

A B C N E W S L E T T E R

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2020 #5

February 7, 2020

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FDA Publishes Final Guidance on HTLV-I/II

The U.S. Food and Drug Administration (FDA) has published a final <u>guidance</u> entitled "Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Type I and II (HTLV-I/II)." It finalizes the previous draft guidance on recommendations for requalification of blood donors deferred due to reactive test results for antibodies to HTLV-I/II. America's Blood Centers (ABC) previously collaborated with AABB and the American Red Cross to submit joint <u>comments</u> in response to the September 2018 draft. The FDA incorporated the recommendations from these comments into the final guidance which consolidates all current recommendations from FDA regarding HTLV-I/II into a single document. ABC has advocated for such consolidation rather than the prior practice of updating parts of multiple older guidance documents.

A new recommendation in this guidance deals with donor reentry for previous HTVL-I/II screening test results. The guidance states that donors who have been indefinitely deferred may be considered for reentry if they had previously tested:

- negative or indeterminate for anti-HTLV-I/II with an investigational test or licensed test, or
- negative or indeterminate with a research-use supplemental HTLV algorithm before a licensed supplemental test was available, or
- had not been tested for anti-HTLV-I/II before a licensed supplemental test was available.

The September 2018 draft guidance did not allow for donors deferred for an indeterminate test result to be tested for reentry but that has changed as recommended in the industry's joint comments.

Also, donors may only be considered for reentry after six months from the date of the deferral with testing by two different licensed screening tests for antibodies to HTLV-I/II, one of which must be the same test used on the index donation if it is still available. If both screening tests are nonreactive, the donor may be reentered if otherwise eligible. Additionally, if both are repeatably reactive, the donor is permanently deferred. For screening test results that are discordant, the donor remains deferred, but a licensed supplemental test may be performed. The guidance provides an algorithm that can be used for interpretation and further testing for these donors.

The agency indicates that this guidance applies to whole blood and blood components. It does not apply to the collection of source plasma. If the recommendations

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FDA publishes HTLV I/II Final Guidance (continued from page 1)

for donor reentry are implemented as described in this guidance, they may be implemented at any time and reported in an establishment's annual report. Deviation from the recommendations in this guidance are considered a major change and require a prior approval supplement.

(Sources: FDA Final <u>Guidance</u>, 2/5/20) ♦

FDA Issues Information for Blood Industry Regarding Novel Coronavirus

In a February 4th notice, the U.S. Food and Drug Administration (FDA) <u>stated</u> that is working with the Centers for Disease Control and Prevention (CDC) in addition to other federal and international agencies monitoring the outbreak of the 2019 novel coronavirus (2019-nCoV). The agency said, "[t]he potential for transmission of 2019-nCoV by blood and blood components is unknown at this time. However, respiratory viruses, in general, are not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus. Routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood. For example, blood donors must be in good health and have a normal temperature on the day of donation (21 CFR 630.10)." Additionally, FDA provides considerations for blood establishments and provides links to the CDC 2019 coronavirus resource webpage, which is being updated three times a week on Monday, Wednesday, and Friday, and the FDA's own coronavirus resource webpage.

America's Blood Centers (ABC) issued a public <u>statement</u> this week on the novel coronavirus outbreak as well. It emphasized that the blood donation process is safe and encouraged all donors and sponsors of blood drives to schedule appointments and keep commitments to donate blood. ABC will continue to monitor the outbreak and provide timely updates to member blood centers.

As of publication, the latest CDC data (February 7th) reported 12 positive cases. On January 31st, AABB provided an <u>update</u> for the blood community on the outbreak that noted:

- "no transmissions by blood or other substances of human origin have been documented or alleged for 2019-nCoV. This is true, as well, for the other two coronaviruses that have emerged over the past two decades (SARS, the Severe Acute Respiratory Syndrome Coronavirus and MERS-CoV, causing Middle East Respiratory Syndrome);
- AABB, FDA, and CDC are not recommending any action by blood collection establishments at this time because there are no data or precedent suggesting risk of transfusion transmission; and
- Voluntary implementation of donor deferral for travel to China may address public concerns about the safety of the blood supply."

