



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Please Note: The ABC Newsletter will not be published on October 19th due to the 2018 AABB Annual Meeting. We will resume regular publication on October 26th. Thank you for your continued interest.

The Effect of Zika Infection During Pregnancy on Babies Born without Apparent Congenital Abnormalities?

Understanding the full spectrum of Zika’s effects on infants and children is a critical public health planning imperative. The population attack rate for Zika infection in French Polynesia during 2013-14, two years before the massive Latin American epidemic, was almost 50 percent, providing a unique opportunity to study this.

Infants with birth defects were matched to controls of infants without birth defects in a case-control study and the association with maternal Zika infection examined. In a second, population-based, cross-sectional study, infants born without apparent birth defects after intrauterine Zika infection were compared to controls.

Ninety-five percent of the mothers of babies with defects were Zika seropositive versus 76 percent of control mothers, confirming an association of birth defects with Zika infection during pregnancy. Before and following adjustment for confounders, asymptomatic maternal Zika was not associated with central nervous system congenital defects.

The cross-sectional study, using validated indices of early childhood development (ECD), included 107 children that were followed more than one and a half years after the epidemic’s end. No evidence existed of an association of maternal Zika (seropositivity or reported Zika infection) with abnormal ECD in children without birth defects.

The cross-sectional study may have been limited by the use of specific ECD indices that could have missed relevant changes, for example in vision and hearing.

Also, the attribution of maternal antibody and of symptomatic maternal Zika to infection during pregnancy is imprecise. This may have resulted in misclassification. While the data are encouraging, further follow-up of broader indices in larger populations over longer periods is needed.

Citation: Subissi, L., Dub, T., Besnard, M. *et al.* Zika virus infection during pregnancy and effects on early childhood development, French Polynesia, 2013–2016. *Emerg. Inf. Dis.* 2018. doi: [10.3201/eid2410.172079](https://doi.org/10.3201/eid2410.172079). ♦



DOD & FDA Partner to Address Countermeasures for Ebola and Other Viruses

The U.S. Food and Drug Administration (FDA) has awarded the Department of Defense's (DOD) U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) with a three-year agency agreement to explore the microbial pathogenesis of viruses that include Ebola, hemorrhagic fever, Chikungunya, and Zika. According to the announcement, the USAMRIID is expected to:

- “Identify patients with previous exposure to the target viruses, and collect serological samples at several time points from the patient’s initial presentation to the hospital, up to 28 days later;
- Assess immune response by re-stimulating peripheral blood mononuclear cells (PBMCs), where available, to measure frequency and breadth of cell-mediated immunity to the infecting antigen (in this case, virus), and by assessing antibody avidity (the overall strength of binding between the antibody and antigen) and neutralizing capability, including kinetic analysis over time; and
- Compare immune responses in patient samples with immune responses from other sample sets (e.g., vaccine studies, etc.) to determine appropriate samples to use in bridging data from natural exposure samples to human vaccine cohorts, animal models, or geographically distinct patient populations.”

The collaboration will leverage the existing U.S. Army Joint Mobile Emerging Disease Intervention Clinical Capability project that allows researchers in the U.S. and Uganda to create the ability to perform clinical trials while treating individuals during a filovirus outbreak.

(Source: FDA [Announcement](#), 9/14/18) 💧



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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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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.

ADRP Webinar: T.R.E.A.T. (Effective Management of Millennials by Millennials)

[Register](#) for the upcoming October 16th ADRP Webinar: T.R.E.A.T. (Effective Management of Millennials by Millennials) scheduled to take place at 1:30 PM EDT presented by Vitalant (formerly Blood Systems, Inc.). The webinar will provide insights into maximizing the performance of millennials and will be conducted by millennials using the acronym T.R.E.A.T., while providing techniques to effectively manage them. To become an ADRP subscriber visit <https://www.adrp.org/Join-Now>.

2018 Service Fee Survey Launched

All ABC member blood centers are asked to participate in the annual survey of member service fees. The survey can be completed online with additional details including the survey link available in [MCN 18-042](#). The results from this survey play an integral role in helping ABC continue to advocate for better reimbursement of blood products for its member blood centers. Individual center data is confidential and not shared. The final report will be aggregate data. Please complete the survey by October 26, 2018 and contact [Ruth Sylvester](#) with any questions or concerns.

