

2017 #42

December 1, 2017

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FDA BPAC Issues Recommendations to Improve Bacterial Detection in Platelets

Bacterial contamination in platelets remains a safety concern for the blood community. Revisions to a 2016 draft guidance including pathogen inactivation (PI) technology and other mitigation strategies were discussed by the Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC), at its meeting in Silver Spring, Md. on Thursday.

The committee recommended the addition of measures including 7-day storage of platelets, without secondary testing if primary cultures were inoculated no sooner than 36 hours after collection using 8 mLs from each product in aerobic and anaerobic culture bottles. This is essentially the approach in use in the United Kingdom's NHS Blood and Transplant, America's Blood Centers (ABC) member Héma-Québec, and most recently at Canadian Blood Services. It has been advocated by ABC in written comments to the 2016 draft guidance. Alternatively, seven-day storage could be recommended after secondary culture on day four or later, or with secondary rapid assays approved with a safety claim. Five-day storage of apheresis platelets without secondary testing was recommended if the platelets undergo culture no sooner than 24 to 36 hours post-collection with a sampling volume of at least 3.8 percent, using both aerobic and anaerobic culture bottles.

A [joint statement](#) presented by ABC Chief Medical Officer and Interim CEO, Louis Katz, MD, from ABC and the American Red Cross (ARC) supported essentially exactly the approaches recommended by the BPAC. "[O]ur organizations support a need to enhance bacterial safety of transfused platelets using measures beyond the current approach of initial bacterial culture performed on apheresis platelets at approximately 24-hours post-collection. We strongly endorse the availability of multiple options to achieve this goal based on operational considerations in collection facilities and hospitals across the U.S. that affect their ability to implement one or more of the allowable interventions...[including] delayed primary culturing (at 36-48 hours)."

The [statement](#) recognized that PI is the most effective intervention available to prevent platelet associated sepsis, but expressed concerns, based on experience to date with the licensed PI platform, that the capacity for universal PI is not yet available. The two organizations expressed a preference to be able to supply hospital customers with a product ready for use without the need for further manufacturing or for relabeling after secondary testing in the hospitals. The AABB presented survey data that suggested hospitals recognized operational constraints with the prior draft guidance that could have resulted in hospital policies, e.g. transfusion only of platelets

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BPAC BACTERIAL DETECTION (continued from page 1)

before day four when secondary testing would be required, that would adversely impact the adequacy of the platelet supply. The recommendations from the committee should overcome these issues if accepted by the agency and are incorporated into the final guidance.

(Source: ABC & ARC Joint BPAC [Statement](#), 11/30/17) ♦

Advisory Committee Recommends Movement to West Nile Virus Model for Blood Donor Zika Testing

Fulfilling a commitment of the leadership at the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research and the FDA's Office of Blood Research and Review at the time of the Zika guidance in the summer of 2016, extensive discussions were held by the FDA's Blood Products Advisory Committee meeting on Friday. Presentations were heard from the FDA on the history of their response to the threat of Zika to blood safety, the Centers for Disease Control and Prevention on the evolving Zika epidemic in the Americas, and from Roche and Grifols describing results from over one year of donor screening with nucleic acid tests (NAT). During the open public hearing that followed, Mike Busch MD, PhD presented data on viral and serologic dynamics in infected donors and evidence addressing the infectivity of donors from both Puerto Rico and the U.S. identified during investigational testing. Based largely on that data, Steven Kleinman, MD AABB's medical consultant, presented the blood community's proposal that the testing guidance be revised to resemble the minipool (MP) to individual donor (ID) NAT algorithms in use for West Nile virus (WNV). This was based on evidence that risk to transfusion recipients should be concentrated in a small group of donors who would be positive in MP-NAT, before immunoglobulin M seroconversion. MP-NAT is estimated to miss ≤ 10 percent of infected donors capable of transmission. Cell culture and early animal data do not suggest that recovering donors who have developed an antibody response are infectious, nor does the limited available data on the transfusion transmissions reported from Brazil, or the clinical follow-up of donors in French Polynesia who received NAT positive units in the past.

