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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2023 #38 October 20, 2023

INSIDE:

FDA Publishes Final Compliance Policy Guidance and Updates CCP Guidance

The U.S. Food and Drug Administration (FDA) released a final guidance on October 17th titled "Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements." The guidance explains the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain requirements in Title 21 of the Code of Federal Regulations 630.30 (21 CFR 630.30) regarding donation suitability; 21 CFR 630.10(c)(2) regarding donor eligibility; and 21 CFR 640.69(f) regarding quarantine hold for Source Plasma. In February 2023, America's Blood Centers (ABC) asked the FDA to finalize the draft guidance to allow the recommendations set forth in the COVID-era Alternative Procedures Guideline to continue to apply outside the context of the public health emergency.

Under the compliance policy guidance, FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain regulations for donation suitability provided certain conditions are met. Specifically, when the donation is otherwise suitable, the FDA will not take regulatory action if blood establishments release certain donations for transfusion or further manufacture when the review of records, required after donation, identifies the donation as unsuitable because of an inadvertent failure to follow procedures to ensure the donation would not adversely affect the health of the donor, specifically for: blood pressure, pulse, weight, donation frequency for whole blood and red blood cells collected by apheresis, pregnancy, and red blood cell loss for plasma collected by plasmapheresis. Contrary to ABC's recommendations to FDA, blood establishments that elect to release unsuitable units must submit a summary report in the reporting category of an Annual Report to FDA describing the number and type of donations released under these conditions, and the corrective actions taken to prevent recurrence of errors.

Additionally, FDA does not intend to take regulatory action if a blood establishment clarifies a donor's response or obtains omitted information required to determine donor eligibility and donation suitability within 72 hours of the time of collection, instead of within 24 hours of the time of collection, provided all other donor eligibility requirements are met. The agency also does not intend to take regulatory action if source plasma is released after a quarantine hold of 45 calendar days, instead of 60 calendar days, provided all other steps in 21 CFR 640.69(f) are followed and all other donor eligibility and donation suitability requirements are met.

(continued on page 2)

FDA Publishes Final Compliance Policy Guidance and Updates CCP Guidance (continued from page 1)

Finally, licensed establishments that intend to implement changes described in the guidance must report changes to their standard operating procedures (SOPs) to reflect this compliance policy guidance as Changes Being Effected (CBE) supplements. If, consistent with the April 2020 guidance, a licensed establishment reported changes to their SOPs under 21 CFR 601.12(c)(5), a new CBE supplement does not need to be submitted to reflect the compliance policy guidance. However, the establishment should report that they are retaining the SOPs in their Annual Report under 21 CFR 601.12(d).

COVID-19 Convalescent Plasma Guidance Update. The FDA also updated the guidance titled "Investigational COVID-19 Convalescent Plasma (CCP)" on October 13th. In August 2020, FDA issued an Emergency Use Authorization (EUA) for CCP for the treatment of hospitalized patients with COVID-19. FDA subsequently reissued the EUA with revisions. Most recently, FDA revised the EUA to limit authorization to the use of CCP with high titers of anti-SARS-CoV-2 antibodies for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting.

The recommendations in the updated guidance are unchanged from the January 2022 guidance. However, FDA has removed the language limiting the duration of the policy in the guidance to the public health emergency. The policy in the guidance will now remain in effect for the duration of the declaration under section 564 of the Federal Food, Drug, and Cosmetic Act by the Secretary of Health and Human Services on March 27, 2020 declaring that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, or until the time that FDA determines it is appropriate to revoke the EUA for CCP because the circumstances that justify its issuance no longer exist.

In preparation for when the EUA is no longer in effect, blood establishments interested in submitting an investigational new drug (IND) application or biologics license application (BLA) for CCP may contact the Center for Biologics Evaluation and Research's (CBER) Office of Blood Research and Review (OBRR). ABC will continue to keep member blood centers informed of its advocacy efforts and encourages members to contact ABC's Director of Regulatory Affairs and Public Policy, Justine Coffey, JD, LLM, with any questions.

