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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #15 **April 26, 2024**

INSIDE:

ABC Comments to FDA Regarding Informed Consent

America's Blood Centers (ABC) submitted comments to the U.S. Food and Drug Administration (FDA) on April 25th in response to the recently published draft guidance titled, "Key Information and Facilitating Understanding in Informed Consent; Draft Guidance for Sponsors, Investigators, and Institutional Review Boards."

The comments expressed concern that the agency, "does not address health literacy and the need for this key information to be at an appropriate reading level." Specifically, ABC recommended that FDA, "should ensure that key information is written at no higher than an eighth grade reading level, and preferably at a sixth or seventh grade reading level." In addition to citing and providing multiple examples of other organizations and federal entities that urge health literacy in the form of key information being written at a middle school-reading level, ABC noted that, "[w]hile FDA states in the draft guidance that 'information should be presented in plain language at a level prospective subjects would likely comprehend,' critical parts of the key information [in the] sample included in the appendix of the draft guidance, which is likely to be used as a template if the guidance is finalized as is, are close to a college reading comprehension level using Dale-Chall, the most accurate and reproducible analyzer available through Datayze…FDA should further recommend instruments that can be [used] to ensure these recommendations pertaining to reading levels are met."

The comments also explained that FDA should clarify the recommended length of key information, "[t]he draft guidance recommends [that] the 'key information section of a consent document be relatively short (e.g., generally no more than a few pages).' ABC recommends that FDA provide further clarity around the recommended length of the key information, to ensure this information is understandable and consistent."

The FDA explained in the draft guidance that it contains, "recommendations on provisions of the U.S. Department of Health and Human Services (HHS) regulations on the protection of human subjects as well as certain proposed revisions to FDA's current regulations for the protection of human subjects. Specifically, this guidance addresses the presentation of key information and includes recommendations for the content, organization, and presentation of informed consent information in FDA-regulated clinical investigations of drugs, devices, and biologics…and in HHS-supported or -conducted nonexempt human subjects research."

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

(Sources: ABC Comments, 4/25/24; FDA Draft Guidance, 3/1/24) ♦

GLAAD Summer of Giving Campaign to Promote Blood Donation

GLAAD will raise awareness of the need for blood donations in the coming months through the "Summer of Giving" campaign. This initiative will also promote the U.S. Food and Drug Administration's (FDA) shift to individual donor assessments.

GLAAD, the largest LGBTQ media advocacy organization worldwide, plans to announce the "Summer of Giving" national blood drive campaign in mid-May. This initiative will take place from May 28th through September 4th (National Blood Donation Day). As part of the campaign, GLAAD will also encourage businesses to host blood drives and urge members of the LGBTQ+ community and its allies to donate blood.

ABC will support this initiative by providing resources that can be used both during and after the campaign to build long-term relationships with the LGBTQ+ community, including a customizable public service announcement, digital videos, a campaign one-pager, and an FAQ document for prospective donors.

Additionally, as part of the campaign, GLAAD will urge its corporate partners to host blood drives with community blood centers. Such partners include Netflix, Procter & Gamble, The Walt Disney Company, the National Basketball Association (NBA), the Women's National Basketball Association (WNBA), and more. "Summer of Giving" branded materials are anticipated to be released the week of May 13th. ABC will provide campaign resources to interested members while promoting collaborations with leading companies across the country. Please contact ABC Director of National Partnerships and Strategic Communications Jeff Gohringer with questions.