(Source: FDA Notice, 2/4/20; ABC Statement, 2/7/20, AABB Update, 1/31/20)

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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. America's Blood Centers Chief Executive Officer: Kate Fry

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Red Blood Cell Guidelines for Hemoglobinopathies

Established in 2011, The International Collaboration for Transfusion Medicine Guidelines (ICTMG) includes transfusion experts and provides evidence-based transfusion medicine guidelines to optimize transfusion care. A systematic review was performed and used to develop recommendations to assist physicians in decision making for optimizing choice of red cell units when transfusing patients with hemoglobinopathies. The resulting position paper published in the *British Journal of Haematology* made six recommendations in the ICTMG guidelines.

Recommendation 1. Patients with sickle cell disease (SCD) who do not have alloantibodies and who are anticipated to have a transfusion (simple or exchange) should be transfused with CcEe- and K-matched red blood cells (RBCs) to reduce the risk of alloimmunization (low quality of evidence, weak recommendation). Matched RBCs can be provided by phenotyping or genotyping. The typing should be done prior to the first transfusion. For those who have been transfused within the last three months, genotyping is the preferred method.

Recommendation 2. Patients with SCD who have one or more clinically significant alloantibodies should be transfused with antigen-negative blood to the corresponding antigen(s) alloantibody (-bodies) if feasible (low quality of evidence, strong recommendation). Inform individuals of their alloantibodies by providing cards/letters that can be presented at each hospitalization. The United Kingdom Serious Hazards of Transfusion (SHOT) Hemovigilance reported risks of potential adverse consequences including failure to give antigen-matched blood for "evanescent" or historical antibodies where these special requirements have been missed due to a breakdown in communication.

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<u>RBC Guidelines for Hemoglobinopathies</u> (continued from page 3)

Recommendation 3. Patients with SCD who have one or more alloantibodies should be transfused with CcEe-, K-, Fy^{a-}, Fy^{b-}, Jk^{a-}, Jk^{b-}, Ss- matched RBCs to reduce the risk of alloimmunization but only if matching does not cause undue delays that adversely affect patient care (low quality of evidence, weak recommendation). This recommendation recognizes that those with some antibodies often have a predilection to form further antibodies, making them progressively more difficult to transfuse. To meet the needs of these patients, blood centers continue to increase donations from black and ethnic minority donors.

Recommendation 4. Patients with thalassemia syndromes who do not have alloantibodies and who require RBC transfusion should be transfused with CEK matched RBCs to reduce the risk of alloimmunization (low quality of evidence, weak recommendation). Matched RBCs can be provided by phenotyping or genotyping. Providing matched RBCs is recommended although patients may not have developed alloantibodies in the past as there is a potential for alloantibody development with future transfusion.

Recommendation 5. Patients with thalassemia syndromes who have one or more clinically significant alloantibodies should be transfused with antigen-negative blood to the corresponding antigen(s) alloantibody (-bodies) if feasible (low quality of evidence, strong recommendation). Inform individuals of their alloantibodies by providing cards/letters that can be presented at each hospitalization.

Recommendation 6. Patients with thalassemia syndromes who have one or more alloantibodies should probably be transfused with CcEe-, K-, Fy^{a-}, Fy^{b-}, Jk^{a-}, Jk^{b-}, Ss- matched RBCs to reduce the risk of alloimmunization if feasible and if matching does not cause undue delays that adversely affect patient care (low quality of evidence, weak recommendation). Alloimmunization in this patient cohort is often historical and often against Rh and Kell antigens.

"Thalassemia syndromes" were used throughout this paper but not defined. The authors also noted that most of the references were drawn from papers on transfusion-dependent or independent (usually beta) thalassemia. There was no mention of use of HbS-negative units although the paper refers to other sources such as the ICTMG guidance. The authors concluded by stating that more work needed to be done to determine the optimal age of blood recommendation for these patient cohorts.

Citation: Trompeter, S., Massey, E., Robinson, S., *et al.* Position paper on International Collaboration for Transfusion Medicine (ICTM) Guideline 'Red blood cell specifications for patients with hemoglobinopathies: a systematic review and guideline.' *British Journal of Haematology*. 2020. Doi: <u>10.1111/bjh.16405</u>.