(Sources: FDA Compliance Policy Guidance, 10/17/23; FDA CCP Guidance, 10/13/23; MCN 23-087, 10/18/23)

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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 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.

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Can Switching to Small-Volume Blood Collection Tubes Lower Transfusions in the ICU?

Researchers in the *Journal of the American Medical Association* (*JAMA*) sought to determine whether "transitioning from standard-volume to small-volume tubes for blood collection in adult [intensive care units] (ICUs) would reduce [red blood cell] (RBC) transfusion without compromising laboratory testing procedures." To be eligible to participate in the trial, ICUs had to, "admi[t] adult medical-surgical critically ill patients, ha[ve] at least 14 ICU beds, ha[ve] capacity for invasive mechanical ventilation, us[e] standard-volume blood collection tubes for blood collection, and ha[ve] capacity for electronic data sharing." According to the authors, the "primary efficacy outcome was the number of RBC units transfused per patient during ICU admission. Secondary outcomes were the proportion of patients receiving at least one RBC transfusion, decrease in adjusted hemoglobin concentration during the ICU stay (adjustment was to decrease hemoglobin value by 1 g/dL for each RBC unit received), length of stay in the ICU and hospital, and mortality in the ICU and hospital. To assess the effect of transition to small-volume tubes on laboratory analysis, we measured the number of blood specimens reported as insufficient volume for testing (as defined at each hospital determined prior to trial initiation) from laboratory information systems using the two most frequently used tubes (ethylenediaminetetraacetic acid and sodium/lithium heparin)…For the primary analysis, the number of RBC transfusions was modeled as the outcome measure, and the ICU stay was incorporated as an offset term to account for variations in the number of RBC transfusions administered during ICU stays of varying duration."

The study included, a "total of 28,549 RBC units [given] to 6,362 patients (30 percent) in the primary analysis population and 35,687 were given to 8,136 patients (30 percent) in the secondary analysis population. In the primary analysis population, which excluded 6,210 patients admitted during the pandemic-related trial hiatus, least-squares mean RBC units transfused per patient was 0.79 (95 percent CI, 0.58 to 1.07) before transition and 0.72 (95 percent CI, 0.52 to 0.98) after transition to small-volume tubes (RR, 0.91 [95 percent CI, 0.79 to 1.05]; P = .19). The absolute difference in RBC units given per 100 patients per ICU stay was 7.24 RBC units (95 percent CI, −3.28 to 19.44)…In the secondary analysis population (whole cohort with ICU stay ≥48 hours), the least-squares mean number of RBC units transfused per patient during ICU stay was 0.80 (95 percent CI, 0.61 to 1.06) before transition to small-volume tubes and 0.71 (95 percent CI 0.53 to 0.93) after transition (RR, 0.88 [95 percent CI, 0.77 to 1.00]; P = .04), corresponding to an absolute difference of 9.84 (95 percent CI, 0.24 to 20.76) RBC units transfused per 100 patients during their ICU stay…In a prespecified secondary analysis, the median transfusion-adjusted reduction in hemoglobin during ICU admission was 1.50 g/dL (IQR, 0.40-3.20) before transition and 1.40 g/dL (IQR, 0.20-3.00) after transition (mean difference, 0.10 g/dL [95 percent CI, −0.04 to 0.23]; P = .16)"

The authors explained that, "RBC transfusions did not differ significantly before and after transition from standard- to small-volume blood collection tubes in the primary analysis population of ICU patients admitted for 48 hours or more, which excluded those admitted during a COVID-19 pandemic-related trial hiatus. However, in secondary analyses, RBC transfusion was lower among the larger cohort of all patients admitted for 48 hours or more, as was the decrease in hemoglobin concentration in both populations after the transition to small-volume tubes." They concluded that, "[t]he transition from standard-volume to small-volume tubes for blood collection in the ICU may reduce RBC transfusion without impacting biospecimen sufficiency for laboratory analysis."