(Source: MCN 24-027, 4/16/24)

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) is requiring, "boxed warning for T cell malignancies following treatment with BCMA-directed or CD19-directed autologous CAR T cell immunotherapies." In a summary of the issue published on April 18th, the agency stated, "FDA has determined that the serious risk of T cell malignancies is applicable to all currently approved BCMA-directed and CD19-directed genetically modified autologous CAR T cell immunotherapies…FDA concluded that changes to the Boxed Warning are warranted to highlight the serious risk of T cell malignancies. In addition, FDA has required related updates to other sections of the label (Warnings and Precautions, Post-marketing Experience, Patient Counseling Information and Medication Guide). Patients and clinical trial participants receiving treatment with these products should be monitored for life-long secondary malignancies. In the event that a new malignancy occurs following treatment with these products, contact the manufacturer to report the event and obtain instructions on collection of patient samples for testing for the presence of the CAR transgene. To report suspected adverse events including T cell malignancies, contact the FDA." The agency previously announced in January 2024 that it had issued, "safety labeling change notification letters to all manufacturers of licensed BCMA-directed and CD19-directed genetically modified autologous CAR T cell immunotherapies requiring a revision to the package insert due to risk of T cell malignancies, with serious outcomes, including hospitalization and death." That announcement came in the wake of a November 2023 communication from the agency notifying the public that the agency was, "investigating reports of T-cell malignancies including chimeric antigen receptor CAR-positive lymphoma, in patients who received treatment with BCMA- or CD19-directed autologous CAR T cell immunotherapies."

(Source: FDA Announcement, 4/18/24)

WORD IN WASHINGTON

***Inside Health* Policy reported this week that the White House Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) has completed its review of the U.S. Food and Drug Administration's (FDA) "Medical Devices; Laboratory Developed Tests" final rule and "signed off" on it.** The news organization explained that publication of the final rule could now take place "at any time." The FDA's draft regulation explicitly stated that *in vitro* diagnostic products (IVDs) are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. In addition to this change, the agency proposed a policy under which the FDA intends to provide greater oversight of laboratory developed tests (LDTs), through a phaseout of its general enforcement discretion approach to LDTs, so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs. America's Blood Centers (ABC) responded to the proposed rule in comments submitted to the FDA in December 2023 that outlined four areas of concern. Additionally, Sen. Bill Cassidy, MD (R-La.), ranking member of the Senate Health, Education, Labor, & Pensions (HELP) Committee, issued a request for information (RFI) on March 13th seeking ways to improve the regulation of clinical tests and the House Committee on Energy and Commerce's Health Subcommittee held a March 21st hearing on, "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule." ABC provided comments in response to the RFI urging that an exemption for LDTs used by blood centers should exist to exclude such LDTs, "from any reforms to diagnostics regulation since these tests do not fall within the categories of laboratory services and diagnostic products that Congress and FDA are looking to regulate." If the proposed rule is finalized, litigation is anticipated that could impact implementation.

(Source: *Inside Health Policy*, "Controversial Final FDA LDT Rule Cleared By White House," 4/23/24)

The FDA has announced that the agency has granted emergency use authorization, "for Pemgarda (pemivibart), [a monoclonal antibody,] for the pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescents (12 years of age and older weighing at least 40 kilograms [about 88 pounds]). Pemgarda is authorized for individuals:

- who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2;
- and who have moderate-to-severe immune compromise due to a medical condition or due to taking immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination."

(Source: FDA Announcement, 3/22/24)

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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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RESEARCH IN BRIEF

