America's Blood Centers®
It's About Life.

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2024 #16 **May 3, 2024**

INSIDE:

ABC Recommendations to BPAC Regarding Malaria Testing

America's Blood Centers (ABC) has submitted comments to the U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) in response to proposed strategies to reduce the risk of transfusion-transmitted malaria (TTM). The ABC comments "strongly recommended" that the agency delay publishing draft guidance until modeling studies are finished and additional malaria testing assays are approved and available. "Prior to publication of a draft guidance on malaria testing, real world modeling studies should be performed to determine the sensitivity of available tests, including studies performed in malaria-endemic locations and including data on semi-immune donor populations." The comments specified that, "there is currently only one malaria test approved for screening of the blood supply. As FDA knows, this raises concerns about the blood supply's reliance on a single test. Without an alternative, supply chain challenges could cripple the blood supply."

Additional recommendations and acknowledgments from ABC also included:

- "ABC applauds FDA for recognizing universal testing of all donations is not a cost-effective strategy for blood safety in the U.S.;
- ABC strongly recommends that FDA maintain the current deferrals as an option:
  - while also allowing for a selective testing strategy for individuals with a history of malaria who were not prior residents of a malaria-endemic country;
  - while also allowing for a selective testing strategy for prior residents of malaria-endemic countries;
- ABC supports an option for selective testing for residents of nonendemic countries who have traveled to malaria-endemic areas in the past three months;
- ABC supports a testing strategy for donations in regions of the U.S. with local, mosquito- borne malaria transmission, but recommends having a higher minimum threshold for triggering testing; [and]
- ABC applauds the FDA for allowing the use of an FDA-approved pathogen reduction technology device in lieu of using the screening questions for malaria risk followed by nucleic acid testing (NAT) for malaria."

(continued on page 2)

ABC BPAC Malaria Testing Comments (continued from page 1)

The BPAC is set to meet on May 9th. ABC has formally requested that ABC Chief Medical Officer Jed Gorlin, MD, MBA be able to comment during the meeting, "in support of the safety of the current deferral strategy and express the need to ensure that any changes to that strategy are evidenced-based, cost effective, and operationally feasible."

Meeting materials are available ahead of the meeting and include a briefing document and meeting discussion questions. The committee is specifically being asked to comment on:

- "FDA's proposed strategies for selectively testing blood donations from donors at risk for malaria using an FDA-licensed nucleic acid test (NAT); [and]
- FDA's proposal that blood establishments should implement time limited NAT screening of all donations collected in area(s) of the U.S. when a single case of local mosquito-borne malaria is reported by public health authorities."

An archive of ABC comments and letters is available on the ABC website.

(Source: ABC BPAC Comments, 4/30/24) ♦

LDTs Final Rule Published

The U.S. Food and Drug Administration (FDA) has released the "Medical Devices: Laboratory Developed Tests (LDTs) final rule according to a April 29th news release from the agency. The final rule is effective July 5th and, "amend[s] the FDA's regulations to make explicit that *in vitro* diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA issued a policy to phase out, over the course of four years, its general enforcement discretion approach for LDTs. The agency also published targeted enforcement discretion policies for certain categories of IVDs manufactured by laboratories."

America's Blood Centers previously provided comments to the agency advocating that general enforcement discretion be applied to all blood centers' LDTs. Though the agency did not fully agree with all of ABC's proposed recommendations, the final rule does address some of the concerns raised by community blood centers with provisions outlining instances where enforcement discretion is allowed.