Citation: Siegal, D., Belley-Côté, E., and Lee, S.F., *et al.* "Small-Volume Blood Collection Tubes to Reduce Transfusions in Intensive Care." *JAMA*. 2023

WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) is hosting a webinar titled "Proposed Rule: Medical Devices; Laboratory Developed Tests (LDTs)." The virtual event will take place on October 31st at 1 p.m. EDT. On this webinar, the agency plans to:

- "[p]rovide an overview of the rulemaking proposal to amend the FDA's regulations to make 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;
- [d]escribe the proposed phaseout of FDA's general enforcement discretion approach to LDTs;
- [h]ost a Q&A session based on questions that have been submitted prior to the webinar at CDRHWebinars@fda.hhs.gov. Questions will not be taken during the live webinar. All questions are due by October 23rd to be considered for the discussion.

More information on the webinar is available on the FDA website.

(Source: FDA Announcement, 10/16/23)

The FDA's Center for Devices and Radiological Health (CDRH) has published its fiscal year 2024 proposed guidances. The list includes guidance documents that the agency, "intends to publish during the fiscal year, as well as previously issued final guidances which CDRH is interested in receiving external feedback about whether these guidances should be revised or withdrawn."

(Source: CDRH Announcement, 10/10/23)

BRIEFLY NOTED

The Centers for Disease Control and Prevention (CDC) has published new preliminary data on pre-exposure prophylaxis (PrEP) coverage. According to the report, "in 2022, 36 percent of the 1.2 million people who could benefit from PrEP were prescribed it [in the U.S.], compared to 23 percent in 2019…Increasing PrEP coverage is one of the key prevention strategies outlined in the Ending the [U.S. Department of Health and Human Services'] (HHS) HIV Epidemic in the U.S. (EHE) initiative.

(Source: CDC Announcement, 10/17/23)

Four biopharmaceutical companies (Regeneron Genetics Center®, AstraZeneca, Novo Nordisk, and Roche) have announced an $80 million contribution to an "industry-academic initiative [that] aims to create the largest ever database of genomes exclusively from people with African ancestry." According to *Science*, the companies are collaborating with the Meharry Medical College, a historically Black college in Nashville, Tenn., on initiative called "Together for Changing Healthcare for People of African Ancestry through an InterNational Genomics & Equity (Together for CHANGE)." The initiative seeks to, "recruit up to 500,000 African Americans and people from Africa and combine their DNA and medical data into a biobank for health studies."

(Sources: *Science*, "New initiative aims to sequence half a million genomes of people with African ancestry for health studies," 10/18/23; Regeneron News Release, 10/18/23)

ABC Women's Executive Leadership Community Aims to Empower Women Leaders and Diversify Blood Community Leadership

America's Blood Centers (ABC) recently launched the Women's Executive Leadership Community (WELC), a new initiative aimed at inspiring and connecting women leaders throughout the blood community. WELC will hold its inaugural virtual event, "Taming the Tyranny of the Urgent," on October 26th at 2 p.m. EDT. WELC was developed following conversations among ABC Chief Executive Officer (CEO) Kate Fry, MBA, CAE, Lisa Entrikin, CEO of Rock River Valley Blood Center, and Kim Kinsell, JD, president and CEO of LifeSouth Community Blood Centers.

"Kate came to Kim and I as female CEOs on her board and said that there were 15 female CEOs within the ABC group. Kim and I were very surprised, because when you think about who is employed across community blood centers across the nation, it's predominantly female," explained Ms. Entrikin. "I think we see a lot of females in the C-suite who hold the positions of medical director or chief financial officer. But really, they don't quite make it to the top at the percentage that they probably should, when you consider how many women are in significant positions within the industry," added Ms. Kinsell. "I think for Lisa and I, the data itself really hit home." According to McKinsey & Co. and LeanIn.Org's Women in the Workplace report, "women face their biggest hurdle at the first critical step up to manager," an effect they called the broken rung. The report found that for every 100 men promoted from entry level to manager in the most recent reporting year, just 87 women were promoted. The data also found that women are unable to catch up to their male counterparts due to this broken rung.

