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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2021 #42 **December 3, 2021**

INSIDE:

FDA Updates Safety Communication for Blood Establishments Regarding Bacterial Contamination of Platelets

The U.S. Food and Drug Administration (FDA) published an update to the April 16, 2019 safety communication "informing" blood establishments and transfusion services of "additional cases of septic transfusion reactions from apheresis platelets contaminated with *Acinetobacter* species and certain other bacterial species seen in combination." The agency stated that recent cases of note "have involved pathogen reduced platelet components."

The agency communication explained that the FDA and Centers for Disease Control and Prevention (CDC) are reviewing and investigating the reports. The FDA notes in the communication the importance of blood establishments and transfusion services [recognizing] "the residual risk of bacterial contamination of platelets, including pathogen-reduced platelet components. Signs and symptoms of potential septic transfusion reactions include fever, chills, hypotension, or unexplained tachycardia. Suspected reactions should be immediately reported to the transfusion service and blood supplier. Blood establishments and transfusion services, as appropriate, must conduct and record a thorough investigation of suspected septic transfusion reactions and notify FDA as soon as possible when a complication of transfusion is confirmed to be fatal (21 CFR 606.170)." The agency encourages blood establishments and transfusion services to contact the FDA "[w]hen they identify suspected contamination of platelets with *Acinetobacter spp.*, *Staphylococcus saprophyticus*, or *Leclercia adecarboxylata*, or suspected septic transfusion reactions involving pathogen-reduced platelet components, and report the cases via MedWatch or by emailing CBER."

FDA states that it is "aware" of three additional cases of septic transfusion reactions "involving either *Acinetobacter spp.*, *Staphylococcus saprophyticus, Leclercia adecaboxylata*, or combinations thereof" since previous safety communication was issued in 2019. The most recent safety communication also noted that "since 2018, seven cases of platelet septic transfusion reactions have been reported to FDA associated with *Acinetobacter* species and certain other bacterial species seen in combination, and where additional genetic testing indicates relatedness of the organisms. Based on the genetic testing conducted by the CDC, these organisms may have a common source; however, no such source has been identified to date. FDA and the CDC will continue their investigation." ABC members are encouraged to contact ABC Chief Medical Officer Rita Reik, MD with medical questions that may arise from outreach to their hospital partners regarding this safety communication from FDA.

(Source: FDA Safety Communication, 12/2/21) ♦

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) published a final order in the *Federal Register* on November 22nd titled "Medical Devices; General and Plastic Surgery Devices; Reclassification of Blood Lancets." The final order took effect on November 22nd and states, [the agency is reclassifying] three types of blood lancets used to puncture skin to obtain a drop of blood for diagnostic purposes from class I (general controls) exempt from premarket notification into class II (special controls) and subject to premarket notification, specifically, single use only blood lancets with an integral sharps injury prevention feature, single use only blood lancets without an integral sharps injury prevention feature, and multiple use blood lancets for single patient use only. FDA is designating special controls for these three types of blood lancets based on the determination that general controls only are not sufficient and there is sufficient information to establish special controls to provide a reasonable assurance of their safety and effectiveness. FDA is also reclassifying a fourth type of blood lancet, multiple use blood lancets for multiple patient use, from class I (general controls) exempt from premarket notification into class III (premarket approval). FDA is reclassifying these four types of blood lancets on its own initiative based on new information." The agency also published another final order titled "Effective Date of Requirement for Premarket Approval for Blood Lancets" that also took effect on November 22nd. That final order states, "[FDA] is issuing a final order to require the filing of a premarket approval application (PMA) or notice of completion of a product development protocol (PDP) following the reclassification of multiple use blood lancets for multiple patient use from class I to class III."