Contributed by Richard Gammon, MD, Medical Director at OneBlood 🌢

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has issued a final call for nominations to fill the nonindustry representative position on the Blood Products Advisory Committee (BPAC) for the Center for Biologics Evaluation and Research (CBER). America's Blood Centers (ABC) previously requested nominations from interested parties (MCN 19-059) and is in the process of preparing the nomination packages of those individuals previously nominated and volunteered. If any additional ABC members are interested in being considered, please send your name and *curriculum vitae* to ABC's Director of Regulatory Services <u>Ruth Sylvester</u> no later than February 17th and ABC will include it in the slate of candidates currently being submitted.

(Source: <u>MCN 20-013</u>, 2/5/20)



BRIEFLY NOTED

ABC Newsletter

The U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) announced the "Public Health Emergency Medical Countermeasures (MCM) Enterprise (PHEMCE) Multiyear Budget Report for fiscal years 2018-22. It revises and updates funding data from the fiscal year 2017-21 report submitted last February. This year's report estimates total spending at HHS to be \$28.8 billion over the five -year period, a 14 percent increase from the 2017-21 projections, for entities involved in MCM development and stockpiling including the National Institutes of Health (NIH), ASPR's Biomedical Advanced Research and Development Authority (BARDA) and Strategic National Stockpile (SNS), and the U.S. Food and Drug Administration (FDA). It also provides projected funding for pandemic and seasonal influenza, radiological and nuclear threats, filoviruses such as Ebola, and arboviruses including Zika, and the Middle East Respiratory Syndrome (MERS) coronavirus. The full report is available on the ASPR public health emergency website along with an executive <u>summary</u>.

(Source: ASPR <u>Announcement</u>, 1/29/20)



Upcoming ABC Webinars – Don't Miss Out!

• SMT Journal Club Webinar – March 30th from 2 – 3 p.m. (E.T.) More information coming soon.

RESEARCH BRIEFS

America's Blood Centers welcomes contributions or briefs from guest authors for scientific/medical peerreviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers. If you are interested in contributing a brief for potential publication please contact us <u>here</u>.



IN MEMORIAM

ABC Newsletter

Ernest R. Simon, MD former executive vice president for Medical, Technical, and Research Affairs at Blood Systems, Inc. (now Vitalant) passed on way January 13th. Dr Simon was a hematologist and medical ethicist who discovered adenine as an additive to blood bags for extending the shelf life of blood. Born June 24, 1929 in Germany, he and his family immigrated to California in 1938. Dr. Simon received his medical degree from Harvard Medical School in 1954, graduating cum laude, and conducted his post-graduate work at Stanford University, the National Institutes of Health, and the University of Washington. He became a founding faculty member and Professor of Medicine at the University of New Mexico School of Medicine. In 1973, Dr. Simon was appointed as the first director of the National Institutes of Health's Blood Division. In this role, he implemented federal policies that designated blood as a "national resource" and promoted funding of blood research studies. He joined Blood Systems, Inc. in 1981 helping the organization navigate the technical and ethical issues of the AIDS crisis. He received the 1993 Morten Grove-Rasmussen Memorial Award from AABB for "many significant contributions to blood banking and transfusion science, continued interest in ethical issues relating to blood transfusion and especially for his seminal research leading to the implementation of adenine as an additive in blood transfusions." Dr. Simon is survived by his wife Eve Simon, and his daughters Carol Simon Levin, Lori Joan Rosolowsky, and Renee Simon Hamilton. Donations may be made in his honor to the Grayhawk Classic Residence Foundation Scholarship Fund, 7501 E. Thompson Peak Pkwy, Scottsdale, Ariz. 85255.

