx.doi.org/10.15585/mmwr.mm6533e2>.

The Food and Drug Administration (FDA) announced Bayer issued an extension to their voluntary drug recall for Kogenate FS Antihemophilic Factor (Recombinant) for hemophilia A patients. The recall was originally issued on July 21 on two lots of Kogenate FS 2000 IU vial adapters. Now Bayer is extending that recall to include eight additional lots, including Kogenate FS 250, 500, 1000 and 3000 IU vial adapter lots. For the full recall, lot numbers, NDC numbers, and expiration dates, click [here](#). (Source: FDA, August 22, 2016.) ♦

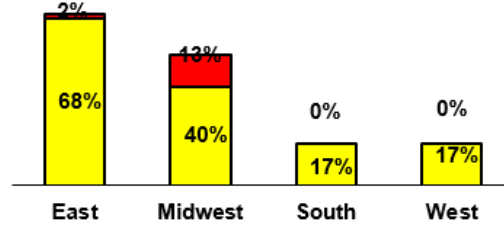


STOPLIGHT®: Status of the ABC Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, August 25, 2016



Daily updates are available at:
www.AmericasBlood.org

Percent of Total ABC Blood Supply Contributed by Each Region
 East: 20%; Midwest: 25%; South: 24%; West: 31%

AMERICA'S BLOOD CENTERS' Information Technology Workshop

Minneapolis, MN – September 13-14, 2016



Innovative Blood Resources and our Minnesota Division, Memorial Blood Centers, are pleased to host the 2016 ABC Information Technology Workshop near our headquarters in St. Paul, Minnesota. Attendees will benefit from the shared knowledge of fellow IT professionals while exploring topics impacting our changing and interconnected healthcare environment. We look forward to seeing you in September!

– Donald C. Berglund, CEO, Innovative Blood Resources



Negotiated hotel room rate: \$199 + tax
http://bit.ly/renaissance_minneapolis

2016 Workshop Fees (early bird/regular)
 2-day registration: \$410/\$465

Registration opens **July 13**. Non-members (non-vendor), contact Lori Beaston at lbeaston@americasblood.org for invitation, registration fees and information.

Scholarship opportunities available to ABC members to cover the cost of registration fees and help with travel expenses. Application form and details will be made available when registration opens.

Sponsorship opportunities available. Contact Jodi Zand at jzand@americasblood.org for details.

Minneapolis–Saint Paul International Airport (MSP) is served by most major US airlines. Visit www.mspairport.com.



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INFECTIOUS DISEASE UPDATES



The Centers for Disease Control and Prevention (CDC) researchers announced babies infected with Zika late into a mother's pregnancy can develop late-onset microcephaly. Previous statements from the CDC had noted a strong association with Zika infections within the first trimester and microcephaly, but only a "negligible association" in the second and third trimesters. While mothers infected in later stages of their pregnancies may appear to give birth to babies with normal-sized heads, some of those babies' brains are actually afflicted with microcephaly, said William Dobyns, MD, professor of pediatrics and neurology at Seattle Children's Hospital, during a press conference on August 10. By about six months of age, the babies' brains have stopped developing, he noted. The findings have not been published as of yet. Babies infected in utero are also thought to have a heightened risk of [contracting other birth defects](#), including vision and hearing problems, developmental delays, seizures and more, as listed by the CDC. (Source: *MedScape*, [New Zika Threat to Infants: Late-Onset Microcephaly](#). August 11, 2016.)

The first locally-acquired vector-borne Zika virus (ZIKV) infection was confirmed outside Miami-Dade County this week. On August 23, Governor Rick Scott of Florida announced the new infection in Pinellas County, which contains Tampa Bay. The Florida Department of Health was conducting epidemiological investigations to uncover who had contact with the infected person. ♦

REGULATORY NEWS

A Food and Drug Administration panel met to discuss over-the-counter (OTC) tests for infectious disease diagnostics last week. There were no particular infectious disease OTC test applications presented or discussed at the panel; however, the panel did agree OTC tests for sexually transmitted diseases were likely to be more beneficial than harmful to the public. The committee members did agree that any OTC infectious disease tests must adhere to the same sensitivity and specificity standards as laboratory tests and should include information that encourages the patient to contact their primary care physician with the results, especially those tests indicating a positive result. (Source: *MedPage Today*, [FDA Advisors: Over-the-Counter Tests for STIs Offer Benefits](#). August 17, 2016.) ♦

GLOBAL NEWS

Twelve districts of Greece have banned blood donations after four cases of locally-contracted malaria were reported this year. According to the Hellenic Center for Disease Control and Prevention, 65 cases of malaria were reported in Greece this last year, 50 of them from immigrants and 11 from travel-related cases. The country has had a debt crisis for six years, tanking its economy and causing government-run programs like municipal spraying for mosquitoes to be severely cut back. (Source: *BBC News*, [Greece bans blood donations in 12 districts over malaria – reports](#). August 21, 2016.)