(Source: MCN [18-042](#)) 💧

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LOCAL APPROACH**

SAVE THE DATE!
March 26, 2019

AMERICA'S BLOOD CENTERS'
CAPITOL HILL DAY
WASHINGTON, D.C.

More details coming soon!



RESEARCH IN BRIEF

Quantifying as association of refusal of transfusion with mortality and myocardial ischemia. Severe perioperative anemia in patients for whom transfusion is not an option has been previously correlated to increased mortality. A single-center, retrospective study from Duke University among 263 patients admitted with “severe anemia” (hemoglobin \leq 8.0 g/dL) who refused transfusion for religious or moral reasons between 2004-15 has broadened the kinds of patients studied and estimated an association with myocardial ischemia. In a multivariate analysis, the authors found a 30-day all-cause mortality of 19.8 percent in the cohort, with the odds of death increasing 1.55-fold (95 percent confidence interval 1.25-1.91) for each 1 g/dL hemoglobin decrement. Myocardial ischemia was identified in 10.5 percent with 1.42-fold increased odds for each 1 g/dL decrement (95 percent confidence interval 1.07-1.9). Major limitations include the inability to draw causal inferences from observational studies and potential for confounding due to the absence of a severity of illness adjustment (the database did not contain that information).

Citation: Guinn, N.R., Cooter, M.L., Villalpando, C., Weiskopf, R.B. Severe anemia associated with increased risk of death and myocardial ischemia in patients declining blood transfusion. *Transfusion*. 2018. doi: [10.1111/trf.14768](https://doi.org/10.1111/trf.14768). ♦

RECENT REVIEWS

Pediatric massive transfusion. Very limited evidence is available to guide approaches to massive transfusion in pediatrics according to authors from the Australasian College for Emergency Medicine and the Australian and New Zealand College of Anaesthetists. They reviewed 35 of 422 papers returned by their database search through February 2016, finding only 25 relevant articles that included no randomized and only 4 nonrandomized trials. Data were too limited for meta-analysis. They recommend, based on low quality evidence, absent support for improved outcomes using a fixed 1:1:1 ratio of red blood cells, platelets, and plasma, that goal directed therapy guided by viscoelastic monitoring is the “way forward.” The utility of tranexamic acid and fibrinogen replacement are also emphasized.

Citation: Maw, G. and Furyk, C. Pediatric massive transfusion: a systematic review. *Pediatric Emerg. Care*. 2018. doi: [10.1097/PEC.0000000000001570](https://doi.org/10.1097/PEC.0000000000001570). ♦

REGULATORY NEWS

The Biomedical Advanced Research and Development Authority (BARDA) will host its annual conference (BARDA Industry Day) in Washington, D.C. October 29-30th at the Grand Hyatt. BARDA Industry Day 2018 will feature:

- BARDA’s new Division of Research, Innovation, and Ventures (DRIVE) – goals, objectives, and impacts;
- BARDA’s strategy, goals, and areas of interest for FY19 and beyond;
- Opportunities to network with potential government and private sector partners;
- Updates and details about BARDA’s Broad Agency Announcements, and how to partner with BARDA;
- Opportunities to develop medical countermeasures for both government and commercial markets; and
- Industry Speakers, including those featured in a new Innovation Lightning Talks Session.

Registration is [open](#). Additional information, including the [draft agenda](#) for the conference is [available](#).