(continued on page 3)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes 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 health care 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
Chief Medical Officer: Jed Gorlin
Editor: Mack Benton
Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: $420

Send subscription queries to
memberservices@americasblood.org
America's Blood Centers
1717 K St. NW, Suite 900, Washington, DC 20006
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

LDTs Final Rule Published (continued from page 2)

Specifically, FDA is grandfathering IVDs offered as LDTs under the final rule. The agency explained that, "FDA intends to exercise enforcement discretion…for currently marketed IVDs offered as LDTs that were first marketed prior to the date of issuance of this rule and that are not modified, or that are modified in certain limited ways." However, FDA stated that it, "expects compliance with premarket review and quality system (QS) requirements for currently marketed IVDs offered as LDTs when a laboratory's modifications:

- change the indications for use of the IVD;
- alter the operating principle of the IVD (e.g., changes in critical reaction components);
- include significantly different technology in the IVD (e.g., addition of artificial intelligence or machine learning to the test algorithm, a change from targeted sequencing to whole genome sequencing, a change from immunoassay to mass spectrometry, or a change from manual to automated procedures); or
- adversely change the performance or safety specifications of the IVD."

Furthermore, FDA intends to address IVDs offered as LDT's that are "problematic" by using available mechanisms to target manufacturers of inaccurate or poorly validated IVDs offered as LDTs. Such mechanisms include requesting labs to submit labeling to help FDA monitor these tests, "and identify those that may lack analytical validity, clinical validity, or safety." Additionally, FDA will enforce records requirements to, "facilitate FDA's review of these IVDs during inspections." Finally, FDA "expects laboratories to comply with applicable requirements other than premarket review and most QS requirements, including Medical Device Report (MDR) requirements, corrections and removals reporting requirements, registration and listing requirements, and labeling requirements."

The agency also noted in the final rule that it will exercise enforcement discretion, "for non-molecular antisera LDTs for rare red blood cell (RBC) antigens where such tests are manufactured and performed in blood establishments, including transfusion services and immunohematology laboratories and where there is no alternative available to meet the patient's need for a compatible blood transfusion. This policy does not apply to molecular tests used for genotyping RBC antigens." The agency recognized, as noted in ABC's comments, that, "non-molecular antisera LDTs within the scope of this policy share certain characteristics with '1976-Type LDTs,' as they use manual techniques performed by laboratory personnel with specialized expertise. For such LDTs, in instances where there is no available alternative to ensure that a patient receives a compatible transfusion, FDA has determined it is in the best interest of public health to adopt this enforcement discretion policy." The policy applies to premarket review and QS requirements. FDA will still expect compliance with records requirements for non-molecular antisera LDTs.

The FDA explained in the final rule that it plans to exercise enforcement discretion and, "generally does not intend to enforce premarket review requirements for certain laboratory changes to another manufacturer's lawfully marketed test. In particular, this policy applies when a laboratory certified under CLIA and meeting the regulatory requirements under CLIA to perform high complexity testing modifies another manufacturer's 510(k) cleared or *De Novo* authorized test, following design controls and other quality system requirements for which FDA expects compliance…in a manner that could not significantly affect the safety or effectiveness of the test and does not constitute a major change or modification in intended use, and where the modified test is performed only in the laboratory making the modification." The FDA stated that its resources to review such changes could be better spent elsewhere, taking into account the low risks associated with these minor changes.

FDA also finalized its proposal to continue to apply the current general enforcement discretion approach to 1976-Type LDTs, and provided specific examples of tests that would be included under this enforcement

(continued on page 4)

LDTs Final Rule Published (continued from page 3)

discretion policy, including: "adsorbing warm-reactive autoantibodies using allogeneic or autologous red blood cells, the Donath-Landsteiner test for aiding in the diagnosis of paroxysmal cold hemoglobinuria, Ham's test to aid in the diagnosis of paroxysmal nocturnal hemoglobinuria, tests to evaluate drug-induced hemolysis or interference in compatibility testing, monocyte-monolayer test to assess possible clinical significance of RBC alloantibodies, modified Kleihauer-Betke, and SDa antigen neutralization with urine."

The agency has published several resources regarding LDTs and the final rule on its website including FAQs. FDA is hosting a May 14th webinar to go over the final rule. The webinar will:

- "[p]rovide an overview of the final rule amending the FDA's regulations to make it explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act including when the manufacturer of the IVD is a laboratory; and
- [d]escribe the phaseout of the FDA's general enforcement discretion approach to laboratory developed tests (LDTs)."

Questions for potential discussion on the webinar can be emailed to the agency by May 7th.