The presentations were the basis for a series of options from the FDA to the committee. On Friday afternoon, the committee recommended to the agency that universal ID-NAT in the U.S. should be replaced by

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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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ZIKA TESTING (continued from page 2)

universal MP-NAT with “regional” triggering to ID-NAT based on criteria to be defined. This is the approach recommended by ABC, ARC, and AABB in a joint blood community [statement](#) to the committee presented during the open public hearing of the Zika discussion.

Other options considered and rejected (and the committee votes) included:

1. Maintenance of the status quo of universal ID-NAT (0 yes, 10 no, no abstentions);
2. Stopping all testing (0-10-0), use of ID-NAT in prespecified areas identified as “at risk” by the agency with MP-NAT elsewhere with triggers for ID-NAT (3-8-0);
3. Regional MP-NAT and ID-NAT triggers in some areas, with areas of minimal risk identified and not required to test (5-4-2);
4. Selective ID-NAT based on donor risk histories, e.g. travel and sexual contact (0-11-0); and
5. A “CMV” model providing ID-NAT negative components to “at risk” recipients only (2-9-0).

Potential triggers for conversion from MP to ID-NAT were discussed but their details will be left to the FDA with attention to the evolution of the epidemic, our understanding of viral dynamics, and ongoing infectivity studies.

(Source: AABB, ABC, ARC Joint [Statement](#), 12/1/17) ♦



AMERICA'S BLOOD CENTERS'

56TH ANNUAL MEETING

March 17-19, 2018 | Scottsdale, AZ

2018 ANNUAL MEETING SCHEDULE

Saturday, March 17:	ABC Board Meeting Opening Session
Sunday, March 18:	ABC Members Meeting SMT Forum & Celso Bianco Lectureship Host Event by Blood Systems
Monday, March 19:	General Session 21st Annual Awards of Excellence

“ I look forward to welcoming America’s Blood Centers back to Scottsdale, where the organization began more than 55 years ago. Along with opportunities to discuss emerging issues in our field, the Annual Meeting is a great forum for exchanging ideas and developing collaborations. The more who attend – the greater the value to all involved! ”



Blood Systems — Dave Green, MSA, President and CEO
Blood Systems, Inc.



Hotel Information
Scottsdale Plaza Resort
Hotel room rate:
\$219 Single/Double



For registration information, visit http://bit.ly/abc_annual_meeting.

For sponsorship opportunities, please contact Leslie Maundy at Imaundy@americasblood.org.



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It's About *Life*.



America's Blood Centers®
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.

ABC Submits Response Letters on Cybersecurity to HHS & Congress

This week, America's Blood Centers (ABC) sent letters to the House Energy and Commerce Committee and Department of Health and Human Services (HHS) addressing cybersecurity concerns with medical devices raised in a November 16th letter from the [committee](#) to HHS. ABC stated that, “[o]ur members take steps every day to assure the security of their cyber systems; however, they are only able to act on those threats about which they know. ABC concurs that it is essential that end users of medical devices be aware of the specifics of software components and risks embedded in each medical device. A “bill of materials” approach would assist our members in these efforts. ABC commends the recommendation to “convene a sector-wide effort to develop a plan of action...” based on an “open and collaborative process” and stands ready to participate and offer subject matter expertise.” Both the letter [to House Energy and Commerce Committee](#) and letter [to HHS](#) are available on the ABC members website.

(Sources: House Energy and Commerce Committee [Letter](#), 11/16/17; ABC HHS [Letter](#), 11/27/17; ABC House Energy and Commerce Committee [Letter](#), 11/27/17)

ABO October Meeting Materials Now Available

Presentations and resources from the October [Alliance of Blood Operators](#) (ABO) Meeting are available for [ABC Members](#). If you have questions concerning any of the materials, or would like to participate in the working groups, please contact [Kate Fry](#). ABC members are encouraged to utilize the ABO “Knowledge Exchanges” to assist with question or issues that may benefit from an international perspective. This service helps identify and promote good practices and encourages performance improvement among the international blood community.