(Source: Ernest Simon, MD Obituary, 1/13/20)

PEOPLE

Eva Quinley, MS, MT(ASCP)SBB has announced that she will be retiring as of March 28th after 46 years of providing service and leadership within the blood banking community. She currently holds the position of regional director for Vitalant's Chicago-based operations. During her career, Ms. Quinley has been actively involved within America's Blood Centers and AABB serving on multiple committees. Her list of accomplishments includes numerous academic appointments, recognition in several publications spanning 30 years, and being a recipient of AABB's Hemphill-Jordan Leadership Award. "Blood banking is a huge part of who I am, and I have made so many great and lifelong friends in this industry," said Ms. Quinley in an announcement by Vitalant. "Because I love what I do, this decision was indeed a difficult one to make. I have been truly blessed to work in so many different areas and to experience all the various aspects of our industry. I could never have imagined



this when I first began my career." She received her B.S. in Medical Technology from the University of Tennessee (Memphis) in addition to a Master of Healthcare Administration and Education degree from the University of Memphis. Prior to joining Vitalant, Ms. Quinley held senior management positions in operations and leadership at New York Blood Center, the American Red Cross, AABB, and St. Jude's Research Hospital.

(Vitalant Announcement, 2/4/20)

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 <u>calendar of events</u> 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!





Marisa Saint Martin, MD, FASCP has been appointed medical director for OneBlood in Jacksonville, Fla. She is a pathologist with board certifications in Anatomic and Clinical Pathology, and Transfusion Medicine and Blood Banking. Dr. Saint Martin holds an Academic Affiliate appointment with Loyola University in Chicago where she has served as an Assistant Professor in the Department of Pathology. Additionally, she has served in leadership roles as the associate director of Loyola Medicine's Blood Bank and Apheresis Services as well as the associate director of the Residency Program. Dr. Saint Martin was also previously named medical director for the Department of Pathology and medical director for Laboratory Medicine at Trinity Gottlieb Memorial Hospital. She is also a certified Life Career and Executive Coach with experience and expertise on the topics of resilience, burnout, and well-

ness. Dr. Saint Martin has chaired hospital multidisciplinary wellness committees, developed and established an ACGME compliant wellness curriculum for residency programs, and been an invited speaker on this subject at the local, national, and international events. In 2019 she won the prestigious Roger Schenke Award from the American Association for Physician Leadership and became the Medical Education 2019 Robert T. Wong Lectureship Award Recipient from the University of Hawaii Medical School - John A. Burns School of Medicine.

(OneBlood Announcement, 2/7/20)

COMPANY NEWS

Fresenius Kabi recently held a ribbon cutting ceremony to celebrate the opening of an expansion of its production operations in the Dominican Republic. Local government officials joined the Fresenius Kabi leadership team at the event as the €30 million expansion doubles the square footage of the facility to 160,000 square feet. "Broadening our production activities in the Dominican Republic will increase our ability to produce and supply essential products for patients around the globe," said Dr. Christian Hauer, president of the Fresenius Kabi's Transfusion Medicine and Cell Therapies Division in a company news release. The facility is located in Haina and will house production equipment, plasma kit assembly lines, sterilization units, and a large warehouse. "We are proud to continue and further develop our decades-long presence in this region, and we are very excited about this expanded facility," said Fresenius Kabi Chief Executive Officer Mats Henriksson in a news release. "This is yet another step in improving the lives of chronically and critically ill people around the world. We all look forward to putting ever more leading-edge disposables and devices in the hands of the people who are caring for patients and collecting life-saving plasma donations."

(Source: Fresenius Kabi News <u>Release</u>, 1/24/20)



Photo courtesy of Fresenius Kabi (from left to right): Dr. Christian Hauer, Fresenius Kabi's President Transfusion Medicine and Cell Therapies Division, Danilo Medina, President of the Dominican Republic, Mats Henriksson, CEO Fresenius Kabi, Luisa Fernandez, National Free Zone Council Director, and Angel Estevez of the Environment and Natural Resources Ministry.