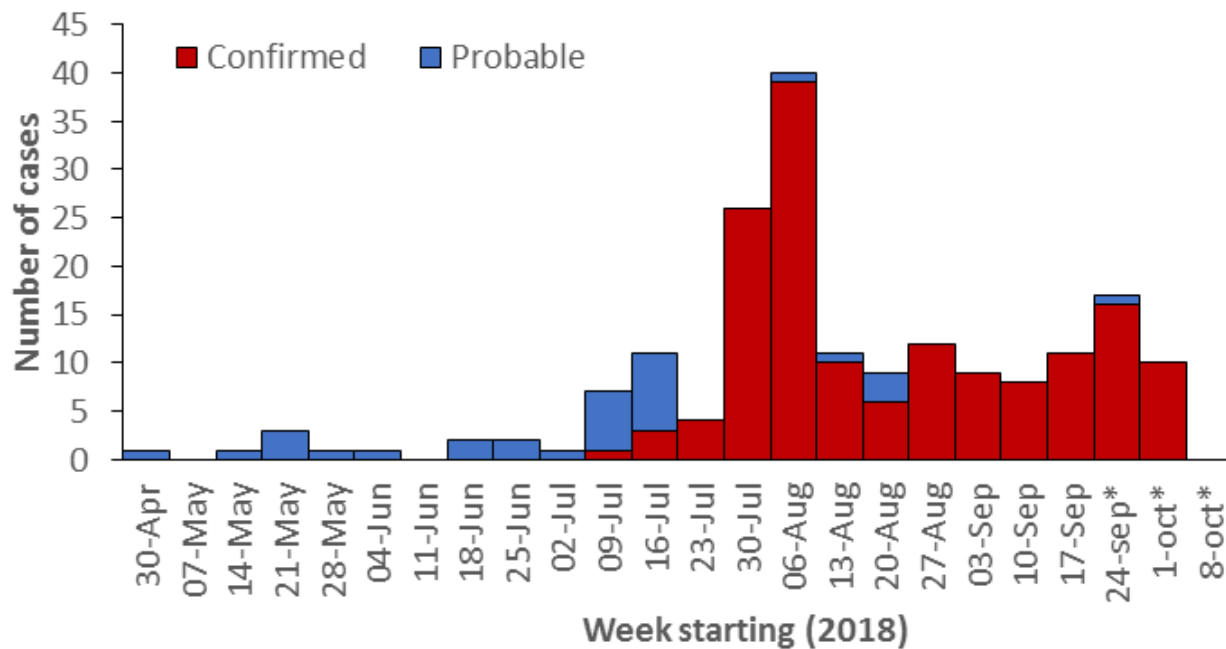
(Source: BARDA Industry Day [Website](#)) ♦

INFECTIOUS DISEASE UPDATES

EBOLA

The Ebola outbreak in the Democratic Republic of Congo persists. Ongoing transmission in part reflects the occurrence of the outbreak in a region with substantial social and political instability making establishment of control procedures difficult. The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) have not classified the affected areas as having “widespread transmission of Ebola virus,” which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) [guidance](#) requires that “in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2).”

Confirmed and probable Ebola virus disease cases by week of illness onset, data as of October 9th (n=187)



* Data in recent weeks are subject to delays in case confirmation and reporting, as well as ongoing data cleaning. Date of illness onset unknown for n=7 cases.

(Source: World Health Organization, [Ebola virus disease – Democratic Republic of the Congo](#), 10/11/18)

Upcoming ABC Webinars – Don’t Miss Out!

- **Development and Implementation of a Platelet Prediction Model** – October 25 at 3 p.m. EDT. Additional details forthcoming!
- **Quality Integration Part II** – November 27th at 3 pm. EST. Additional details forthcoming!
- **SMT Journal Club** – December 12th at 12 pm. EST. Additional details forthcoming!



MEMBER NEWS

Community Blood Center (Appleton, Wisc.) is joining eleven other independent blood centers in the Alliance for Community Transfusion Services (ACTS). “For over 63 years, The Community Blood Center has been a trusted healthcare partner, committed to fulfilling the lifesaving role it plays in patient care,” said John Hagins, president & CEO of Community Blood Center. “ACTS is a collaborative and innovative group of independent blood centers, focused on enabling blood centers, such as ours, to achieve their mission in the communities they serve. Joining ACTS is a natural extension of the work we’ve been committed to since 1955 and will help to strengthen our organization and hospital and patient relationships for years to come.” ACTS members strive to collaborate in their approach to strengthening relationships between blood centers and hospitals. “We’re excited to have The Community Blood Center join our Alliance,” said Nelson Hellwig, MBA chief executive officer of ACTS. “Their leadership and history of quality, innovation, success and commitment to the communities they serve makes their addition a great fit.” ACTS other members include:

- Carter BloodCare (Dallas/Fort Worth, Texas);
- Central Pennsylvania Blood Bank (Hummelstown, Penn.);
- Coastal Bend Blood Center (Corpus Christi, Texas);
- Community Blood Center of the Ozarks (Springfield, Mo.);
- LifeShare Blood Center (Shreveport, La.);
- Oklahoma Blood Institute (Oklahoma City, Okla.);
- Sheppard Community Blood Center (Augusta, Ga.);
- South Texas Blood & Tissue Center (San Antonio, Texas);
- SunCoast Blood Bank (Sarasota, Fla.);
- The Blood Center (New Orleans, La.); and
- We Are Blood (Austin, Texas).