(Sources: *Federal Register* Medical Devices; General and Plastic Surgery Devices; Reclassification of Blood Lancets Final Order, 11/22/21; Effective Date of Requirement for Premarket Approval for Blood Lancets Final Order, 11/22/21) ♦

RESEARCH IN BRIEF

Prediction and Impact of Personalized Donation Intervals. A study in *Vox Sanguinis* noted that "deferring a person from donating due to low hemoglobin (Hb) can be demotivating for the donor [and can cause] extra costs to be incurred [by the] blood establishment. [Additionally, it] may indicate that a donor has donated blood too frequently causing anemia." The authors of this study also explained that "[t]he blood donation information [used for this study came from] the Finnish Red Cross Blood Service (FRCBS) [and] was collected in eProgesa…The Biobank dataset [used for the study] contains genome-wide ingle nucleotide polymorphisms (SNP) genotyping data obtained from the Blood Service Biobank [along with] height, weight, and smoking variables from the Biobank enrolment questionnaire…The final testing data had 695,658 donations from 47,820 donors." The study noted that "[t]he FinDonor dataset contains information about donation events such as blood counts, iron indices, and questionnaire data…This dataset [has] 7,994

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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 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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RESEARCH IN BRIEF (continued from page 2)

donation events from 2,580 donors." The authors described how they "built linear and non-linear predictors of Hb deferral…[E]conomic impacts of deploying such predictors" were also estimated. "[P]revious Hb was the most important variable…[They stated that a] fixed deferral of 12 months is likely to reduce deferrals in the most vulnerable group, women younger than 30." The researchers explained that "[f]or ferritin levels of the same group, even a six-month deferral would decrease the number of yearly donations by up to two or three and significantly decrease the prevalence of low iron…"[T]he economic effect was a savings of 0.15 euro per donation…Deployment of this model would result in avoiding 51 percent of the deferrals…In the models that were trained by stratifying by sex, the average cost effect for males was 0.02 euro per donation, whereas, for women, the effect was -0.11 euro per donation…As the baseline model predicts based on previous Hb only, the probability thresholds that were found to provide the largest savings correspond to specific Hb values…For six-month deferral, these were 14.7 g/dL for men and 13.5 g/dL for women; and for 12-month deferral, 14.1 g/dL for men and 12.2 g/dL for women." The authors explained that "the incorporation of genetic information as predictors improves the prediction [as the] RNF43 gene was discovered as a lead SNP for iron deficiency anemia" They authors concluded that, "[the]results suggest that pre-donation Hb data could be used much more efficiently to bring savings and health benefits."

Citation: Toivonen, J., Koski, Y., Turkulainen, E., Prinsze, F., della Briotta Parolo, P., Heinonen, M., *et al*. Prediction and impact of personalized donation intervals. *Vox Sang*. 2021.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) published a statement addressing potential impacts of the Omicron variant of SARS-CoV-2. In the statement, the agency explains that it is "working as quickly as possible to evaluate the potential impact of this variant on the currently available diagnostics, therapeutics, and vaccines. We are closely monitoring the situation and are committed to communicating with the public as we learn more. Historically, the work to obtain the genetic information and patient samples for variants and then perform the testing needed to evaluate their impact takes time. However, we expect the vast majority of this work to be completed in the coming weeks. The FDA has been actively monitoring for the possible emergence of SARS-CoV-2 variants since early in the pandemic and has worked with medical product developers when a new variant (or mutation) emerges that could impact product performance." The statement comes in the wake of the World Health Organization's (WHO) Technical Advisory Group on Virus Evolution recommending designating Omicron as a "variant of concern" due to it having "several mutations that may have an impact on how it behaves, for example, on how easily it spreads or the severity of illness it causes." The WHO is suggesting that nations "enhance surveillance and sequencing of cases, sharing genome sequences on publicly available databases."