ABC will continue to provide updates on its advocacy efforts as they become available. Please contact us with comments or additional questions.

(Sources: FDA LDTs Final Rule, 4/29/24; FDA News Release, 4/29/24)

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has published a level two final guidance on April 30th titled "Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels." In the guidance, the agency explains, "[w]e are recognizing as acceptable for use by you, manufacturers of blood and blood components, subject to U.S. statutes and regulations, the document entitled 'U.S. Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128," Version 4.0.0, dated January 2024 (Version 4.0.0 Standard). The Version 4.0.0 Standard is the revised version of the "United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128,' Version 3.0.0, dated March 2013. The Version 4.0.0 Standard describes a system of uniform container labels for blood and blood components intended for transfusion or for further manufacturing use. We believe that this uniform container label standard will assist manufacturers in complying with the container label requirements under Title 21 of the Code of Federal Regulations 606.121 (21 CFR 606.121). This guidance supersedes the guidance of the same title dated June 2014."

(Source: FDA Final Guidance, 4/30/24)

The FDA has announced that it will hold a listening session on June 13th from 9 a.m. to 4 p.m. EST, "as part of its broader work to optimize the use of, and processes for, advisory committees." According to the agency, the virtual June listening session aims to, "focus on the composition of advisory committees, ways to improve the experience for members serving on committees, and ways to ensure public awareness and understanding of the role of FDA advisory committees." FDA explained that, "[f]or the listening session, the agency is seeking input on whether there are ways the FDA can better incorporate a variety of diverse perspectives and experiences, as well as consumer and patient voices into advisory committee meetings. The FDA also wants feedback on how it could streamline any administrative burdens (e.g., the amount of onboarding paperwork and processing time) that may make it less likely for an individual to want to serve on a committee. Additionally, the agency is interested in hearing about how it could improve

(continued on page 5)

REGULATORY NEWS (continued from page 4)

the public's awareness and understanding of the role of FDA advisory committees." Specific efforts from the agency towards their goal of optimizing advisory policies and practices include:

- "initiatives to modernize systems to reduce paperwork burden and streamline processes;
- exploring ways to improve the utility of advice received from advisory committees;
- considering ways to amplify recruitment of potential committee members, possibly through increasing dedicated staff and engaging existing committee members;
- establishing mechanisms to share and standardize certain practices and procedures across the agency; and
- working to improve public understanding of advisory committees and the roles they play."

Registration is open and complimentary. The deadline to request to speak during the session is May 13th at 3 p.m. EST.

(Source: FDA Announcement, 4/29/24)

WORD IN WASHINGTON

The U.S. Federal Trade Commission (FTC) has announced pre-publication of a final rule that bans non-competes. The rule states that, "that it is an unfair method of competition—and therefore a violation of section five — for persons to, among other things, enter into non-compete clauses ("non-competes") with workers on or after the final rule's effective date. With respect to existing non-competes — i.e., non-competes entered into before the effective date — the final rule adopts a different approach for senior executives than for other workers. For senior executives, existing non-competes can remain in force, while existing non-competes with other workers are not enforceable after the effective date." The final rule is set to take effect 120 days from the publication date in the *Federal Register* and, "defines seniors executives as workers earning more than $151,164 annually and who are in policy-making positions."

(Sources: FTC Final Rule, 4/23/24; FTC News Release, 4/23/24)

The U.S. Food and Drug Administration (FDA) published a draft guidance on April 30th titled, "Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products." The draft guidance features, "recommendations for determining the appropriate cell safety testing to support an Investigational New Drug Application (IND) or a Biologics License Application (BLA)." According to the agency, "[c]ell safety testing should be based on a risk analysis that considers the expansion potential of the cells, the reagents that are used to expand the cells in culture, and the number of individuals the cell-based medical product is capable of treating. This guidance supplements the following two final guidances:

- "'Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Guidance for Industry,'" dated January 2020, and
- 'Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs),' dated April 2008."