(Source: ACTS New [Release](#), 10/9/18)

Vitalant recently held a memorial blood drive at the Las Vegas Convention Center on the one-year anniversary of the mass-casualty shooting in Las Vegas, Nev. Close to 300 donors turned out to remember the victims and honor all who were impacted by the tragedy. The drive included several players from the National Hockey League’s Las Vegas Golden Knights along with representatives from the National Football League’s Raiders Foundation. “A lot of people [were] affected and it’s the least we could do as a team,” said Cody Eakin of the Las Vegas Golden Knights according to KSNV NBC3.

(Source: KSNV NBC3, [Vegas Golden Knights help the valley heal off the ice](#), 10/1/18) 💧

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 and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. 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.



PEOPLE

Coastal Bend Blood Center announced that **R. Corey Survant** will be the next president and CEO following the retirement of Lynn Hipp. Mr. Survant has 24 years of blood banking experience and expertise in a variety of areas including strategic planning, financial and employee management, regulatory compliance, supply management, operations, and human resources. He serves as the vice president of Operations currently. “Corey has guided the [Coastal Bend] Blood Center through tough transformations such as regulatory changes, economic shifts in the health care industry, and technological changes. This deep industry knowledge makes Corey uniquely qualified to lead [Coastal Bend] Blood Center successfully into the future,” stated an announcement from Rodney Senterfitt, chairman of the Coastal Bend Blood Center Board of Directors in a memo to ABC.

(Source: Coastal Bend Blood Center CEO Announcement, 10/8/18)

Versiti, Inc. has announced that **Ilke Panzer**, executive vice president and chief innovation officer will be leaving as of October 19th for the role of CEO at another organization. Ms. Panzer joined BloodCenter of Wisconsin (a part of Versiti, Inc.) in 2006 and has led their diagnostic laboratories, since that time. “Ilke has been an exceptional leader for Versiti. In her more than 12 years with the organization, The Diagnostics Labs have experienced tremendous growth. She has been invaluable as a leader in providing direction, coaching, strategic insight, and passion. I also personally value her depth of knowledge about not only the Labs, but across all areas within Versiti. Ilke was consistently engaged in finding a better way for us to operate across all of our service lines and functions...with a focus first and foremost on our mission to serve,” said Versiti, Inc. President and CEO Chris Miskel, MBA in an email announcement.

(Source: Versiti, Inc. Email Announcement 10/9/18) ◆

GLOBAL NEWS

NHS England will provide adult patients with access to CAR-T therapy axicabtagene ciloleucel (Yescarta) for large cell lymphoma. “CAR-T cell therapy is one of the most promising new treatments in a generation for lymphoma and leuk[e]mia, and NHS patients will now be among the first in the world to benefit,” said Simon Stevens, chief executive of NHS England in a NHS England [announcement](#). “The speed of this decision shows how research-based life-sciences companies and the NHS can partner together for the benefit of patients.” The announcement follows a similar agreement one month [earlier](#) that NHS made providing children with access to CAR-T therapy Tisagenlecleucel (Kymriah). The National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) recommended against the use of Yescarta previously on the grounds of cost-effectiveness. “This is an important day for patients with lymphoma who may have run out of effective treatment options leaving them just months to live,” said Hilary Hutton-Squire, general manager of Gilead Sciences in the UK and Ireland. “We are delighted to have been able to reach an agreement by working closely with NHS England and NICE which allows us to bring this new generation of personali[z]ed cancer treatment to patients.” This product was [approved](#) by the U.S. Food and Drug Administration for adult patients with certain relapsed or refractory high grade B-cell lymphomas in October 2017.