(Source: FDA Statement 11/30/21; WHO News Release, 11/28/21)

Congressional members have asked the FDA to reassess its tissue donation deferral policy for men who have sex with other men (MSM). U.S. Senators Tammy Baldwin (D-Wisc.), Michael Bennet (D-Colo.), Elizabeth Warren (D-Mass.), and Congressmen Joe Neguse (D-Colo.), David Cicilline (D-R.I.), and Mike Quigley (D-Ill.) issued a joint news release stating "[we] are leading a bicameral effort in asking the FDA to review and update its longstanding policy." They sent a letter to the U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra, JD and Acting FDA Commissioner Janet Woodcock, MD that explains, "[t]his policy originated from the discriminatory notion that gay and bisexual men, by virtue of their sexuality, have HIV (human immunodeficiency virus). Unfortunately, the FDA continues to recommend that establishments making donor eligibility determinations disqualify [MSM] in the preceding

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WORD IN WAHSINGTON (continued from page 3)

five years as potential donors of human cells, tissues, and cellular and tissue-based products, based on agency guidance issued in 2007, despite current science and the serious need for tissue donations. [FDA's]policy should be derived from the best available science, not historic bias, and prejudice. As with blood donation, we believe that any deferral policies should be based on individualized risk assessment rather than a categorical, time-based deferral that perpetuates stigma," they continued. "It is imperative that we move away from discriminatory deferral policies that prohibit individuals from contributing much-needed tissue donations." The members of Congress requested a written update from FDA on its "progress in reassessing its policy."

(Source: Tammy Baldwin News Release, 11/30/21)

FDA published an update of the "Resiliency Roadmap for FDA Inspectional Oversight." The update notes that as of the end of September 2021, the agency "has exceeded the Base-Case Scenario projections for FY21, completing more than twice as many domestic surveillance oversight activities than projected in the Roadmap. FDA's development of new oversight approaches and expanded use of a variety of surveillance tools significantly contributed to the agency's ability to exceed these goals. This enabled the agency to provide oversight to as many facilities as possible, while utilizing our resources to protect consumers and patients and promote public health…FDA also completed outstanding inspectional work to inform decisions on applications submitted for medical product approval or authorization…As we have done throughout the pandemic, FDA will use every option available to meet our regulatory responsibilities and protect the public health, including continued collaboration with state, local, tribal, territorial, and foreign regulatory partners. We will continue to look for new ways to accomplish our work and fulfill our mission."

(Source: FDA Update, 11/22/21)

Upcoming ABC Webinars – Don't Miss Out!

- **ABC SMT Journal Club Webinar** – Dec. 13th from 1-2 pm EST. Contact us for additional details and login info or a copy of MCN 21-099.

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:

- Cryo Shortage: Cost of Cryo vs Fibrinogen Concentrate (MEDICAL ISSUES)
- Requests for Irradiated (Never Frozen) Liquid Plasma (MEDICAL ISSUES)

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

America's Blood Centers®
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INSIDE ABC

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

Nominations Deadline Extended for 25th Annual *Awards of Excellence*

America's Blood Centers (ABC) has extended the deadline for accepting nominations for the 25th Annual *Awards of Excellence* to Friday, December 10th. The program provides an opportunity for member blood centers to provide national recognition and showcase the best and brightest in the blood donation community. This year's ceremony will take place Tuesday, March 8, 2022, at the Ritz-Carlton (Pentagon City in Arlington, V.A.) in conjunction with ABC's 60th Annual Meeting in Washington, D.C. We encourage member blood centers to take advantage of this opportunity to recognize your supporters by submitting your nominations before the December 10th deadline. Nominations may be submitted via this form. Additionally, two complimentary tickets will be given to award winners. Additional details are available in MCN 21-094. Please contact Member Services with any questions.

ABC Seeks Input for 2022 Advocacy Agenda

ABC is requesting input from member blood centers for its 2022 Advocacy Agenda. Participation from members is important as ABC continues to develop the 2022 Advocacy Agenda in consultation with the ABC Policy Council and the ABC Board of Directors. Input for the Advocacy Agenda should reflect the federal legislative and regulatory issues most important to blood centers. The items on the Advocacy Agenda should have clearly defined legislative or regulatory fixes. Please feel free to share the survey link from MCN 21-097 within your blood center to make your voice heard. Please provide any feedback by Friday, December 10th and contact Diane Calmus, JD, senior director of Federal Government Affairs at ABC, with questions or comments.