(Source: FDA Draft Guidance, 4/30/24)

The FDA also published another draft guidance on April 30th titled, "Considerations for the Use of Human-and Animal-Derived Materials in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products." The draft guidance aims to provide, "manufacturers of cellular and gene therapy (CGT) and (tissue-engineered medical products) TEMP products, with recommendations regarding

(continued on page 6)

WORD IN WASHINGTON (continued from page 5)

assuring the safety, quality, and identity of materials of human and animal origin used in the manufacture of these products. In addition, recommendations are provided regarding the chemistry, manufacturing, and control (CMC) information submitted in an investigational new drug application (IND) relating to the use of human- and animal-derived materials."

(Source: FDA Draft Guidance, 4/30/24)

BRIEFLY NOTED

The National Institutes of Health's (NIH) "Research Matters" blog published an article this week describing synthetic platelets being used to stop bleeding in animals. According to the blog post, "synthetic blood platelets stopped bleeding and sped wound healing in animals with internal injuries; [and the] synthetic platelets did not accumulate in other organs and were rapidly excreted, indicating that they're likely safe for testing in people." The synthetic platelet-like particles (PLPs) consist of, "ultrasoft microgel particle linked to a piece of an antibody that binds to fibrin. Fibrin is a protein found in wounds that helps blood clot. Targeting fibrin allows the PLPs to home in on wounds. The ultrasoft nature of the particles lets the PLPs change shape and compress their size. Such traits might let them mimic the behavior of real platelets and speed the healing process." In the study partially funded by NIH, the researchers, "optimized PLP binding to fibrin and tested several versions of their synthetic platelets in mice, rats, and pigs with internal injuries." The article noted that, "[w]hile the PLPs bound to fibrin at the wound sites, the current versions don't have all the functions of natural platelets. The team plans to develop next-generation synthetic platelets with additional features like the ability to clump together and to send signals to immune cells. They also hope to begin human studies within the next several years."

(Source: NIH Research Matters, "Synthetic platelets stop bleeding in animal studies," 4/30/24)

***TIME* has named U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research Director Peter Marks, MD, PhD as one of its 100 most influential people in health (TIME100 Health).** According to the publication, the list recognizes, "a community of leaders from across industries—scientists, doctors, advocates, educators, and policymakers, among others — dedicated to creating tangible, credible change for a healthier population. Together, they are a reminder that many things are going right, and their work is enough to inspire the belief that the world of health is in the middle of a golden age of accomplishment and transformation."

(Source: TIME100 Health, "Peter Marks, MD, PhD," 5/2/24)

RESEARCH IN BRIEF

Lipidomic Changes in Cold Stored Platelets. Researchers have published a study in *Transfusion Medicine* that is "an assessment of the lipidomic changes resulting from cold storage [of platelets] with a specific focus on the phospholipid and sphingolipid profile and their derived bioactive lipid mediators." They explained that, "[d]ouble-dose, leukoreduced apheresis platelet components (n = 8) were stored in 40 percent plasma and 60 percent PAS-E." For this study, "[t]he platelet components were split into single-dose equivalents, and the matched components were randomly assigned for storage at either room temperature (RT) (20–24ºC) with constant agitation or refrigerated (2–6ºC) without agitation." The authors explained that a, "[g]lobal lipidomic analysis was conducted using ultra-pressure liquid chromatography coupled to a mass spectrometer…The concentration of arachidonic acid in the supernatant was determined using commercially available enzyme-linked immunosorbent assay kits." The researchers wrote that, "[t]he total phospholipid and sphingolipid content of the day 1 platelets was 44,544 ± 2,915 µg/mL and was similar over 14 days, regardless of whether the platelet components were stored at RT (48,101 ± 9,704 µg/mL) or in the cold (44,405 ± 3,908 µg/mL, p = 0.99)." They explained that, "[c]ompared to day 1, the percentage of phosphatidylcholine was significantly lower in platelets after 14 days of cold storage, while the percentage of lysophosphatidylcholine was significantly lower in RT platelets at the same time point…Overall, the phosphatidylserine and phosphatidylethanolamine lipid classes were significantly increased by cold storage at day 14, compared to day 1 (2.7 and 12.2 percent, respectively). The study found that, "[s]phingomyelin was significantly increased during cold storage, compared to day 1 (4.1 percent). In contrast, ceramide was significantly decreased in cold-stored platelets after 14 days (p = 0.0016) (1.6 percent), while being significantly higher in platelets stored at RT…The concentration of arachidonic acid and 5-hydroxyeicosatetraenoic acid remained relatively constant over storage, regardless of storage temperature." The authors stated that the study, "demonstrate[d] that the sphingolipid and phospholipid profile of platelets and the supernatant were differentially altered by storage time and temperature." "It is apparent that storage for 5 days does not drastically affect the lipid profile…However, as storage progresses, differences in lipid classes and species associated with coagulation, apoptosis, and inflammation become apparent."