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

Register for the 2020 ABC Annual Meeting

<u>Registration</u> is open for America's Blood Centers' (ABC) 58^{th} Annual Meeting in Washington, D.C. March $9^{th} - 11^{th}$, 2020 at the Ritz-Carlton (Pentagon City). Join us for the premiere blood community meeting that brings blood center, regulatory, legislative, and medical leadership together to focus on key issues which will ultimately impact blood center bottom-lines. From implementation challenges for the new bacterial guidance to the operational complexities entailed in gender identification, the ABC Annual Meeting will provide you with the latest updates on these topics and more, along with the opportunity to help shape the association's advocacy and policy efforts. Additionally, attendees will have the chance to work collaboratively with their peers and ABC leadership in developing solutions that address internal and external needs ranging from health policy to donor motivations. This meeting also includes a day on Capitol Hill to let our voices be heard. Contact Jeanette Brown for available sponsorship opportunities and to see if hotel availability still exists at the group rate. Registrant substitutions are accepted any time at no charge. Registrations cancelled after February 16 will be refunded, less \$200. No refunds after March 8. CME and P.A.C.E.® credits will be offered. Schedule at a glance:

- ABC Board Meeting (*open to ABC Members only) (March 8th)
- General Sessions & SMT Forum & Celso Bianco Lectureship (March 9th)
- ABC Members' Meeting (*open to ABC Members only) & Public Awareness Forum & Advocacy Forum (March 10th)
- 23rd Annual *Awards of Excellence* (March 10th)
- Advocacy Day Capitol Hill Visits (March 11th)

(Source: MCN <u>19-086</u>, 12/18/19)

ABC Newsletter

ABC Survey on Donor Deferrals Due to Blood Pressure

The America's Blood Centers (ABC) Scientific, Medical, and Technical (SMT) Committee is evaluating the mandatory donor blood pressure and prescribed ranges set forth by the Final Rule in 21 CFR 630.10. Members of ABC have indicated that donors are unnecessarily being deferred for out of range blood pressure because of the requirement in 630.10(f)(2) that a "physician examines the donor and determines and documents that the health of the donor would not be adversely affected by donating." This cannot be delegated to the blood drive supervisor or other qualified staff per 630.5(b)(1)(i). Since doctors are not generally on mobile drives, any donors with blood pressures outside the established range are deferred. We need member assistance to measure the impact of this issue. A survey has been designed for ABC members to complete to objectively determine how many donors are being deferred because of blood pressure outside of the U.S. Food and Drug Administration's (FDA) established range and to estimate the impact on donors and staff time. ABC members can access a link to the survey and a copy of the survey questions in MCN 20-010. The survey will gather data on the number of donors with blood pressures outside of established ranges and how many of them are qualified or deferred. ABC understands that not all organizations are able to easily break that information down between donors with low or high blood pressures. Please provide as much data as possible completing the survey by February 28th. If you have any questions, please contact ABC Director of Regulatory Services Ruth Sylvester.

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MEMBER NEWS



Photo Courtesy of KERO-TV

Houchin Community Blood Bank recently unveiled a new bloodmobile. This is the fourth bus in their fleet with funding provided in part by the charitable contributions of the Ethel West Foundation and the Ben H. and Gladys Arkelian Foundation. "We live in the third largest county in California, and the blood donations from our local communities provide 100 percent of the blood to all of Kern County," said Houchin Community Blood Bank President and CEO Brad Bryan, PhD, MBA to KERO-TV (Bakersfield, Calif.). "From Frazier Park to Ridgecrest to Delano and everywhere in between, we use our fleet of

buses to provide convenience to those willing to donate blood and help save lives in our county."

(Source: KERO-TV, Houchin Community Blood Bank unveils new Big Red Bus, 2/6/20)

Shepeard Community Blood Center held two ribbon cutting ceremonies and luncheons late last month in preparation of its planned expansion in Lexington, S.C. The ceremonies took place with the Cayce West Columbia Chamber on January 23rd and the Greater Irmo Chamber of Commerce on January 28th. "Shepeard is a proven organization consistently providing donors with a quality collection experience," said Shepeard Community Blood Center President and Chief Executive Officer Kevin Belanger, DHA, MS, MT(ASCP)SBB. "Our vision is to partner with the community and hospitals providing a seamless transition of blood from donor to patient." The new satellite location is set to open in downtown Lexington by summer 2020.



Photo Courtesy of Shepeard Community Blood Center: Ribbon cutting with the Greater Irmo Chamber of Commerce.