Ms. Entrikin and Ms. Kinsell decided to help form WELC and become its co-chairs to provide all women and those who support them across the blood community, the kind of support they have received. "When I stepped into my role, I had a CEO from another blood center reach out to me and offer to mentor," said Ms. Entrikin. "It was just a wonderful opportunity for me to really have somebody that I could bounce ideas off." Ms. Kinsell noted, "I had a female mentor. My former CEO was female and that that made a huge difference for me in terms of my belief in myself that I could do the position. Oftentimes as the CEO or in any leadership position, you need to have a sounding board. You need to have somebody who can provide guidance and can really help talk through a lot of the things that you go through, especially as you're learning or with any challenging situation. Having someone, male or female is important."

The co-chairs believe that ensuring women are better represented across the workplace can make a lasting difference. The WELC aims to be a resource not just for women, but also for the men who work and manage them. "The issues that face women as leaders face everyone as leaders. They may be more pronounced in certain aspects for women, but they do face everyone. So, men can learn from the things we're going to tackle as well," said Ms. Entrikin. "I really do believe this is a community for everyone and all can get something out of it." Ms. Kinsell also stated, "I know that while we're in our infancy, I think a lot of the program development we want to do in terms of education really is in many ways some of the soft skills. One of the avenues that WELC really wants to sort of take the community down, men and women, is really just not only on being inclusive, but it's a lot of the soft skills, the leadership development and things that I think our industry as a whole probably doesn't really focus on," explained Ms. Kinsell.

The importance of soft skills — areas like leadership, communication and problem-solving — is well known. Many industries are just now starting to comprehensively provide these skills as employees increasingly seek them. "We focus on donor recruitment, policy, and supply chain. But you know any leader, male or female, all need these soft skills to make them not only better leaders of their organization, but to also help them be better peers to help them be better managers. We are really excited to see an opportunity for WELC to really take on an area in our industry that we feel like has probably not been addressed as robustly as it as it could be," said Ms. Kinsell.

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ABC Women's Executive Leadership Community Aims to Empower (continued from page 5)

WELC will hold its first-ever event later this month, a webinar titled, "Taming the Tyranny of the Urgent," which will take place on October 26th at 2:00 pm ET. Meghan D. Kinter, PhD, will be the guest speaker. This webinar will feature breakout sessions for attendees and a question-and-answer session with Dr. Kinter who has, according to her bio, spent more than two decades "expertly guid[ing] businesses and individuals through the complexities of their challenges, helping them navigate from feeling 'stuck' to achieving clarity and momentum." By the end of the event, attendees will discover the Power of the 3Ms – Mindful Mindset, Managing Time, and Mastering Habits, understand the psychology behind urgency and its impact on productivity, develop a resilient, proactive approach to daily challenges, and curate a personal toolkit of habits, tools, and strategies to optimize every day. WELC is a complimentary offering open to all employees of ABC member blood centers and ABC sponsor partners. Through this initiative, ABC strives to empower leaders throughout the blood community through networking and professional development. ABC encourages eligible individuals to join WELC and its LinkedIn Community, and share this information with those who may be interested.

WELC is the first initiative launched as part of ABC's new Executive Leadership Initiative, designed to help blood center leaders get the professional development they need to meet today's challenges."I applaud Kate and the ABC team for recognizing this need and helping to fill a void. And I'm very thankful to the ABC board outside of Kim and I that really embraced this and recognized that it's a great idea and a role that ABC can fill for its members," said Ms. Entrikin. "I'm just looking forward to seeing what we're going to develop into 2024," she added.

Contributed by Jeff Gohringer, Director of Strategic Communication and National Partnerships at America's Blood Centers

PEOPLE

Aaron Tobian, MD, PhD has become president of the Association for the Advancement of Blood & Biotherapies (AABB) Board. Dr. Tobian's term began at the conclusion fo the 2023 AABB Annual Meeting this week. He is, "a professor of pathology, medicine and epidemiology at The Johns Hopkins University School of Medicine and Bloomberg School of Public Health. [Dr. Tobian] is also director of transfusion medicine and vice chair for clinical affairs in pathology at Johns Hopkins Hospital. Prior to serving as a member of the AABB Board of Directors, he served on 10 AABB committees or working groups, including as chair of the Clinical Transfusion Medicine Committee for six years."