(Source: [MCN 17-076](#))

ADRP Registration & Call for Speaker Abstracts Open

Early bird registration for the ADRP, an international division of ABC, [2018 Conference and Expo](#) is open. [Register](#) by December 31st to take advantage of the discounted rate (\$525). ADRP also invites you to submit abstracts to speak at the conference in Dallas, Texas. All marketing and communications innovators, recruitment visionaries, and collections experts are invited to [submit](#) abstracts on topics including donor collections staffing, the impact of technology on donor flow, internal communications strategies for regulatory changes, reinventing your brand, fixed site recruitment, lead generation for new sponsor groups, first time donor retention programs, and emerging medical issues. Speakers who are chosen will receive a 30 percent discount off conference registration and a complimentary one-year subscription to ADRP. Interested individuals may submit abstracts [here](#).

Reminder: ADRP Award Nominations Open

Recognize a peer or outstanding donor group by nominating them for an [ADRP Award](#). Submissions are being accepted until December 31st via the online [nomination form](#). This year's categories include: Donor

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INSIDE ABC (continued from page 4)

Recruiter of the Year, Donor Collections Team Member of the Year, Leader of the Year (Recruitment & Collections), Franzmeier Lifetime Achievement Award, Gilcher MD/CEO Award, Media Partner Award, Blood Drive Award (Creative & Most Productive), School Blood Drive Award, and the Humanitarian Service Award. 💧

RESEARCH IN BRIEF

A recent study demonstrates no decrement in red blood cell (RBC) recovery in premature infants using a non-radioactive RBC labeling technique after 42 days of storage. Investigators at the University of Iowa and ABC member Hoxworth Blood Center have compared 24-hour additive-RBC recovery in 76 adults measured with radioactive chromium to that in 46 preemies with biotin labeling. The latter spares exposure to radiation that is ethically questionable in the babies. Neonatal transfusions are often small aliquots from a single component designed to limit the number of donor exposures, and thus they can be regularly exposed to units at the end of allowable storage. This study compared historical adult data using chromium and autologous RBCs to newer data with the non-radiometric biotin assay on allogenic transfusions in the neonates. While adult 24-hour recoveries fell to near the Food and Drug Administration (FDA) imposed 85 percent recovery threshold, in the children, they remained above 95 percent on average. Limits include the use of historical data, and the small sample sizes. Also, there were institutional differences among the recipients and transfusion protocols. The infant RBCs were irradiated pre-transfusion and the adults were not. The authors concluded “these observations support the practice to transfuse RBCs, stored throughout the currently permitted FDA 42-day storage limit”, and “given the moratorium on radiation exposure to children in research, the biotin label seems to be the best alternative to radioactive” chromium in children.

Citation: Nalbant, D., Cancelas, J.A., Mock, D.M. *et al.* In premature infants there is no decrease in 24-hour posttransfusion allogeneic red blood cell recovery after 42 days of storage. *Transfusion*. 2017. doi:10.1111/trf.14396. 💧

WORD IN WASHINGTON

Senate Republicans are nearing a vote in hopes of successfully passing their version of a tax overhaul plan. Republican leaders received support late this week from Sen. John McCain (R-Ariz.), in addition to fellow Republican holdouts Sens. Jeff Flake (R-Ariz.), Ron Johnson (R-Wis.) and Steve Daines (R-Mont.) giving them the 50 votes necessary for passage under fast-track procedures. Discussions are ongoing as leaders finalize the more than \$1 trillion bill that will reform the nation’s tax code. It could include significant cuts annually in several programs such as Medicare, which may see cuts of \$25 billion a year according to *Politico*. The corporate tax rate would be cut to 20 percent.