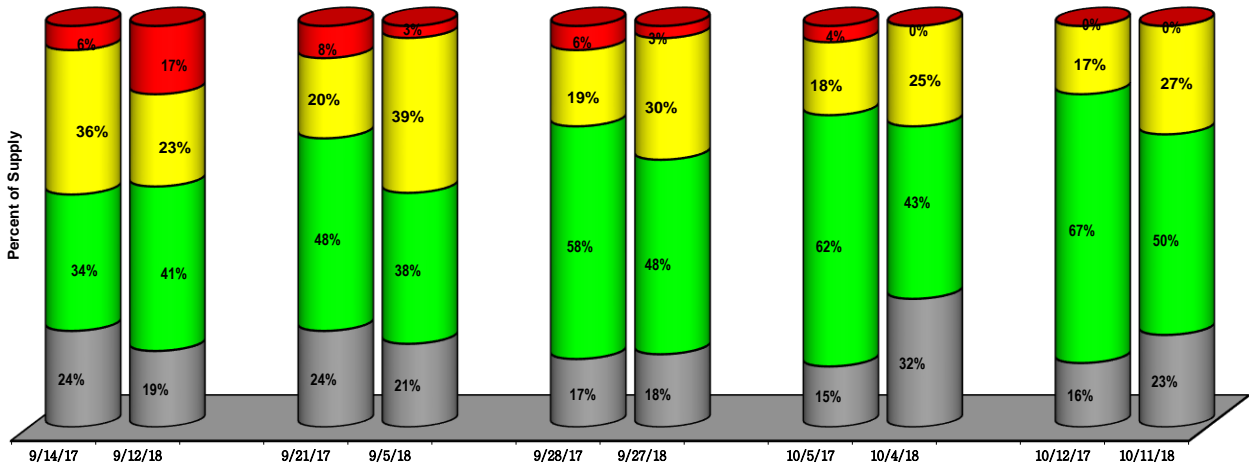
(Source: NHS England [Announcement](#), 10/5/18) ◆

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!



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



The order of the bars is (from top to bottom), red, yellow, green, and no response
 ■ No Response ■ Green: 3 or More Days ■ Yellow: 2 Days ■ Red: 1 Day or Less

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) 899-2621. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)

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- 2018**
- Oct. 15-16. **510(k) Submissions Workshop, Washington, D.C.** More details available [here](#).
 - Oct. 29-30. **BARDA Industry Day, Washington, D.C.** More details available [here](#).
 - Nov. 14. **2018 Cybersecurity Summit, Washington, D.C.** More details available [here](#).
 - Nov. 29-30. **FDA Pathogen Reduction Technologies for Blood Safety Public Workshop, Silver Spring, Md.** More details available [here](#).
- 2019**
- Feb. 4-5. **15th Annual FDA and the Changing Paradigm for HCT/P Regulation, Washington, D.C.** More details available [here](#).
 - March 23-26. **2019 ABC Annual Meeting, Washington, D.C.** More details coming soon.

(continued on page 9)



CALENDAR (continued from page 8)

May 14-16. **ADRP Annual Conference, Indianapolis, Ind.** More details available [here](#).

May 22-23. **IPFA/PEI 26th International Workshop on “Surveillance and Screening of Blood-Borne Pathogens”, Krakow, Poland.** More details available [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) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Sr. Director, Clinical Services (Pittsburgh, PA). The Institute for Transfusion Medicine is now Vitalant! Vitalant, one of the nation’s oldest and largest nonprofit community blood service providers, supplies comprehensive transfusion medicine services to nearly 1,000 hospitals and health care partners for patients in need across 40 states. We are currently seeking an experienced and dynamic **Sr. Director of Clinical Services** to be responsible for the leadership, management, and direction of operating departments to expand the organization’s effectiveness and its delivery of service to both health care providers and patients. Based in Pittsburgh, PA, this critical role will oversee the management of our Transfusion Service and Red Cell Reference Laboratory (RCRL) operations throughout our Eastern Region to ensure that procedures, controls and systems are in place to ensure accurate test results and timely provision of appropriate blood products while maintaining compliance with all federal and state regulatory requirements and industry accreditation standards. The Sr. Director will also ensure that all service offerings meet or exceed customer expectations by overseeing the development of organizational strategies to achieve core corporate goals aligning with the strategic initiatives of Division and Corporation. Vitalant is an Equal Opportunity and Affirmative Action Employer. Interested candidates can learn more and apply online at <https://www.vitalant.org/Our-Organization/Careers.aspx>