(Source: AABB Announcement, 10/17/23)

MEMBER NEWS

The Blood Center (New Orleans, La.) recently recognized telerecruiter Judy Sumner for going above and beyond. Ms. Sumner called an individual to recruit him as a donor when the person on the other end answered in distress. He told her he was having trouble breathing and that the emergency medical services (EMS) team was already on the way. However, he asked if she could stay on the phone with him since he had no one else to talk to and was scared. Ms. Sumner remained on the phone with him for several minutes, calmly talking until the EMS team arrived. "I've called him six times to check-in on him since this occurred," said Ms. Sumner. The breathing problems stem from long-term COVID-19 complications, which will stop this donor from giving in the future. However, Ms. Sumner stated that, "I will keep him in my call lists to check-in on him periodically to ensure he's okay." Billy Weales, president and chief executive officer of The Blood Center, commended Ms. Sumner. "We know what we're doing every day saves lives...but this was a unique way of reminding us all how important our role is to our community."

(Source: The Blood Center Announcement, 10/10/23)

Contributed by Paul Adams, Public Relations Manager at The Blood Center

NEW on Coll*ABO*rate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC Coll*ABO*rate Online Member Community include:

- Procedure Change Process (COLLECTIONS & DONOR SERVICES)
- Platelet Collections (COLLECTIONS & DONOR SERVICES)
- Ultracrit Verification after Repair (COLLECTIONS & DONOR SERVICES)
- Pulse Recheck Policy (COLLECTIONS & DONOR SERVICES)
- Procedure Change Process (COLLECTIONS & DONOR SERVICES)
- Unlicensed Products (QUALITY BYTES)
- Reentry SOPs (TECHNICAL DIRECTORS)
- Terumo COBE 2991 (TECHNICAL DIRECTORS)

ABC members are encouraged to login and join the conversations today!

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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 staffs only, unless otherwise specified.

Registration Opens for 2024 ABC Annual Meeting

Registration is open for the America's Blood Centers (ABC) 2024 Annual Meeting. The meeting will take place March 4th-6th in Arlington, Va. at the Ritz-Carlton in Pentagon City and features several exciting changes, including expanded content offerings and a new format. With a focus on advocacy, leadership, operations, and science and medicine, the program will feature a mix of general and breakout sessions, external speakers and blood center-led case studies, committee and council meetings, networking events, and more. *Awards of Excellence* (AoE) winners will be recognized throughout the Annual Meeting and at a reception on Capitol Hill, where we can celebrate their achievements with fellow meeting attendees, members of Congress and their staff, our federal agency partners, Blood Advocacy Week partners, and more. The call for AoE nominations is open. Secure your room today to take advantage of the group rate. The deadline to book a room is February 16th. Sponsorship opportunities are also available. Contact us with any questions.

ABC Advocacy Forum Set for November 1st

ABC will hold its next Advocacy Forum: Congressional, Agency, and State Updates on November 1st at 2 p.m. EDT. The forum will include updates and discussions on:

- the ABC meeting on surge capacity and preparedness with the Biomedical Advanced Research and Development Authority (BARDA) and the Office of the Assistant Secretary for Preparedness and Response (ASPR);
- congressional updates;
- licensure reform efforts; and
- state advocacy and the ABC Council of States.

Additional information including a link to registration is available to ABC members in MCN 23-083.

(Source: MCN 23-083, 10/5/23)

Registration Opens for ADRP's October Webinar

Join ADRP, the Association for Blood Donor Recruitment Professionals on Wednesday, October 25th at 1 p.m. EDT for the "Innovations in Donor Recruitment and Inventory Growth" webinar. This event will feature successful case studies from blood center professionals as they describe the creative programs and incentives that their blood centers have implemented, while taking risks that ultimately resulted in substantial inventory boosts. This strategy ensured that their local hospital partners consistently had blood products on their shelves, especially during challenging times of the year. Registration is open. Donor recruitment professionals will find this webinar particularly enriching, as speakers share data, results, and new and effective ways that can help you meet your collection goals. Join us to hear speakers from:

- Our Blood Institute;
- LifeSouth Community Blood Centers;
- ConnectLife; and
- Memorial Blood Centers.