(Source: *New York Times*, [Republicans have enough votes to pass tax bill](#), 12/1/17; *Politico*, [Tax bill could trigger significant Medicare cuts](#), 12/1/17)

Alex Azar appeared before the Senate Health, Education, Labor, and Pensions Committee during a [hearing](#) on November 29th. President Trump’s nominee to head the U.S. Department of Health and Human Services has faced criticism for his career as a pharmaceutical executive. Mr. Azar stated that, “I believe I can bring the skills and experiences to the table that can help us address these issues, while still encouraging discovery so Americans have access to high quality care.” He addressed the concerns of critics and indicated

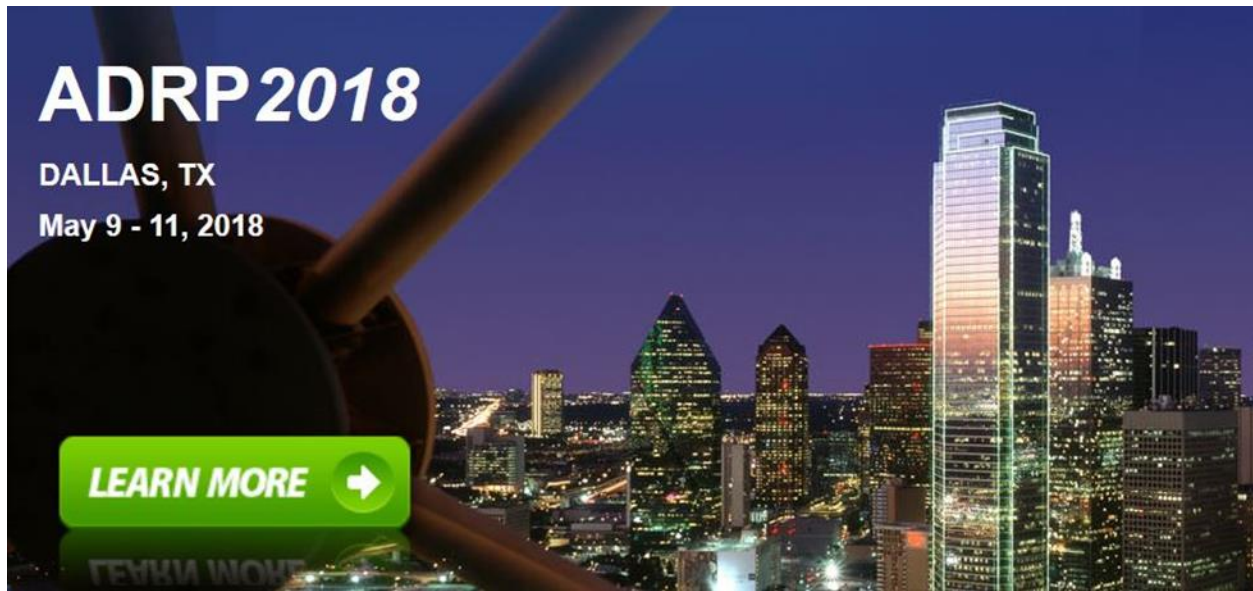
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WORD IN WASHINGTON (continued from page 5)

That, “[t]his is the most important job I will ever have in my lifetime, and my commitment is to the American people and not any industry I have worked for.” A transcript of his full testimony is [available](#).

(Source: *Washington Post*, [HHS nominee Alex Azar testifies on government role in lowering drug costs](#), 11/29/17; Senate Health, Education, Labor, and Pensions Committee [Transcript & Video](#), 11/29/17) ♦



BRIEFLY NOTED

Centers for Disease Control and Prevention (CDC) Director Brenda Fitzgerald, MD announced that changes are on the horizon in the form of a reorganization for the agency. According to Dr. Fitzgerald, “the intent of this refocus is on creating increased synergy and effectiveness of our approach. We [all] need to work together and start thinking of ourselves as One CDC,” she wrote in an email distributed to employees according to *Politico*, “with [a] focus on science, surveillance and service.”

(Source: *Politico*, [CDC to Reorganize for Increased Synergy](#), 11/20/17)

Global Healing will host a webcast on December 6th entitled *Building Coalitions to Advance International Blood Safety: Lessons Learned from Vaccines and Drugs*. Attendees will hear nonprofit leaders discuss “how their organizations overcame the challenges of forming and leading global consortia to make advances in healthcare affordable for developing countries. It will feature three panelists from Gavi, the Vaccine Alliance, Aeras, and PATH, respectively, to discuss essential lessons learned by these coalitions formed to address developing country needs for childhood vaccination, new and better vaccines against tuberculosis, and new drugs to treat intestinal parasites.”