(Source: Shepeard Community Blood Center Announcement, 2/4/20)

Coastal Bend Blood Center and HALO-Flight announced a partnership to provide whole blood onboard HALO-Flight air ambulances to provide prehospital transfusions to patients in need. "The Coastal Bend Blood Center is excited to be teaming up with HALO-Flight," said Coastal Bend Blood Center President and CEO Corey Survant to the *Alice Echo News-Journal*. "This strategic partnership is a game changer in our community for trauma care, and we are very proud to be working with HALO-Flight and their Mission of saving more lives throughout the Coastal Bend." HALO-Flight has treated close to 30 patients since the inception of a pre-hospital blood program last summer. "Research has proven that the number one intervention for patients facing such a fate is whole blood and whole blood as soon as possible," stated HALO-Flight Nurse and Blood Program Coordinator Christal Tressider in the article.

(Source: Alice Echo News-Journal, Partnership brings new addition to pre-hospital blood, 2/3/20)

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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 <u>newsletter@americasblood.org</u> or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2020

Mar. 9-11. 2020 ABC Annual Meeting, Washington, D.C. Registration is open.

Mar. 25-26. IPFA 5th Asia Workshop on Plasma Quality and Supply, Chonburi, Thailand. More details available <u>here</u>.

April 1. U.S. Food and Drug Administration (FDA) Public Meeting on FDA's Communications About the Safety of Medical Devices. Silver Spring, Md. More details available <u>here</u>.

April 14-15. 16th Annual FDA and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C. More details available <u>here</u>.

May 13-14. IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal. More details available <u>here</u>.

May 19-21. 2020 ADRP Conference, Phoenix, Ariz. More details available here.

July 21-23. 2020 ABC Medical Directors Workshop and Summer Summit, Cleveland, Ohio. More details coming soon.

Sept. 23-25. 4th European Conference on Donor Health and Management. Hamburg, Germany. More details coming soon.

Oct. 3-6. 2020 AABB Annual Meeting, Baltimore, Md. More information available here.

ABC 2020 Meetings & Workshops					
Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees	
2020 ABC Annual Meeting	March 9 th -11 th	Washington, D.C.	Ritz-Carlton (Pentagon City)	Registration now open!	
ADRP 2020 Conference	May 19 th -21 st	Phoenix, Ariz.	Hyatt Regency	Registration now open!	
2020 ABC Medical Directors Workshop and Summer Summit	July 21st-23rd	Cleveland, Ohio	Westin Downtown	More details coming soon!	

Notes:

For the most up-to-date information on all events, members of ABC may check the <u>calendar</u> on ABC's Member Site. Non-members may attend all events; information will be updated on ABC's <u>Public Site</u>.



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, e-mail: <u>newsletter@americasblood.org</u>

POSITIONS

Assistant Director of Quality Assurance. This position at Shepeard Community Blood Center assists the Director of QA in management and implementation of organizational Quality Plan. Monitors regulatory compliance in all areas of operation and reviews new and revised regulations, standards and other compliance documents. Assists in management of corrective and preventative action, change control, document control, record storage, equipment and validation. Coordinates and facilitates center training and competency programs. Serves as resource for quality and compliance issues for staff. Qualifications: bachelor's in laboratory science or related discipline required; three to five years' experience in blood bank or transfusion service, management experience, working knowledge of PC software using Windows, Microsoft Word, Excel and other software programs as required, familiarity with FDA/AABB Regulations/Standards, OSHA and CLIA requirements; working knowledge of regulations and standards for biologics to include blood and blood products. Working knowledge of donor suitability criteria and infectious disease testing. Must maintain knowledge of and perform according to Standard Operating Procedures (SOPs) and policies. Must maintain knowledge of cGMP, CLIA regulations, applicable OSHA rules, and current industry standards. Licenses/Certifications: MT or MLT with appropriate certification preferred or BS-RN acceptable with appropriate work experience. Please upload cover letter, resume, relevant documentation and complete an application at www.shepeardblood.org.

Outside Sales Representative/Event Planner. Oklahoma Blood Institute (Ada, O.K.) Account Consultants/Outside Sales Representatives must develop new partnerships with targeted decision makers in comorganizations, educational & religious munity institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing & promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact

effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, life insurance, long term disability, 401(k), paid time off, etc. Apply at: http://obi.org/careers/.