Health officials in the Bahamas have confirmed three new cases of Zika infection. The first confirmed Zika infection on New Providence island in the Bahamas was found on August 10 and was determined to be travel-related. The three new cases are a mix of travel and vector-borne cases, [said the Minister of Health in a press statement](#) on the same island. Of the four total cases, two are travel-related, two were locally acquired. (Source: Bahamas tourism press release, August 23, 2016.)

In an opinion-editorial (op-ed) in a local Caribbean newspaper, the writer calls for an end to Venezuelan tourists without a health certificate. The writer notes that Venezuelan travelers have brought dengue and chikungunya to the island(s) before and now a recent outbreak of malaria has hit the economi-

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GLOBAL NEWS (continued from page 8)

cally unstable South American country. “One thing we can be sure of if malaria comes to the Caribbean as a pandemic, we can say goodbye to the tourism industry as we know it,” writes the author. (Source: *Curaçao Chronicle*, [Time to Stop Visitors From Venezuela From Entering The Caribbean Without A Treatment Certificate](#). August 17, 2016.)

The European Commission recently published the results from a 2013 survey of 30 member nations in the European Union on their blood product industry. The document titled “The Application of Directive 220/98/EC on Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components” reports on 2012 activities from separate E.U. member nations. Some highlights included the export of blood components from E.U. member nations Finland, France and Italy to countries Switzerland and the U.S. to E.U. nations Greece and Ireland. The export of plasma for fractionation, or lack thereof, and which countries had surpluses, e.g., Italy and Germany, and shortages, e.g., Bulgaria and Hungary, were also included in the report. (Source: *International Blood and Plasma News*, July 2016.) ♦

COMPANY NEWS



A developer of infectious disease testing products, Chembio Diagnostics, announced its products will become available throughout the Caribbean via an exclusive distribution agreement with Isla Lab Caribbean. Chembio Diagnostics will now be available in 25 nations throughout the Caribbean Islands with the new agreement. Some of the products being distributed through Isla Lab Caribbean will be those testing for Zika, HIV, syphilis, dengue, and chikungunya. (Source: [Chembio press release](#), August 18, 2016.) ♦

MEETINGS

- Sept. 8 **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.**
This free, first-come-first serve, public workshop titled the “[Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval](#)” was organized to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products subject to premarket approval, including stem cell-based products. The workshop will take place at White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room in Silver Spring, Md.
- Sept. 12 - 13 **FDA Public Hearing on HCT/Ps, Bethesda, Md.**
This public hearing was created to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found [here](#).

MEETINGS (continued from page 9)

Sept. 13-14

ABC IT Workshop, Minneapolis, Minn.

Experts in the field will gather in Minneapolis to discuss the implications of blood center corporate mergers on IT, service metrics, and cost saving initiatives. Come for the discussions on pressing IT topics and stay to network with your peers at this ABC workshop. To register or learn more, contact the ABC Meetings Department at (202) 654-2901 or e-mail: meetings@americasblood.org.

Sept. 21

Red Cell Genotyping 2016: Clinical Steps, Bethesda, Md.

The BloodCenter of Wisconsin (BCW) and the Department of Transfusion Medicine at the National Institutes of Health (NIH) Clinical Center, are co-hosting the 6th Annual Red Cell Genotyping Symposium at Lister Center Auditorium, National Library of Medicine, NIH Building 38A, 8600 Rockville Pike, Bethesda, Md., from 8:25 a.m. to 4:15 p.m. This symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. For information, program fee and advance registration visit BCW's [website](#) or contact Phyllis Kirchner phyllis.kirchner@bcw.edu.

Oct. 6 – 7

Pre-Clinical Evaluation of Red Blood Cells for Transfusion, Bethesda, Md.