(Source: Global Healing Announcement, 11/29/17) ♦



Accurate hemoglobin measurements are key to donor safety



CompoLab TS

Hemoglobin Screening Devices from Fresenius Kabi can help you screen your donors.

For more information contact your local Fresenius Kabi representative.



Please refer to the instructions for use for a list of warnings and precautions associated with the device.

MEMBER NEWS

Global Blood Fund (GBF) and **Community Blood Bank of Northwest Pennsylvania and Western New York** recently donated a bloodmobile to Centro Estatal de la Transfusión Sanguínea (CETS), Mexico's state blood transfusion service. According to the release, GBF's latest initiative secures and transports "surplus bloodmobiles" from the U.S. and the United Kingdom to resource-constrained nations. "For the majority of recipients, these will be the first bloodmobiles ever seen in their country," said Gavin Evans, executive director of GBF. "Introducing a bloodmobile is expected to add many thousands of units to annual blood collection. It will do this by increasing flexibility, enabling the receiving blood center to access communities previously restricted by distance or the lack of a suitable local collection venue." CETS previously received bloodmobiles from **San Diego Blood Bank** and **Oklahoma Blood Institute** through GBF, which estimates that each bloodmobile is approximately \$100,000.



(Source: Global Blood Fund News [Release](#), 11/1/17)

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!



GLOBAL NEWS

The United Kingdom implemented a revised policy for men who have sex with men (MSM) this week. The revision changes the blood donation policy from a 12-month deferral to 3-months. According to NHS Blood and Transplant (NHSBT), “[t]he rules are now consistent for all groups” deferred based on sexual behaviors. “The [Advisory Committee on the Safety of Blood, Tissues and Organs] review took into account the latest available medical and scientific evidence,” said Dr. Gail Mifflin, medical and research director at NHSBT. “This included more information about the risk of acquiring infections that can be passed on in blood, more evidence on how well donors comply with our guidelines and also more evidence that supports the reliability of the blood screening tests we use. We have one of the safest blood supplies in the world. Anyone may require a blood transfusion in the future and so it’s in all our interests to ensure that we work hard to keep blood safe for patients.”

(Source: NBC News, [‘It’s still a ban:’ Gay blood deferrals still discriminatory, LGBTQ advocates say](#), 11/29/17; NHSBT [Statement](#))

SAVE THE DATE

Current Status of Donor Iron Depletion Mitigation Efforts in the U.S. Webinar

December 7 at 3 PM ET

[Register Today!](#)

Additional details available to ABC members in [MCN 17-078](#)

By participating in this webinar, attendees will be able to:

- Know the magnitude of iron depletion in key donor groups.
- Understand the lack of consensus regarding its clinical impacts.
- Understand the strategies under consideration for its mitigation.

PEOPLE

Oklahoma Blood Institute (OBI) has announced **Tuan N. Le, MD** as chief medical officer. Dr. Le has previously held numerous medical leadership roles including Vice President of Medical Affairs and Medical Director at Bonfils Blood Center and most recently at AlloSource. He is board-certified in blood banking and transfusion medicine, and a graduate of the University of Colorado School of Medicine. Dr. Le follows James W. Smith, MD, PhD, who filled the role for more than 30 years and will become chief medical officer emeritus. According to the release, Dr. Le will play an integral role in the growth of OBI’s cellular therapies activities.