Assistant Manager, Donor Testing. Innovative Blood Resources (St. Paul, Minn.) is seeking an Assistant Manager for Donor Testing. Join our team today and start making a difference in the community and saving lives. Provide day-to-day supervision of personnel in their shift and laboratory area and responsible for the engagement of Donor Testing staff through proper personnel management, training, development and evaluation of staff. Work with all of IBR management to ensure that organizational needs are being met. Promote the Mission, Vision, Values, and strategic objectives of the organization. Requirements: a Bachelor Degree in Medical Technology/Clinical Laboratory Science highly preferred; BS degree in chemical, biological, or CLIA equivalent (Associates of Science Degree/MLT plus four years related experience) with relevant leadership experience acceptable; graduate of a CLIA approved degree program where laboratory experience was obtained and accompanies a working knowledge of good laboratory practices in addition to a minimum of 3 plus years' experience in the Donor/Clinical Testing Laboratory; must possess attention to detail, accurate in transcription of numbers, good written and oral communication skills, and computer input/retrieval skills, ability to work in a team environment or independently, good decision making skills, ability to work irregular hours or overtime as dictated by departmental needs. Must comprehend and apply clinical laboratory procedures and theory. View full job descriptions at: https://innovativebloodresources.org/careers/.

Director, Regulatory Affairs. America's Blood Centers (ABC), North America's largest network of communitybased, independent blood programs, is seeking a Director, Regulatory Affairs. The position will be actively involved and accountable for the development, implementation, execution and advancement of the ABC



<u>POSITIONS</u> (continued from page 11)

regulatory agenda before federal agencies and other stakeholders. In addition, the position will assist in the facilitation of member education, evaluation and coalescing of member input in the development of industry positions, data collection from internal and external sources, and primary and secondary research. The position will report directly to the Senior Director, Federal Government Affairs, providing strategic guidance on regulatory affairs and public policy issues pertaining to the nation's blood supply. A bachelor's degree is required for the position, which is based in Washington, D.C. This individual should: have a thorough understanding of the federal regulatory processes and landscape, particularly with the FDA; have knowledge of and experience in health policy; blood industry knowledge preferably (but not required); be able to collect, analyze, and synthesize information from varied sources; have strong critical thinking, analytical, and problem-solving skills; be selfmotivated and goal oriented; have the ability to multitask and determine priorities; be able to network and collaborate effectively with colleagues and volunteers; have strong communication skills - verbal, written, and presentation; and be able to travel, sometimes at short notice. ABC offers a salary commensurate with experience as well as an excellent benefit package including medical, dental, LTD, and 401k contribution. We are a hybrid virtual office that promotes a flexible work environment. This is a full-time staff position including benefits and a stipend for internet and telephone services. ABC prohibits discrimination and provides equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws. The full job description is available here. Interested applicants should send a cover letter and resume to careers@americasblood.org.

Clinical Laboratory Scientist. Sign- on bonus \$1,000 to \$5,000. Hoxworth Blood Center seeks a full-time, third shift, Clinical Laboratory Scientist for the Immunohematology Reference Laboratory. This position will perform complex immunohematology serological testing; evaluate/interpret test results, prepare reagents, maintain rare blood inventories; perform quality control, data entry/retrieval functions; effectively communicate and requires participation in on-call. Must qualify as High Complexity Laboratory Testing Personnel and General Supervisor defined by CLIA. Registry eligible, must take and pass theMLS (ASCP) or BB (ASCP) exam within 12 months. Sign on bonus after one-year Work Performance Review of acceptable performance. Qualifications: Bachelor's degree and MT(ASCP), CLS(ASCP), MLS(ASCP) or BB(ASCP); or bachelor's degree and registry eligible; OR Bachelor's degree and HEW certified medical technologist with two years related experience; or MLT(ASCP) with three years related experience. Degree must be in biological science or related field. Apply for position number 40463 at: <u>https://jobs.uc.edu/</u>.