Citation: Green, S.M., Padula, M.P., Dodgen, T.M., Batarseh, A., Marks, D.C., Johnson, L. "Lipidomic changes occurring in platelets during extended cold storage." *Transfusion Medicine*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Gut Bacteria as Enzyme Sources for Universal Blood. The authors of a paper published in *Nature Microbiology*, "report [on their] work establish[ing] the conversion of extended A and B antigens as a previously unexplored solution to the enzymatic conversion of group A and/or B red blood cells (RBCs) to the ABO-universal group O (ECO) blood incompatibility and highlights the potential of gut microbiota specialists for the discovery of efficient human glycoconjugate-active enzymes." They explained that, "[o]ur strategy proved fruitful in the discovery of all required enzymatic specificities and remarkably high efficiencies towards all ABO epitopes, including extended structures on RBCs. They concluded that, "our work identified high-efficiency enzymes for conversion of all four described extensions of group A and B antigens, besides canonical A and B antigens, resulting in enzyme blends for one-pot conversion of group A and B core antigens. This provided compelling evidence for the antigenicity of the extended A and B antigens, thereby offering a missing link towards production of ABO-universal blood for transfusion and potentially organs for transplantation. This work offers insight into the extended A and B antigens as determinants of transfusion compatibility for the A and B RBC phenotypes and highlights mucin-degrading specialists of the gut microbiota as an important reservoir for discovery of glycoconjugate converting enzymes."

Citation: Jensen, M., Stenfelt, L., Hagman, J.R., *et al*. "Akkermansia muciniphila exoglycosidases target extended blood group antigens to generate ABO-universal blood." *Nature Microbiology*. 2024

PEOPLE

Jonathan Hoiles MBA has joined the Kentucky Blood Center (KBC) senior leadership team as the vice president of Quality and Regulatory Affairs. In his new role, he will, "[focus] on continuous process improvement and managing a comprehensive quality assurance plan. Mr. Hoiles will also serve as KBC's contact for all regulatory and accreditation agencies," according to a blood center news release. He most recently served as the associate director of product management at Cerus Corp. " Prior to his time there, he boasted a long tenure with the U.S. Navy, including four years as the director of the U.S. Navy Blood Program in Falls Church, Va., three years as the chief of Blood Services at Walter Reed National Military Medical Center in Bethesda, Md., and three years as the director of the U.S. Pacific Command Armed Services Blood Bank Center in Okinawa, Japan. He also served two years at the U.S. Navy Blood Donor Center in Jacksonville, N.C. and a combined five years at Naval Medical Center in San Diego, Calif. Mr. Hoiles is a Specialist in Blood Banking and has a certification in Medical Laboratory Science through the American Society for Clinical Pathology. He has been an Association for the Advancement of Blood & Biotherapies Assessor in blood center and transfusion service operations since 2011 and is a member of the International Society of Blood Transfusion where he serves as a member of the working party for global blood safety."

(Source: KBC News Release, 4/22/24)

Carter BloodCare Chief Administrative Officer **Veronica Moore, MBA** has been named to the "100 Latinas for 2024 List" by *Latino Leaders* magazine. The annual ranking recognizes Latina leaders who are blazing new trails in their communities and areas of expertise. Ms. Moore stated in the magazine, "as a Latina Leader, I embrace the beauty of my Hispanic heritage and aspire to show my community that the power to create change is within each of us. Do not be afraid. Raise your voice and be the joy that is part of our Hispanic culture and family traditions."