Director of Information Systems Quality & Compliance (Scottsdale, AZ). Blood Systems, Inc. is now Vitalant! Vitalant, one of the nation’s oldest and largest nonprofit community blood service providers, supplies comprehensive transfusion medicine services to nearly 1,000 hospitals and health care partners for patients in need across 40 states. We are currently seeking a Director of Information Systems Quality & Compliance to be responsible for managing the review and approval of quality systems and compliance in all areas of computerized medical devices and computer applications for Vitalant and its business units. Based in our national corporate offices in Scottsdale, AZ, this position provides

subject matter expertise, consultation, guidance, coaching, and direction for computer-related quality and compliance issues to process owners. Vitalant is an Equal Opportunity and Affirmative Action Employer. Interested candidates can learn more and apply online at <https://www.vitalant.org/Our-Organization/Careers.aspx>

Regional Director. LifeShare Blood Center is seeking a Regional Director for our Texarkana, Texas location. The Regional Director is responsible for the operation, performance, and safety of the region’s recruitment, collection and support team members. Responsibilities include the strategic and tactical plans of their region. This includes direct oversight, adherence, compliance, and meeting of Goals, Key Performance Indicators (KPI), and Regulatory compliance. Directs the supervision of team members to adhere to all cGMP, SOP, FDA, AABB, and other regulatory bodies, as well as departmental policies and procedures. Acts as direct liaison for external inspections and onsite corporate leadership. Follows and ensures compliance of Quality, Payroll, Budgets and Fiscal responsibility of their operational site. Requirements include bachelor’s degree in related field or equivalent experience in management or administration. Prior Blood Banking or healthcare management experience a plus. Must have demonstrated supervisory experience in the direction, control and planning of the activities of other personnel. A working knowledge and understanding of FDA regulations governing Blood Banking, AABB standards, OSHA regulations and current Good Manufacturing Practices for all center departments is preferred. Must have experience in the development and maintenance of an operating budget. For complete job description and to submit applications please go to www.lifeshare.org/careers.

Medical Director. Blood Bank of Hawaii (BBH) is seeking a dynamic, impactful leader to be its Medical Director. The successful candidate will have at least three

(continued on page 10)



POSITIONS (continued from page 9)

years' experience in blood banking/transfusion medicine, preferably, two years' blood center experience. As a member of the blood center senior leadership team, the Medical Director oversees medical and technical aspects of blood center operations, is the CLIA laboratory director, and serves as the clinical and medical consultant. This person will direct transfusion medicine educational endeavors for pathology residents, students, blood center staff, and other trainees; provide transfusion medicine education to the local medical community; represent BBH regionally and nationally to promote transfusion medicine best practices, such as patient blood management. BBH, the sole provider of blood components and services to hospitals in Hawaii, is a diverse organization offering professional development, a competitive salary, comprehensive benefits, relocation package, and a collaborative team environment. To apply, please submit a resume and cover letter to HR@bbh.org. BBH is an Equal Opportunity employer. All qualified applicants will receive consideration for employment without regard to sex, gender identity, sexual orientation, race, color, religion, national origin, disability, protected veteran status, age, or any other characteristic protected by law.

Reference Laboratory Technologist. Kentucky Blood Center, located in Lexington, Ky. is seeking a medical technologist to perform and interpret serological procedures on specimens submitted for compatibility testing or problem resolution. Will resolve typing problems, antibody problems, and crossmatch problems; and communicate with hospitals as needed. MT, MLS, CLS (ASCP) with minimum two years recent blood bank experience, SBB preferred. Strong written and oral communication skills, a do-what-it-takes work ethic, and a team player attitude required. Proof of education/certifications required during the interview process. Benefits: Health/Dental/Vision/Life/Short Term Disability/Long Term Disability/Cancer Insurance/Accident Insurance/Flexible Spending Accounts/Health Savings Accounts/Paid Time Off/Paid Holidays/Employee Assistance Program/Retirement Savings Plan. For more information or to apply online, please visit www.ky-bloodcenter.org. Drug-free and EOE/AAP. 💧