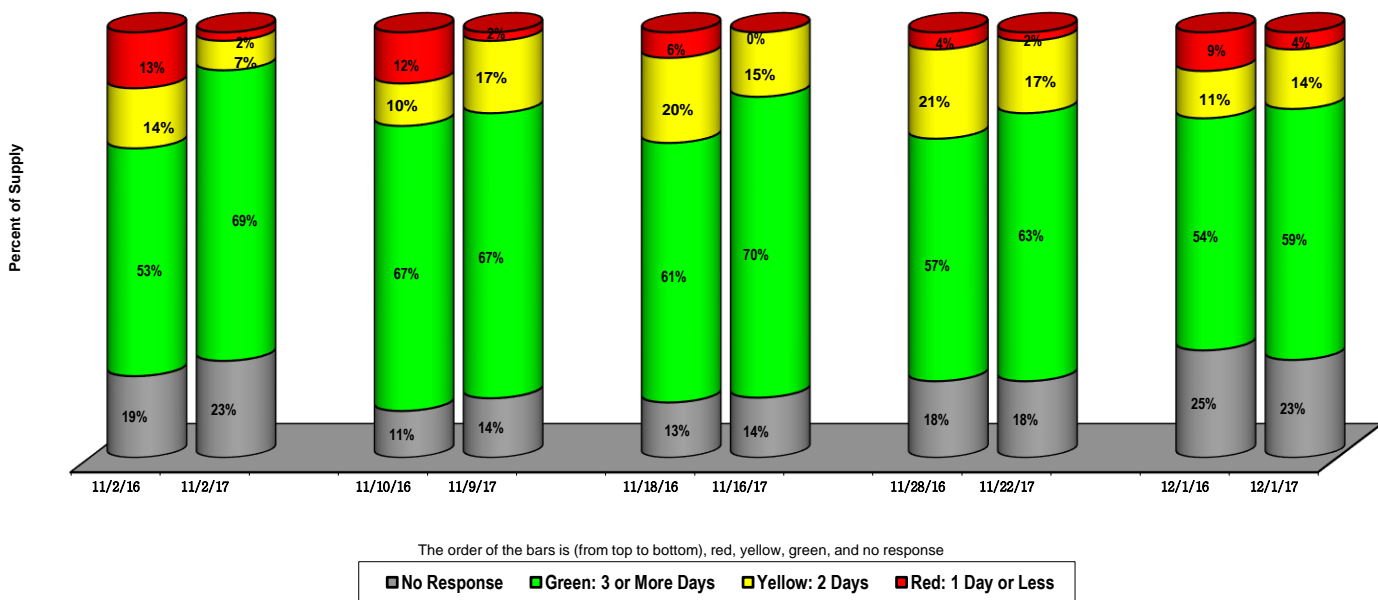


(Source: Oklahoma Blood Institute News Release, 11/30/17)

Nina Salamon has joined the ADRP Board. She is the executive vice president of Blood Centers of America, Inc. (BCA). “We are thrilled to have Nina join our [board],” said ADRP President Marie Forrestal. “This is an exciting time for our industry and our partner organizations we learn from each other. These emerging relationships will only benefit our subscribers.” Ms. Salamon leads BCA’s metrics program, recruitment and collection initiatives, reagent relations, and red cell demand forecasting. ♦



STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply



Daily updates are available at:

www.AmericasBlood.org

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.)

2017

Dec. 9-12. American Society of Hematology Annual Meeting & Expo., Atlanta, Ga. Register [here](#).

2018

Feb. 5-7. 14th Annual FDA and the Changing Paradigm for HCT/P Regulation., Alexandria, Va. Register [here](#).

Mar. 17-19. ABC Annual Meeting, America’s Blood Centers, Scottsdale, Ariz. More details available [here](#).

Mar. 21-22. IPFA 3rd Asia Workshop on Plasma Quality and Supply, Kuala Lumpur, Malaysia. More details available [here](#).

May 8-10. ABC Human Resources and Training/Development Workshop, Dallas, Texas. More details available [here](#).

May 9-11. ADRP Conference & Expo., Dallas, Texas. More details available [here](#).

May 16-17. IPFA/PEI 25th Workshop on “Surveillance and Screening of Blood-borne Pathogens,” Athens, Greece. More details available [here](#). 💧



Learn ♦ Grow ♦ Lead Shed Light on Your Future



This Month's Featured API Resources

1. *Jerry Haarmann Leadership Program*

Six courses on leading teams

"This course gave me many ideas on how to work with the team in my department as well as working with other teams outside my department."