(Source: *Latina Leaders*, "100 Latinas for 2024," 5/1/24)

Contributed by James Black, Senior Public Relations Specialist at Carter BloodCare

MEMBER NEWS

San Diego Blood Bank (SDBB) recently hosted a donor/recipient reunion of April 29th. During the event, 10-year-old Kamila Saradpon and her family got a chance to, "than[k] donors for the blood she's received since she first started getting blood transfusions at two-months old. To date, Kamila has received 175 blood transfusions. [She] spends four-to-six-hour days at the hospital for blood transfusions every three weeks and will continue to need transfusions for the rest of her life." Her mom stated in a SDBB news release, "I can't even describe how it feels — these are the people who are the reason that she is here and happy, and smiling and healthy. I'm so grateful…[B]efore Kamila's diagnosis, blood donation was not something we ever thought about. But now, our family depends on those who give blood every day. If you've never donated blood before, please consider becoming a blood donor so kids like my daughter can grow up and have the life they deserve." Blood donor Michael Kim added in the news release, "[i]t was an amazing experience to be able to meet someone who received the donation that I gave. To be able to impact someone like that, it's pretty amazing. It means a lot to be able to see how this little donation really makes a big impact on someone."

Kamila Saradpon poses with blood donors from San Diego Blood Bank.

(Source: SDBB News Release, 4/29/24)

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 staffs only, unless otherwise specified.

ADRP Marketing Survey Launches

ADRP, The Association for Blood Donor Professionals has launched the first-ever ADRP Marketing Survey to serve as a tool to enhance your blood center's marketing strategy. The anonymized data from this resource can be used to benchmark your blood center's marketing spend and marketing activities to your peers. This survey will also provide participants with key information and insights to drive future decision-making including:

- appointment acquisitions and donor retention;
- spend allocation through various marketing channels; and
- paid advertising, donor incentives, and social media activity.

The deadline to complete the survey is June 14th. Only blood centers who participate in the survey will receive a report of the survey findings. Data is always anonymized, and no raw data will be provided. ADRP recommends that your marketing team complete this brief survey. A webinar will be hosted by ADRP in July to review the findings and key insights. Please contact us with any questions.

Still Time to Register for 2024 ADRP Annual Conference

Time is running out to register for the 2024 ADRP Annul Conference. The schedule is available! Join more than 400 blood center professionals in St. Louis, Mo. May 14th-16th at The St. Louis Union Station Hotel. This year's conference will feature keynotes Jason Kotecki, an expert at helping people "Escape Adulthood" in order to beat burnout and become more innovative and creative by breaking rules that do not exist, and Candy Whirley, a recognized motivational speaker, leadership, and team building expert. The 2024 ADRP Annual Conference is your opportunity to gain insights into industry trends, exchange ideas, and share information with your peers, while taking advantage of networking opportunities. Attendees will be able to participate in pre-conference workshops, educational sessions, roundtables, and have access to an expansive exhibit hall. Learn more about available exhibitor and sponsorship opportunities. Please contact us with questions.

Upcoming ABC Webinars & Virtual Events – Don't Miss Out!

- **ADRP Master Class** – Sept.18th-19th. Registration is open. More information available here.

America's Blood Centers® It's About *Life.*

ADRP The Association for Blood Donor Professionals

COMPANY NEWS

Fresenius Kabi has opened nominations for the National Blood Donation Hall of Fame. This initiative, in collaboration with blood centers, recognizes individuals who support the U.S. blood supply. It applauds the tireless efforts of donors, advocates, and volunteers who highlight the importance of blood donation. Blood centers are invited to nominate someone who exhibits a steadfast commitment to blood donation. Email nominations to: info.usa@fresenius-kabi.com by June 9th. Learn more and see past hall of fame inductees here.