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INSIDE ABC (continued from page 8)

Save the Date: SMT Journal Club on December15th

The next ABC Scientific, Medical, and Technical Journal Club Webinar will take place on December 15th at 12 p.m. EST. The webinar is free to all ABC members. An email announcement with a registration link and the articles to be reviewed on the webinar is forthcoming.

GLOBAL NEWS

A recent report in *The Conversation* describes academic research suggesting that "telling [individuals] who have donated blood when and where the blood was used makes them more likely to do it again." The news organization cites a study from the Austrian Red Cross in collaboration with researchers from the University of Hamburg. The study's authors investigated, "whether nearly 75,000 people who had donated in the prior two years would return to give blood. They were either simply thanked or they also were given specific information about the date their blood was used and the name of the hospital where that happened." According to *The Conversation*, "[t]hose receiving specific information were 10 percent more likely to donate again than the thanks-only group." In a separate study including the Austrian Red Cross, donors received, "a short text message, including the date when a donation was used and the hospital name, either three weeks after their donation or 10 days before they could donate again – roughly one month apart. Getting those details 10 days before they could donate again made them 63 percent less likely to give blood again compared to people who received the same message three weeks after their last donation." The article also highlights findings from a study involving the German Red Cross where information was sent, "to over 16,000 people who had not donated blood for over two years. They were either thanked for their previous donation, thanked and told how their blood was used, or thanked and told how their next donation would be used. These former blood donors were 11 percent more likely to donate again when they were told how their blood was used in the past compared to those who were just thanked or told how their future donation could be used." A separate study with the German Red Cross sought to further, "understand what drives this effect." The investigators conducted an online experiment with 500 lapsed donors. "When these people were prompted to imagine they had received a text message with details about the use of blood they had donated in the past, they felt like the organization cared about them more. Consequently, they said they'd be more likely to donate again." Future studies will, "aim to analyze whether telling regular donors repeatedly about their blood's use will make more or less of a difference over time."

(Source: *The Conversation*, "Being told where their blood ends up encourages donors to give again – new research," 10/2/23)

COMPANY NEWS

Blood Centers of America (BCA) and the **American Friends of Magen David Adom** (AFMDA), the "sole fundraising representative in the U.S. for Magen David Adom (MDA), Israel's national emergency medical and Blood Services," are partnering to, "activate blood donors in the U.S. in support of response efforts in Israel." Through the collaboration, the AFMDA will partner with a portion of BCA's member blood centers to host blood drives. This is, "part of a tenure Contingency Agreement between U.S. blood centers and MDA [which] will ensure there is ample blood supply and products, if required to support MDA and the Israeli community. BCA and MDA have had this agreement in place since 2018 to ensure the ability to support MDA in times of emergency response."

(Source: BCA News Release, 10/20/23)

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COMPANY NEWS (continued from page 9)

The U.S. Food and Drug Administration (FDA) has approved **Roche Diagnostics**' biologics license application (BLA) for the Elecsys HTLV (human T-lymphotopic virus)-I/II. According to the October 17th approval letter, the *in vitro* immunoassay is meant for use on the cobas® pro serology solution, "for the qualitative detection of antibodies to HTLV-I and HTLV-II in human serum and plasma."

(Source: FDA Letter, 10/17/23)

Editas Medicine, Inc. announced that the FDA has granted the Regenerative Medicine Advanced Therapy (RMAT) designation for its investigational gene therapy to treat sickle cell disease (SCD). According to a company news relase, the designation is, "dedicated program designed to expedite the development and review processes for promising regenerative medicine therapies…Advantages of the RMAT designation include all the benefits of the fast track and breakthrough therapy designation programs, including but not limited to intensive FDA guidance on efficient and expedited drug development, possible rolling review, and priority review of the biologics license application (BLA)…The FDA previously granted Orphan Drug Designation and Rare Pediatric Disease designation to EDIT-301 for the treatment of sickle cell disease and beta thalassemia."