- API pilot participant

2. *Strategic Leadership Program*

Six courses on change management and communication challenges

Effective Leadership: How Do You Rate?

Check your leadership effectiveness by answering yes or no to the following questions:

- Do you know exactly what you want employees to understand, think, and do in response to your communications?
- Are trust and commitment part of your team's DNA?
- Do you know what motivates your employees?



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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

Manager of Mobile Blood Drive Collection Operations. Do you have a passion for leadership and fostering great performance in your staff members? Are you a goal-oriented people person? Arkansas Blood Institute is seeking qualified candidates for Manager of Mobile Blood Drive Collection Operations in the Little Rock area. The position will focus on the staff performance of key metrics for the donor services Little Rock mobile operations. The manager will develop programs and work with individual staff to ensure key metric goals are achieved.

Overall success will be realized with an acceptable incomplete, deferral and error rate in addition to conversion rates and excellent customer service scores. Qualifications Three plus years of supervisory or management experience with blood bank focus helpful; post-secondary education required, bachelor's degree preferred; and a valid driver's license and good driving record with zero points and no moving violations in the past three years.

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POSITIONS (continued from page 10)

Benefits: Arkansas Blood Institute offers a competitive salary, excellent benefits package including health, FSA, HSA Health Savings, dental, vision, and life insurance; LTD, 401(k), paid time off, and tuition reimbursement. Apply online only at <http://arkbi.org/careers/>. EEO M/F/D/V/Drug Free Work Environment.

Director of Technical Services. LIFELINE Blood Services is a small independent blood center located in Jackson, Tennessee. Conveniently located between Memphis and Nashville, Jackson was rated “Most Livable Small City in America” (Population less than 100,000) by the Conference of Mayors in 2013. Also, recognized as number 6 of “Best Cities to live in on a \$100K Salary” in the U.S. according to Fortune Magazine’s August issue, 2017. LIFELINE Blood Services is moving into its 71st year of service and has an exciting opportunity for a Medical Technologist. After 40 years of service, the Director of Technical Services is retiring in the coming months. This position is responsible for directing the Reference Laboratory, Component Production, and Hospital Services of the Blood Center. Bachelors of Science, MT required, with an SBB preferred. This person would be capable of gaining a State of Tennessee Supervisory license. For more information please see the job posting at <http://lifelineblood-serv.org/careers/>.

Vice President, Clinical Services Administration. Blood Systems, headquartered in Scottsdale, Arizona, is one of the nation’s largest comprehensive transfusion medicine organizations. Our blood centers provide blood, blood components and special services to patients in over 1,000 hospitals across the country. We are seeking a Vice President, Clinical Services Administration for the Corporate Division. This position is responsible for fostering enterprise-wide collaboration among Blood Systems’ immunohematology reference and centralized transfusion clinical services, promoting cost-saving standardization and enacting approved changes to provide impeccable laboratory and transfusion services for the patients served by our hospital partners. The ideal candidate will have extensive supervisory experience in immunohematology. Experience: Eight years of related experience required, to include five years’ supervisory experience. Knowledge/Education: Bachelor’s degree required. Master’s degree preferred. Knowledge of large system operations management including fiscal policies, human resource management, and strategic planning required. Knowledge of federal, state, and local regulations that affect business operations required. Licenses/Certifications: SBB or equivalent preferred. To view the job description and apply for this position, please click [here](#).

Hospital Services Supervisor. Blood Bank of Hawaii, a medium-size blood center (50,000 RBC distributions annually), has an exciting opportunity for a Hospital Services Supervisor. This leadership position is responsible for performing, documenting and reviewing all tasks associated with inventorying and distribution of blood components. Will also supervise and coordinate operations, staffing and management of the Hospital Services department to include hospital satisfaction in meeting blood product needs, assuring quality customer service to all customers, and management and coordination of blood and blood component inventories. The ideal candidate should have one year experience working in healthcare, account management, distribution or healthcare, as well as one year experience supervisory experience. Please apply via our website: www.BBH.org.