(Source: MCN 21-092, 11/9/21)

Register for the 60th ABC Annual Meeting

Register today for the 60th ABC Annual Meeting and 25th Annual *Awards of Excellence.* These events will take place March 7th-9th, 2022 at the Ritz-Carlton (Pentagon City) in Arlington, Va. Please secure your hotel reservation today. This year's meeting will be in-person while Advocacy Day will be held virtually the following week given continued visitor restrictions on Capitol Hill. This will allow each blood center to bring together multiple colleagues to connect with their members of Congress and their staff. More information will be provided to ABC members as it becomes available. The ABC Annual Meeting brings together blood center executives and national leaders to discuss advocacy and regulatory updates, the latest in science, medicine, and technical affairs, and hot topics facing the blood community. In addition, ABC is excited to share that the final day of this year's meeting will feature two in-depth training workshops focused on building tangible advocacy skills that can immediately benefit your center. The preliminary program-at-a-glance is available. Please contact ABC Member Services with questions.

PEOPLE

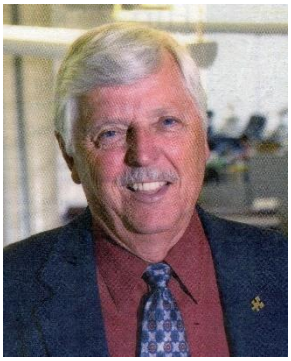
Marian L. Garrard will become president and chief executive officer (CEO) of We Are Blood effective January 1st. Ms. Garrard has served as the chief operations officer at the center since 2010. During that time, she has played a pivotal role in We Are Blood's response to the COVID-19 pandemic including the rapid development of a convalescent plasma program. Ms. Garrard currently serves on the boards of Blood Centers of America, Inc., the National Blood Testing Cooperative, and Alliance for Community Transfusion Services. She will succeed **Marshall Cothran** who is in his 28th year as CEO. Mr. Cothran will transition to chief strategy officer for We Are Blood, its subsidiary United Tissue Resources, and its founding organization Travis County Medical Society also effective January 1st.

(Source: We Are Blood Announcement, 11/29/21)

John Hagins has been appointed the next chair of the Association for the Advancement of Blood & Biotherapies (AABB) Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. His term will begin on January 1st. Mr. Hagins is the president and CEO of Community Blood Center (Appleton, Wisc.). He has also been appointed as member of the AABB Board of Directors. Mr. Hagins succeeds **Brian Gannon**, president and CEO of Gulf Coast Regional Blood Center (Houston, Texas) who will step down as chair of the Task Force at the end of the calendar year, a position he has served in since February 2020, to focus on his role as AABB President-elect.

(Source: AABB Announcement, 11/30/21)

IN MEMORIAM



Norman "Norm" Lee Felker passed away on November 21st. Mr. Felker was the chief executive officer of Michigan Community Blood Center, now Versiti Blood Center of Michigan, for 25 years. He also served in the U.S. Army Reserves. Mr. Felker is survived by his wife Beverly, their children, grandchildren, great-grandchildren, and a great-great-grandchild. A memorial service will be held on Dec. 14th at Matthysse Kuiper DeGraaf Funeral Home. Those who wish may make memorial contributions to Faith Hospice Trillium Woods. Condolences may be sent online at www.mkdfuneralhome.com.