Technician I - Phlebotomist. We Are Blood (Austin, Texas) has been drawing Central Texans together since 1951. As the exclusive community blood supplier, we serve over 40 hospitals and medical facilities in a 10county area. Our mission is to provide and protect the community blood supply, to inspire Central Texans to save lives locally, and to always treat everyone we serve as family. When you work here, you're a vital part of helping to ensure that all Central Texans have access to life-saving blood when they need it! This individual will determine donor eligibility, perform phlebotomy techniques, and manage adverse donor reactions at fixed site. Responsibilities: report to work according to department schedule and comply with organizational timekeeping policy; maintain the donation site and equipment according to SOP: Assembly, daily quality control procedures, routine/preventative maintenance, housekeeping procedures and disassembly; process and accurately document allogeneic whole blood donations according to SOP: registration, medical history interviews and vital signs (pulse, blood pressure, hematocrit, and temperature), phlebotomy; respond to donor reactions according to SOP: Identify/treat symptoms, monitor/perform vital signs (pulse and blood pressure) and accurately document the reaction; review electronic/hard copy documentation, as appropriate, according to SOP; execute special projects and other duties as assigned by Supervisor or Operations Manager. Requirements: high school graduate or equivalent; effective communication skills; compassionate interpersonal skills; excellent customer service skills; basic computer skills; punctual and dependable; experience in phlebotomy and/or taking vital signs is preferred; certification as a phlebotomist, medical assistant, EMT, paramedic or LVN is a plus; ability to interpret and respond appropriately to sensitive/confidential information and situations; ability to maintain focus and make sound judgments in a busy/distracting environment; ability to perform the same task repeatedly while maintaining a high level of accuracy; ability to read/follow SOPs and to maintain complete/accurate records; ability to work well in a team environment; ability to work a flexible schedule including Saturday and/or Sunday; good manual dexterity; ability to lift up to 25 pounds unassisted; and the ability to stand for long periods. Local applicants only; EEO Employer: Minorities/Women/Veterans/Disabled; interested in our organization, but not this job? Apply here; Check us out on our website to find out how you else you can be a part of our family.

Technician I – Mobile Phlebotomist. We Are Blood (Austin, Texas) serves over 40 hospitals and medical facilities in a 10-county area. Our mission is to provide and protect the community blood supply, to inspire Central

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Texans to save lives locally, and to always treat everyone we serve as family. When you work here, you're a vital part of helping to ensure that all Central Texans have access to life-saving blood when they need it! This individual will determine donor eligibility, perform phlebotomy techniques, and manage adverse donor reactions at blood drives across the Central Texas area. Responsibilities: loading/unloading the mobile bus, setting up/taking down the blood drive event, and maintaining excellent donor relations; report to work according to department schedule and comply with organizational timekeeping policy; maintain the donation site and equipment according to SOP: Assembly, daily quality control procedures, routine/preventative maintenance, housekeeping procedures and disassembly; process and accurately document allogeneic whole blood donations according to SOP: registration, medical history interviews and vital signs (pulse, blood pressure, hematocrit, and temperature), phlebotomy; respond to donor reactions according to SOP: Identify/treat symptoms, monitor/perform vital signs (pulse and blood pressure) and accurately document the reaction; review electronic/hard copy documentation, as appropriate, according to SOP; execute special projects and other duties as assigned by Supervisor or Operations Manager.



Requirements: high school diploma or equivalent required; experience in a blood center is preferred, Certification as a Phlebotomist, Medical Assistant, EMT, Paramedic or LVN is a plus; open availability needed; MUST be able to work a full-time schedule with flexible hours to include evenings, weekends, and holidays; effective communication, compassionate interpersonal and excellent customer service skills; basic computer skills; punctual and dependable ability to work well in a team environment able to lift 25 pounds unassisted and ability to stand for long periods; ability to work well in a team environment and good manual dexterity; and the ability to perform the same task repeatedly while maintaining a high level of accuracy. Local applicants only; apply here. Interested in our organization, but not this job? Check us out our website to view other opportunities within our organizations to make you a part of our Family. EEO Employer: Minorities/Women/Veterans/Disabled.