The Food and Drug Administration is holding a free public workshop to discuss new methodologies for pre-clinical evaluation for the safety and efficacy of red blood cell transfusion products. The workshop is being held in partnership with the National Heart, Lung and Blood Institute; National Institutes of Health (NIH); the Department of Defense; and the Office of the Assistant Secretary for Health, Department of Health and Human Services and is located on the NIH campus with the Ruth Kirschstein Auditorium, Natcher Conference Center, Bldg. 45, 9000 Rockville Pike, Bethesda, MD. To register for the workshop, click [here](#).

Oct. 22-25

2016 AABB Annual Meeting, Orlando, Fla.

The AABB Annual Meeting is a health care professional event for those in the fields of transfusion medicine, cellular therapies, and patient blood management. AABB's 2016 Annual Meeting offers opportunities to learn the latest in the field, advance your career, explore state-of-the-art products and services, and network with your colleagues. The meeting will be held at the Orange County Convention Center in Orlando, Fla. More information is available at www.aabb.org/annual-meeting.

Oct. 31 – Nov. 1

FDA 510(k) Submissions Workshop, Washington, D.C.

AdvaMed hosts FDA and industry experts to teach the basics of 510(k) submissions. Learn about the FDA's updates to the 510(k) process, considerations for determining a product's regulatory route to market, factors to consider when planning and assembling a 510(k) submission. The workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register [here](#).

Nov. 2

FDA IDE Submissions Workshop, Washington, D.C.

Learn the regulatory and practical guidelines governing when an investigational device exemption is required during this interactive AdvaMed workshop. The workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register [here](#). ♦



CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for ABC Newsletter subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Chief of Donor Operations. SunCoast Blood Bank, serving four counties on Florida's Gulf Coast is seeking a blood bank professional to direct and oversee our recruitment, collections, therapeutic services, supply chain and facilities operations. The successful candidate will have the ability to think strategically and have the organizational skills necessary to plan and execute varying directives which will further the organization's mission. Requirements for this position include a bachelor's degree in healthcare management or other equivalent field; MBA preferred. Eight years blood bank operational experience, five of which includes senior management experience. Competitive salary and benefits package. To apply please submit cover letter, salary requirement and resumes to jobs@scbb.org. Applicant drug testing required. EOE.

Outside Sales Representative/Event Planner (Lawton, Oklahoma). This position must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain their support in meeting community needs for volunteer blood donors. Responsibilities will include providing service excellence in organizing and promoting mobile and donor center blood programs and blood donation events; assessing, developing and implementing strategic and tactical plans to achieve blood donor recruitment objectives and goals. They are expected to develop a customer-focused culture that will result in successful community partnerships and blood donor awareness. Job duties include scheduling blood drives in established territory to meet established goals, including major and minor holidays. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Solicit and recruit new groups and organizations for mobile drives within established territory or region. Rebook recurring blood drives for the following year. Develop and maintain collaborative working relationships with key accounts. Give presentations and represent Oklahoma Blood Institute in order to promote blood collection. Qualifications: Associate's or bachelor's degree preferred, one to three years' sales experience, and valid driver's license. Salary: Competitive salary, commission plan, and excellent benefits package. How to apply: <https://obi.org/careers>.

Outside Sales Representative/Event Planner (Fort Smith, Arkansas). This position must develop new partnerships with targeted decision makers in community

organizations, educational and religious institutions and businesses to gain their support in meeting community needs for volunteer blood donors. Responsibilities will include providing service excellence in organizing and promoting mobile and donor center blood programs and blood donation events; assessing, developing and implementing strategic and tactical plans to achieve blood donor recruitment objectives and goals. They are expected to develop a customer-focused culture that will result in successful community partnerships and blood donor awareness. Job duties include scheduling blood drives in established territory to meet established goals, including major and minor holidays. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Solicit and recruit new groups and organizations for mobile drives within established territory/region. Rebook recurring blood drives for the following year. Develop and maintain collaborative working relationships with key accounts. Give presentations and represent Arkansas Blood Institute in order to promote blood collection. Qualifications: Associate's or bachelor's degree preferred, one to three years' sales experience, and valid driver's license. Salary: Competitive salary, commission plan, and excellent benefits package. How to apply: <http://arkbi.org/careers/>.