(Source: Norman Lee Felker Obituary, 11/21/21)

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

ABC Calendar of Events

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

MEMBER NEWS

The Blood Emergency Readiness Corps (BERC) recently activated in response to the tragic school shooting in Oxford Township, Mich. to assist **Versiti Blood Center of Michigan**. According to a BERC news release, this is the second time the corps has been activated since its September "launch" as it has now grown in size to 21 participating community blood centers in 30 states. "Nearly every community is at risk for its blood supply being severely depleted in the face of a mass casualty event," said Nelson Hellwig, MBA, chief executive officer of the Alliance for Community Transfusion Services (ACTS), which coordinates BERC logistics and administration. "Through BERC, we are providing the transfusion safety net that provides hope and healing during the darkest times." The news release also stated that, "[t]hrough BERC, blood centers prepare for emergency needs by collecting extra blood products on a rotating on-call schedule." **Central Pennsylvania Blood Bank** (Hummelstown, Penn.), **Coastal Bend Blood Center** (Corpus Christi, Texas), and **Oklahoma Blood Institute** (Oklahoma City, O.K.) were the responding blood centers for this emergency activation. Other BERC members include:

- **Houchin Community Blood Bank** (Bakersfield, Calif.);
- **The Community Blood Cente**r (Appleton, Wisc.);
- **We Are Blood** (Austin, Texas);
- **South Texas Blood & Tissue Center** (San Antonio, Texas); and
- **Carter BloodCare** (Bedford, Texas)
- **LIFELINE Blood Services** (Jackson, Tenn.);
- **ImpactLife** (Davenport, Iowa);
- **The Blood Center** (New Orleans, L.A.);
- **MEDIC Regional Blood Center** (Knoxville, Tenn.);
- **Northern California Community Blood Bank** (Eureka, Calif.);
- **SunCoast Blood Centers** (Sarasota, Fla.);
- **Cascade Regional Blood Services** (Tacoma, Wash.);
- **Blood Assurance** (Chattanooga, Tenn.);
- **Western Kentucky Regional Blood Center** (Owensboro, K.Y.);
- **The Blood Connection** (Greenville, S.C.); and
- **LifeSouth Community Blood Centers** (Gainesville, Fla.)
- **Mississippi Blood Services** (Jackson, Miss.)
- **Vitalant** (Scottsdale, Ariz).

(Source: BERC Announcement, 12/1/21)

GLOBAL NEWS

The World Health Organization's (WHO) World Health Assembly has commenced the "process to draft and negotiate a convention, agreement, or other international instrument under the Constitution of the [WHO] to strengthen pandemic prevention, preparedness, and response." A December 1st announcement from the WHO stated that the World Health Assembly met in a special session for only the second time since 1948. WHO Director-General Tedros Adhanom Ghebreyesus, PhD said "the decision by the World Health Assembly was historic in nature, vital in its mission, and represented a once-in-a-generation opportunity to strengthen the global health architecture to protect and promote the well-being of all people." The intergovernmental negotiating body (INB) charged with drafting the accord "will hold its first meeting by March 1st (to agree on ways of working and timelines) and its second by August 1st (to discuss progress on a working draft). It will also hold public hearings to inform its deliberations; deliver a progress report to the 76th World Health Assembly in 2023; and submit its outcome for consideration by the 77th World Health Assembly in 2024."

(Source: WHO News Release, 12/1/22)

COMPANY NEWS

The U.S Food and Drug Administration (FDA) recently accepted a biologics license application (BLA) for priority review from **bluebird bio, Inc.** for the company's gene therapy to treat individuals with beta thalassemia. According to an announcement from bluebird bio, Inc., the BLA is based on data from three ongoing clinical trials of the gene therapy, which is a "one-time treatment that addresses the underlying genetic cause of disease for patients living with beta-thalassemia in the U.S.— offering an alternative to regular [red blood cell] transfusions and iron chelation therapy. The [FDA] has set a Prescription Drug User Fee Act (PDUFA) goal date of May 20, 2022…[and] previously granted [the gene therapy with the] Orphan Drug status and Breakthrough Therapy designation."

(Source: bluebird bio, Inc. News Release, 11/22/21)

Beam Therapeutics Inc. announced the FDA "has cleared" an investigational new drug application (IND) for its gene editing product candidate (BEAM-101) to treat sickle cell disease (SCD). The company plans to begin a phase I/II clinical trial to "assess the safety and efficacy" of the treatment, which is "a patient-specific, autologous hematopoietic investigational cell therapy which incorporates base edits that mimic single nucleotide polymorphisms seen in individuals with hereditary persistence of fetal hemoglobin (HPFH) to potentially alleviate the effects of mutations causing SCD or beta-thalassemia." According to a company news release, "[t]his is the first open IND for base editing technology, a next-generation form of CRISPR capable of making single base changes without creating double strand breaks in the DNA."