(Source: Editas Medicine, Inc. News Release, 10/16/23)

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

- **ADRP Webinar: Innovations in Donor Recruitment and Inventory Growth** – Oct. 25. Registration is open. More information available here.
- **ABC Women's Executive Leadership Community (WELC) Webinar** – Oct. 26. More information and a link to registration are available to ABC Members in MCN 23-081.
- **ABC Advocacy Forum: Congressional, Agency, and State Updates** – Nov. 1. More information and a link to registration are available to ABC Members in MCN 23-083.
- **ABC Scientific, Medical, and Technical Journal Club Webinar** – Dec. 15. More information coming soon!
- **2023 ADRP International Showcase** – Nov 15. Registration is open. More information available here.

America's Blood Centers®

ADRP
The Association for Blood Donor Professionals

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 meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

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.)*

2023

Oct. 25. **ADRP, The Association for Blood Donor Professionals Webinar: Innovations in Donor Recruitment and Inventory Growth.** Registration is open. More information available here.

Oct. 26. **America's Blood Centers (ABC) Women's Executive Leadership Community (WELC) Webinar.** More information and a link to registration are available here.

Oct. 31. **U.S. Food and Drug Administration (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee Meeting (Virtual).** More information available here.

Nov 1. **ABC Advocacy Forum: Congressional, Agency, and State Updates (Virtual).** More information and a link to registration are available here.

Nov. 8-10. **Blood Centers of America, Inc. (BCA) Innovation Summit, Oklahoma City, O.K.**

Nov. 13-14. **U.S. Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2023. (Hybrid), Washington, D.C.** Registration is open. More information available here.

Nov 15. **ADRP, The Association for Blood Donor Professionals International Showcase (Virtual).** Registration is open. More information available here.

Nov. 18-21. **ISBT Regional Congress, Cape Town, South Africa.** Registration is open. More information available here.

Dec. 15. **ABC Scientific, Medical, Technical (SMT) Journal Club Webinar.** More information coming soon.

2024

Feb.7-8. **International Plasma and Fractionation Association & EBA Symposium on Plasma Collection and Supply. Leiden, Netherlands.** Registration is open. More information available here.

Mar. 4-6. **ABC Annual Meeting, Arlington, Va.** Registration is open. More information available here.

April 12-13. **BEST Meeting, Amsterdam, Netherlands.** More information coming soon.

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

Sept. 4-6. **American Society for Clinical Pathology (ASCP), Chicago, Ill.** More information coming soon.

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

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

EQUIPMENT AVAILABLE

For Sale. Two refurbished Aurora Plasmapheresis System devices with Certificate of Compliance for each device. Both devices have Software 2.0 installed. Asking for best offer. Location: Jackson, TN. Please contact LaTrina Morman, (731) 427-4431, or email latrinamorman@lifelinebloodserv.org.

For Sale. Two NEW Aurora Plasmapheresis System devices with Certificate of Compliance. NEVER USED. Currently, both have Software 2.0 installed. Asking for best offer. Location: Jackson, TN. Please contact LaTrina Morman, (731) 427-4431, or email latrinamorman@lifelinebloodserv.org.

POSITIONS

Manager of Donor Services | Manager of Donor Resources | Manager of Hospital Services. The Blood Connection is expanding our operations into Virginia! We are one of the fastest growing blood centers in the country and we are seeking a Manager of Donor Services, a Manager of Donor Resources, and a Manager of Hospital Services who will be responsible for day-to-day operations within each of their respective departments as we expand our services into this new territory. We offer a generous benefits package including a substantial 401k match, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help make an impact in your community today. *These roles are based in Roanoke, VA. Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Services Application | Manager of Donor Resources Application | Manager of Hospital Services Application.