Advanced Clinical Lab Specialist (Part-time IRL). Blood Systems is one of the nation's oldest and largest comprehensive transfusion medicine organizations. We serve blood centers, hospitals and health systems, offering shared management and support services, quality excellence and effective contracting. Under minimal supervision, this position is responsible for routine testing of biological specimens. This position also provides skilled technical support in the laboratory. Works with other team members to ensure timely, quality, test results. Knowledge/ Education: Bachelor's degree required. Must satisfy CLIA requirements for High Complexity Testing required. California testing requirements must be met within one year required. Licenses/ Certifications: Immunohematology Reference Laboratory (IRL); Certification as a Medical Technologist or Blood Banking Technologist (BB) by a recognized certifying agency required. Experience: Immunohematology Reference Laboratory (IRL); Three years clinical laboratory testing required. One year of transfusion service experience required. One year IRL experience preferred. Blood

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POSITIONS (continued from page 11)

Systems, Inc. is an Equal Opportunity Employer. Apply at: <http://www.bloodsystems.org/careers.html> Req 16000310. EOE/Minority/Female/Disability/Vets

Medical Director (Denver-based). Blood Systems is one of the nation's oldest and largest comprehensive transfusion medicine organizations. We serve blood centers, hospitals and health systems, offering shared management and support services, quality excellence and effective contracting. Knowledge/Education: MD or DO or equivalent degree required. Licenses/Certifications: Medical license in the state(s) of work within six months required. Transfusion Medicine board certification (or eligibility followed by certification within two years of employment) OR board certification in Hematology required. Board certification in Clinical Pathology, Internal Medicine, or Pediatrics preferred. Experience: Fellowship training or equivalent experience in blood banking/transfusion medicine required. Experience at a blood center and/or hospital transfusion service including provision of education, clinical consultations, and some combination of therapeutic apheresis, cell therapy, laboratory, immunohematology, etc. experience required. Two years of experience in the field of Transfusion medicine preferred. Blood Systems, Inc. is an Equal Opportunity Employer. Apply at: <http://www.bloodsystems.org/careers.html> Req. 16000321. EOE/Minority/Female/Disability/Vets

Technical Director. Located in the heart of the magnificent coastal redwoods of Northern California, The Northern California Community Blood Bank is a non-profit blood bank serving Humboldt and Del Norte Counties. The Northern California Community Blood Bank has an immediate opening for a Technical Director. Under the direction of the Administrator and Medical Director, the Technical Director has overall 24-hour responsibility for the Laboratory and all activities related to processing, testing, storage, transportation, and other handling of blood and blood products. The Technical Director oversees component production, inventory, product distribution, reference immunohematological testing, and compliance with regulatory and standard-setting agencies. Experience, Education and Licensure: Four-year degree from an accredited college or university in science, medical technology or a related field. Valid current CA license as a Clinical Laboratory Scientist. Experience as a technologist performing high complexity testing in a clinical laboratory and familiarity with standard laboratory methods and techniques. Demonstrated ability to perform standardized routine testing, specialized testing in blood donor processing, and immunohematology is preferred. Must meet the CLIA defined General supervisor qualifications (42 CFR 493.1461). To Apply: Contact Tom Schallert (TomSchall@aol.com); Northern California Community Blood Bank, 2524 Harrison Avenue, Eureka, CA 95501; (707) 443-8004).

Director of Accounting/Controller. We have an opportunity for an experienced Director of Accounting/Controller who would be responsible for the financial operations of Bloodworks including accounts payable, billing, payroll, cash management and external reporting functions. Requirements for this position include: Bachelor's degree in Finance or Accounting; CPA or Master's degree preferred. Five or more years' experience in a Controller or Assistant Controller role. Five or more years supervising and developing staff. Healthcare/not for profit experience preferred. This is a full-time exempt position based at our Central location in Seattle's First Hill Neighborhood. Salary is DOE, DOQ. **Application Deadline: Open Until Filled.** Interested Applicants should send their application materials to HumanResources@bloodworksnw.org or fax to (866) 286-8495. All correspondence must reference job number 7885. The application can be found at: <http://www.bloodworksnw.org/careers/employment.pdf>. Bloodworks Northwest is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, sex, religion, national origin, age, protected veteran status, disability status, or any other characteristic protected by law. Should you have a disability that requires assistance and /or reasonable accommodation with the job application process, please contact the Human Resources department at HumanResources@bloodworksnw.org, or at (206) 292-6500, or at 921 Terry Avenue, Seattle, WA 98104.