(Source: Beam Therapeutics Inc. News Release, 11/8/21)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2021

Dec. 6-8. **American Association of Tissue Banks (AATB) Annual Meeting (Virtual).** Registration is open.

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CALENDAR (continued from page 8)

Dec. 1. **U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) (Virtual).** More information available here.

2022

Mar. 7-9. **ABC Annual Meeting, Washington, D.C.** Registration is open. More information available here.

Mar. 15-16. **International Plasma and Fractionation Association (IPFA) and the European Blood Alliance (EBA) Symposium on Plasma Collection and Supply, Amsterdam, the Netherlands.** More information available here.

May 10-12. **2022 ADRP Conference, Phoenix, Ariz.** Additional details coming soon and abstract submission is now open.

June 4-8. **37th Annual International Congress of ISBT, Kuala Lumpur, Malaysia.** Additional details 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 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: newsletter@americasblood.org

POSITIONS

Manager Component Production (Gulf Coast regional Blood Center; Houston, Tex.). Oversee and maintain Component Production operations including production, compliance, customer relations, quality control, validations, change controls, error management and new process/technology implementations. Maintains Standard Operating Procedures (SOPs), cGMPs, and other regulatory guidelines as well as establish, monitor, and evaluate Quality Improvement activities. Manage component production and maintain adequate supplies for the department. Oversee salvage product shipments through the Research agreements, pricing, maintenance, and termination. Maintain technical abilities to solve problems and act as subject matter expert. Responsible regional production and compliance and inventory management. Directs staff competency, performance, and training programs, develops, and maintains department budget. Coordinate error management program to proactively identify process improvements. Supports Radiation Safety Officer to act as RSO in the RSO's absence. Serves as the Reviewing Official under NRC guidelines. Oversee RMW program to ensure all regulatory requirements are met. Manages subordinate Assistant Manager, Technical Coordinator, Materials Coordinator, Shift Coordinator, RRPL. Manages employees in the Component Lab, provides direction, coordination, and evaluation of this unit. Carries out supervisory Responsibilities include interviewing, hiring, and training employees; planning, assigning, scheduling, and directing work; appraising performance; rewarding and disciplining employees; addressing complaints and resolving problems. Bachelor's degree plus three years of previous job-related experience. Please click here to apply.

Laboratory Operations Manager (LOM). Cascade Regional Blood Services (CRBS) in Tacoma, Wash. is seeking an experienced leader for our laboratory team to ensure technical proficiency and quality of work in laboratory processes. The LOM is responsible for ensuring quality and regulatory requirements are being met, overseeing processing of components, order taking, packing, and distribution of blood products, and inventory management. This position is also responsible for the review of all quality records and ensuring all quality control in the lab is timely and accurately performed. This individual will also be responsible for development and maintenance of department SOPs, training material and thorough training and day to day management of staff. Resumes may be submitted to hr@crbs.net.

Medical Lab Technician – Licensed. LifeSouth Community Blood Centers is currently seeking an individual to join our team as a Licensed Medical Lab Technician in Gainesville, FL. This position is responsible for the safe handling and processing of blood and blood components with consistency and precision. The selected MLT will be working in a highly regulated environment to prepare components intended for transfusion. Applicants should apply here.

Mobile Phlebotomy Supervisor (Brooksville, FL). LifeSouth Community Blood Centers is currently seeking an individual to join our team as a Mobile Phlebotomy Supervisor in Brooksville, FL. This position is responsible for overseeing phlebotomy functions and for ensuring

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POSITIONS (continued from page 9)

the assigned team functions as a cohesive unit. Applicants should apply here.