Director of Human Resources (San Diego, CA). The San Diego Blood Bank is seeking a dynamic Director of Human Resources. This role is directly responsible for the overall administration, coordination, and evaluation of the human resource function. This position facilitates organization and leadership development efforts with employees and managers to address root causes of human resource issues. The Director of Human Resources plays a vital role in administering talent management, workforce planning, recruitment, and employee relations through a systematic approach. This position supports executive leadership and management in the development of solutions through cultural and process perspective organizational development and drives a culture of performance and results. A strategic planner and partner to all levels of leadership acting as a cultural champion, mentor and consultant for the organization building avenues of healthy and positive work environments. Salary Range: $100,000 - $125,000/annual. Education: Bachelor's degree in related field required. Master's degree preferred. Experience:10 years of directly related experience. Certifications: HR Certificate/SHRM professional certification preferred. Please click here to view the full job description and apply.

Divisional Director. The Blood Connection is expanding our operations into Virginia! We are one of the fastest growing blood centers in the country and we are seeking a Divisional Director who will be responsible for our day-to-day operations and help direct our expansion of services into this new territory. The ideal candidate is a proven and results-focused self-starter with progressive leadership experience and the capacity and drive to help fulfill the needs of our community partners. We offer a generous benefits package including a substantial 401k match, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help make an impact in your community today. *Open to candidates residing in localities state-wide. Prospective candidates may be eligible for relocation assistance.* How to apply: Divisional Director Application

Manager of Technical Services. The Blood Connection is seeking a proactive and results-driven Manager of Technical Services to oversee and manage the daily operations within our technical departments which include Hospital Services, Biologics Processing, and Reference Laboratory. This position requires an understanding of laboratory operations, including specialist (SBB) skills, and involves supervising staff while performing essential functions within the laboratory. The ideal candidate will hold their SBB and have a background in the Reference Laboratory. We offer a generous benefits package including a substantial 401k match, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help make an impact in your community today. *This role is based in Morrisville, NC. Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Technical Services Application.

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POSITIONS (continued from page 12)

Phlebotomist 2 – Donor Centers (Carter BloodCare). Principal Accountability: 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, this position will oversee and assign responsibilities to collections staff, except for hiring and/or terminations. 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 leadership/development training resources, to mentor/assist with on-the-job development of new employees and subordinate staff. This position may be required to participate in special projects or programs. Regular full-time attendance is required during operational hours. Education: High school diploma or equivalent. Some college a plus. Experience: One-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. Bilingual skills and CDL driver a plus. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job # Phlebotomist 2.

Supply Chain Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Supply Chain Manager at our headquarters location in Gainesville, FL is responsible for vendor selection, negotiation, establishment and maintenance of all purchased materials, supplies, equipment, and services used by the company. The Supply Chain Manager oversees daily operations of the Purchasing team, is organized and decisive, and can motivate the team to reach daily and long-range goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Employee Relations Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management and HR experience, and a passion for making a difference. The Employee Relations Manager at our headquarters location in Gainesville, FL is responsible for facilitating employee relations and resolving personnel issues. The Employee Relations Manager deals with grievances and violations invoking disciplinary action, provides guidance, advice, and support to managers and employees on HR related issues, and oversees the work of eight Human Resources Coordinators. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Immunohematology Reference Lab Manager. LifeSouth Community Blood Centers is seeking an individual who enjoys leading a team of lab professionals dedicated to providing high quality products and services for patients. Our Birmingham, AL IRL is supported by Board Certified Pathologists in Transfusion Medicine, and by LifeSouth's accredited HLA Lab, Molecular Lab, and IRLs in Gainesville, FL and Atlanta, GA. The IRL Manager is responsible for providing onsite day-to-day supervision of testing personnel, ensuring compliance with regulatory agency requirements, and reporting of test results under the direction of the laboratory director. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Regional Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference in the community. The Regional Manager in The Villages, FL, oversees daily operations of the region, is organized and decisive, and can motivate the team to reach daily and long-range blood collection goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!