(Source: Fresenius Kabi Announcement, 4/12/24)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2024

May 3-4. **California Blood Bank Society (CBBS) Annual Meeting (Virtual).** More information available here.

May 14-16. **2024 ADRP Annual Conference. St. Louis, Mo.** Registration is open. More information available here.

May 15-16. **International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Aarhus, Denmark.** Registration is open. More information available here.

May 29-30. **U.S. Food and Drug Administration (FDA) Regulatory Education for Industry (Redl) Annual Conference 2024: Innovation in Medical Product Development (Hybrid).** More information available here.

June 4. **U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Town Hall: Chemistry, Manufacturing, and Controls (CMC) Readiness for Gene Therapy Biologics License Applications (BLAs) (Virtual).** More information available here.

June 7-8. **2024 South Central Association of Blood Banks (SCABB) Annual Meeting and Exhibit Show. Orlando, Fla.** Registration is open. More information available here.

June 13. **FDA Public Meeting: Optimizing FDA's Use of and Processes for Advisory Committees (Virtual).** Registration is open. More information available here.

June 23-27. **38th International Society of Blood Transfusion (ISBT) Congress. Barcelona, Spain.** Registration is open. More information available here.

Sept. 3-6. **American Society for Clinical Pathology (ASCP) Annual Metting. Chicago, Ill.** Registration is open. More information is available here.

Sept. 18-19. **2024 ADRP Master Class: Bring in the Coach — The Path to Effective Leadership (Virtual).** Registration is open. More information available here.

Sept. 30-Oct. 3. **American Association of Tissue Banks (AATB) Annual Meeting. Denver, Colo.** More information is coming soon.

(continued on page 11)

CALENDAR (continued from page 10)

Oct. 19-22. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Houston, Texas.** More information is coming soon.

Nov. 6-7. **ABC Women's Executive Leadership Community (WELC) Workshop. San Antonio, Texas.** More information is coming soon.

2025

May 20-21. **International Plasma Protein Congress. Warsaw, Poland.** More information is coming soon.

Oct. 12-15. **AATB Annual Meeting. Atlanta, Ga.** More information is coming soon.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** More information is coming soon.

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 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: newsletter@americasblood.org

POSITIONS

Regional Director, Blood Services. Vitalant is seeking a passionate and results-driven Regional Director to lead all operational activities at our regional blood center in Spokane, Washington. As the driving force behind our daily operations, you will lead by example, ensuring strict compliance with Vitalant' s policies and directives while overseeing every facet of the blood center operations. In this pivotal role, you will thrive in a collaborative environment, working closely with Blood Service Leadership throughout the organization to realize strategic objectives and exceed collection targets. This role will encompass a wide range of responsibilities, including upholding policy compliance, driving performance metrics, and maintaining stringent standards. The primary focus will be spearheading impactful community outreach initiatives to increase exposure and engagement, as well as cultivating new partnerships and accounts to expand our reach and impact in the region. If you are ready to lead with purpose and make a vital impact through your work you will experience a career built on purpose, an organization created to care, and a team committed to lead – together. Please click here to view the full job description and apply.

Director, Donor Marketing. The Director, Donor Marketing is a pivotal leadership role within New York Blood Center Enterprises (NYBCe), overseeing a team of seasoned marketing professionals tasked with driving donor engagement and donor acquisition across various Blood Operations divisions. Working closely with divisional Donor Recruitment and Collections teams to ensure alignment with overarching marketing strategies. As the senior-most authority in donor marketing, the Director, Donor Marketing operationalizes Enterprise Donor Engagement strategies at the local level, guiding and empowering divisional marketing managers to execute targeted initiatives that meet product and service objectives across all divisions. Reporting directly to the Executive Director, Strategy and Planning, Donor Engagement, this role carries significant responsibility in steering local marketing efforts in line with enterprise goals. Candidates must be able to report into one of the following NYBCe locations: New York City, NY; Providence, RI and Newark, DE. New York Location: For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is $160,00.00 p/yr. to $170,00.00 p/yr. Rhode Island Location: For applicants reporting into Rhode Island, the proposed annual salary is $150,00.00 p/yr. to $160,00.00 p/yr. To apply: https://careers-nyblood-center.icims.com/jobs/6268/director%2c-donor-marketing/job?mode=view.