Mobile Phlebotomy Supervisor (Gainesville, GA). LifeSouth Community Blood Centers is currently seeking an individual to join our team as a Mobile Phlebotomy Supervisor in Gainesville, GA. This position is responsible for overseeing phlebotomy functions and for ensuring the assigned team functions as a cohesive unit. Applicants should apply here.

Reference Laboratory Technologist. ImpactLife has full time Reference Laboratory Tech opportunities available on our Davenport, IA and St. Louis, MO teams. These individuals will perform antibody testing, antigen typing, and provide consultation to hospital staff as needed. Must possess MT/MLS certification with ASCP or equivalent, SBB a plus. Three year's blood banking experience in the past five years is preferred. MLT applicants holding an associate degree with two to three year's blood bank experience are encouraged to apply. We offer an opportunity to be a part of a dedicated team that makes us a recognized leader in the blood center industry, an environment that makes work/life balance a priority with a generous paid time off account, a fantastic benefit package and a competitive salary. Please check out our website for more information and to apply: https://www.bloodcenter.org/join/.

Enterprise Records Manager (Scottsdale, Ariz.). Vitalant is a nonprofit organization that collects blood from volunteer donors and provides blood, blood products and services across the United States. Under limited direction, this position is responsible for managing the system wide electronic and manual records management program and overseeing the lifecycle of enterprise records. Qualifications: Bachelor's degree in related area or equivalent combination of education and experience required. Extensive working knowledge of document control, records management and computer technology required. Seven years related experience in a controlled document environment required. To include: Five years of experience managing a records management system. Please click here to apply. EOE

Director of Quality Assurance and Compliance. Located in the magnificent California coastal redwoods, The Northern California Community Blood Bank has a low stress environment and vibrant community relationship. Come join our team! Drive cultural transformation and promote the recognition and reporting of errors and improvement in quality and safety. Our Blood Bank seeks a Director of Quality Assurance and Compliance to oversee the quality assurance (QA) program for all areas of the blood center and its operations. This individual ensures that all pertinent details of the collection, manufacture, and distribution of blood products are in compliance with regulatory and standard-setting agencies. The ideal candidate will have experience leading quality improvement programs and expertise with risk management and accrediting organizations, ideally in a blood bank, health care, or laboratory environment. This candidate will have familiarity with FDA submissions, biologic regulations, and current good manufacturing practices (cGMP). For details, please visit www.nccbb.net/employment.

Divisional Supervisor of Clinical Service (Charleston, SC Region). The Divisional Supervisor of Donor Services at The Blood Connection, Inc. provides direct supervision for mobile staging and operational support staff. This position is responsible for collections staff scheduling and coordinating staff changes post release of schedule. The Divisional Supervisor participates in staff call duties, performs bus driver duties (if applicable), and donor collection duties when required. Other responsibilities include submitting weekly time records for staff and assisting with daily QC review. Essential Operational Functions: Ensures supply of non-warehouse forms/tags used on mobiles and fixed sites are adequate. Assists with departmental equipment validations. Ensures mobile and center staging pods are adequately stocked and made available to outgoing blood drives and/or fixed site centers in a timely fashion. Ensures equipment returning from inside set-up drives are properly stored, and if required, charged. Ensures all box trucks are clean, organized, have adequate supplies and equipment upon return and prior to every departure. Other duties as assigned or acquired. Minimum Qualifications: High School Diploma or GED. Valid Driver's License with no major infractions and dependable transportation. Experience in mobile and apheresis collections required. Ability to organize and prioritize workload and meet deadlines. Ability to establish and maintain effective working relationships with staff, management, and peers. Please click here to apply.

Clinical Laboratory Scientist - MT Certified. LifeSouth Community Blood Centers is currently seeking Level III Clinical Laboratory Scientists in Stone Mountain, GA. This position is responsible for performing and interpreting clinical laboratory tests that require the exercise of independent judgment. Must be MT certified; confirmatory testing experience preferred. Applicants should apply here.