Lab Quality Specialists. Currently, Cleveland Clinic is seeking Lab Quality Specialists for our East, West and South Regions. These positions are responsible for driving operational standardization throughout our laboratories and ensuring daily activities comply with regulatory and accrediting agencies. This will involve the collection and review of quality metrics, the evaluation of compliance gaps, and the continuous implementation of process improvements. Qualifications: Bachelor's degree in Clinical Laboratory Science or a chemical, physical or biological science; Three or more years of experience in quality systems development, implementation and assessment, or in regulatory affairs focused on the manufacturing of biologics or pharmaceuticals; At least three years of experience as a Medical Technologist; A minimum of three years' experience within a blood bank/transfusion service/blood center; and data management experience. To apply, please visit www.ecentralmetrics.com/url/?u=22906184778-215. Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE

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POSITIONS (continued from page 12)

Lead Laboratory Technologist – Blood Bank. The Lead Laboratory Technologist performs various duties that drive the continued success of our Blood Bank and other areas of our lab. From basic to advanced patient and donor testing, to the interpretation and validation of results, your work will determine donor-recipient compatibility as well as solutions for identified irregularities. You'll also be responsible for conducting instrument and equipment qualifications, managing reagent inventory, tracking quality metrics, recommending improvements, and serving as an educational resource for employees, residents and students. Qualifications: Associate's degree in Medical Laboratory Technology or another laboratory science, or a bachelor's degree in Medical Technology or a relevant chemical, physical, biological or clinical laboratory science; two years of blood bank experience; and one year of supervisory or quality assurance experience. To apply, please visit www.ecentralmetrics.com/url/?u=64006184865-215. Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE

Supervisor – Blood Bank. Currently, Cleveland Clinic is seeking Blood Bank Supervisors. In this highly visible role, you'll be responsible for supervising blood bank staff at multiple hospitals for our East, West and South Regions. This will involve overseeing the performance of basic and advanced patient and donor tests, helping train new employees, tracking and reporting on quality metrics, and leading performance improvement initiatives. Through these and many other contributions, you'll build on the continued success of our blood banks while moving forward in your career. Qualifications: Bachelor's degree in Medical Technology or a chemical, physical, biological or clinical laboratory science; Three years of blood bank experience; At least one year of management experience; and Working knowledge of Quality System Essentials. To apply, please visit www.ecentralmetrics.com/url/?u=32946184866-215. Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE. 📌

CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the Newsletter, please include program information.)

2016

Sept. 8. **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.** More information available [here](#).

Sept. 12. **Red Cell Genotyping 2016: Clinical Steps, Bethesda, Md.** For information, program fee and advance registration visit our [website](#) or contact Phyllis Kirchner phyllis.kirchner@bcw.edu.

Sept. 12-13. **FDA Public Hearing on HCT/Ps, Bethesda, Md.** More information can be found [here](#).

Sept. 13-14. **IT Workshop, America's Blood Centers, Minneapolis, Minn.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 17. **14th Annual Canadian Blood Services International Symposium "Intersecting Worlds of Transfusion and Transplantation Medicine," Toronto, ON.** More information can be found [here](#).

Sept. 21. **6th Annual Symposium Red Cell Genotyping 2016: Clinical Steps, Bethesda, Md.** Registration can be found here: www.bcw.edu/rcg2016. Contact: Phyllis Kirchner, Phyllis.kirchner@bcw.edu.

Sept. 22. **35th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** Registration can be completed [here](#). Contact: Karen Byrne, kbyrne@cc.nih.gov.

Oct. 22-25. **AABB Annual Meeting, Orlando, Fla.** More information available [here](#).

Oct. 31 – Nov. 1. **FDA 510(k) Submissions Workshop, Washington, D.C.** Find out more information and register [here](#).

Nov. 2. **FDA IDE Submissions Workshop, Washington, D.C.** Find out more information and register [here](#).

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CALENDAR (continued from page 13)**2017**

Mar. 24-28. **Annual Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Mar. 25. **Board Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 1-4. **Summer Meeting, MD Workshop & Golf Tournament, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 3. **Board Meeting, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