Donor Recruitment Manager. Blood Assurance is seeking a **Donor Recruitment Manager** to lead field recruitment efforts that build new and existing business in our Chattanooga and North Georgia region. Primary responsibilities include direct leadership of Account Managers in expanding blood drive activity on mobiles primarily, and in facilities as needed, based on growth strategy in a specific type of blood product recruitment and collection. Assist in developing long-term community business partnerships, and coordinating internally with all leadership levels to support or expand Blood Assurance recruitment efforts. Work closely with Donor Services leadership to ensure recruitment and collection

(continued on page 12)

POSITIONS (continued from page 11)

teams are working together toward meeting overall product collection goals. Qualified applicants will have: Bachelor's degree-preferably in business, marketing, or related field. Seven to 10 years sales experience, preferably in blood banking. Three to five years sales staff management. Advanced communication skills. Public presentation and networking skills. Advanced organizational, customer service and teamwork skills. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Paid Time Off, 401K, a Wellness Program, and Relocation Assistance. Qualified candidates are encouraged to submit an online application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco-Free Environment.

Mobile Site Supervisor – Donor Centers (Carter BloodCare). The Site Supervisor position provides a vital link in the procurement of a safe quality blood product. Essential functions are to assist in smooth and efficient donor flow, determine donor acceptability, perform sterile venipuncture for the collection of blood, provide excellent customer service, and ensure compliance with regulations and standard operating procedures throughout the donation process. This position oversees and assigns duties to staff and may be involved in the following processes: discipline, performance reviews, hiring and terminations. This includes effectively and discreetly solving personnel and donor issues, addressing procedural or behavioral problems, and making verbal or written reports to management. Additionally, this role requires completing annual leadership training and assisting with on-the-job development of employees. Education: High school diploma or equivalent. Some college a plus. Experience: Minimum 2 years general work experience. Customer service experience required. Minimum 6 months to 1-year supervisory experience. Previous Phlebotomy 2, blood banking experience, or medical field experience. Background in a highly regulated industry. Fluency in English/Spanish skills and CDL driver a plus. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job # Mobile Site Supervisor Donor Center.

Phlebotomist 2 – Donor Centers (Carter BloodCare). The Phlebotomist 2 assists in smooth and efficient donor flow, determine donor acceptability, performs sterile venipuncture for the collection of blood, provides excellent customer service and ensures compliance with regulations and standard operating procedures throughout the donation process. In the absence of a supervisor, you will oversee and assign responsibilities to staff. This includes effectively and discreetly solving personnel and donor problems, addressing procedural or behavioral problems, and making verbal or written reports to management. Additionally, the Phlebotomist 2 will be required to attend and complete annual development training resources and assist with on-the-job development of staff. Education: High school diploma or equivalent. Some college a plus. Experience: 1-year general work experience, preferably working with the public, or education that includes comparable experience such as an internship or externship. Customer service experience required, intern and/or externship experience will satisfy this requirement. Previous Phlebotomy 1, blood banking experience or medical field experience. Background in a highly regulated industry. Fluency in English/Spanish skills and CDL driver a plus. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job # Phlebotomist 2.

Manager of Donor Resources. The Blood Connection is seeking a Manager of Donor Resources for our operations based out of Augusta, GA. This position will be responsible for monitoring progress to goal proactively, and effectively coaching and managing their team to success. The ideal candidate for this position possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Resources – Augusta, GA.

Manager of Donor Services. The Blood Connection is seeking a Manager of Donor Services for our operations based out of Raleigh, NC and Rock Hill, SC. These positions will oversee donor collection operations within their assigned divisional territory. These positions provide leadership and discipline to direct reports, interviews, and hire staff, and ensure staff are appropriately trained. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Services – Raleigh, NC. Manager of Donor Services – Rock Hill, SC.