Bacteria in Cold-Stored Platelets. A multinational study published in *Vox Sanguinis* was, "aimed at addressing the gaps of information existing in the literature regarding the potential safety risk posed by cold-stored platelet concentrates (CSP) inoculated with concentrations of transfusion relevant bacterial strains, including psychrotrophic species." The authors explained that, "[e]ight sites participated in this study." According to the paper, "[t]he study had a pool and split approach [and] [f]ive transfusion relevant bacterial reference strains were used for platelet concentrate (PC) spiking experiments." The researchers noted that, "[a]fter the 2-hour (h) acclimation period, one split PC unit remained under standard storage for seven days, while the other split PC unit was stored under refrigeration (1–6ºC) with no agitation for 21 days…All species tested grew in PC units stored at 20–24ºC under agitation over 7 days. *K. pneumoniae* and *P. fluorescens* displayed fast growth reaching concentrations to approximately 10^9 colony forming units (CFU)/mL by day seven of storage." The study found that, "*S. liquefaciens* increased to 10^6–10^8 CFU/mL by day seven of PC incubation [and] [g]rowth of *S. aureus* reached loads of 10^7–10^8 CFU/mL by day seven." Additionally, the authors reported that, "[t]he growth of *L. monocytogenes* reached concentrations of 10^6–10^7 CFU/mL by day seven." They explained that, "[b]acterial proliferation in CSP [of] *K. pneumoniae* did not survive in any of the PC units [and] that *S. aureus* did not grow in CSP in seven of the eight testing sites. [Additionally, they discovered] that *S. liquefaciens* did not survive in two of the eight sites that used pooled PC prepared in platelet additive solution (PAS). [However, at five sites, it] grew up to 10^8 CFU/mL by day 21. *P. fluorescens* did not survive in one site but grew consistently fast [in the other sites], reaching loads of 10^5 CFU/mL in some cases by day seven of PC storage and 10^9 CFU/mL by day 21." The researchers also discovered that, "*L. monocytogenes* consistently grew slower than the other two psychrotrophic species. [They found in] the five laboratories where it proliferated, the bacterial load at the end of PC storage (day 21) varied from 10^2 to 10^4 CFU/mL." This study showed that, "transfusion relevant psychrotrophic bacteria are able to proliferate in CSP just as in red blood cell concentrates (RBCC) and could pose a safety risk to transfusion patients if clinically significant loads are reached." The authors concluded that, "[o]verall, [the] results demonstrate that CSP results in bacterial safety comparable with RBCC, which is a significant improvement over room temperature storage."

Citation: Ramirez-Arcos, S., Kumaran, D., Cap, A., *et al*. "Proliferation of psychrotrophic bacteria in cold-stored platelet concentrates." *Vox Sanguinis*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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:

- 2 Door Blood Storage Fridge and Temperature Monitoring (TECHNICAL DIRECTORS)
- BacT Alert Temp Range (TECHNICAL DIRECTORS)
- B Medical Systems Contact Freezer (TECHNICAL DIRECTORS)
- Outdated AB Units (MEMBER RESOURCES)
- Change in Rules for Laboratory Developed Tests (FEDERAL ADVOCACY)
- Hereditary Hemochromatosis (ALL MEMBER FORUM)
- Alzheimer's and Therapeutic Donors (ALL MEMBER FORUM)

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

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.

Schedule Available 2024 ADRP Annual Conference

The schedule is available for the 2024 ADRP Annual Conference. Register today! 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. Remember to book your hotel room by April 30th. Please contact us with questions.

PEOPLE

Mohandas Narla, DSc of New York Blood Center Enterprises has started his term as president of the American Society of Hematology (ASH). According to an ASH news release, "Dr. Narla is the head of the laboratory of red cell physiology at New York Blood Center Enterprises. His research interests include red cell physiology and pathology, with a special focus on inherited red cell membrane disorders and sickle cell disease – inherited conditions in which red blood cells are either spherical or elliptocytic or sickle shaped. He also studies thalassemia, a condition in which the body doesn't make enough hemoglobin, and Diamond-Blackfan anemia, a congenital anemia that affects the bone marrow." He has been a member of ASH for 30 years and has, "served on the Nominating Committee; the ASH Research Collaborative; Committee on Scientific Affairs; and Awards Committee. He was an associate editor of Blood, ASH's flagship journal, for 10 years. In 2020, he received the Society's highest honor, the Wallace H. Coulter Award for Lifetime Achievement in Hematology, for his significant contributions to the field." Dr. Narla stated in the news release, "[h]ematology has always been at the forefront of biomedical research and global research has only grown in the 50 years I've been in hematology. ASH has always been my professional home, and I am honored to serve as ASH president…ASH has become a global influence in hematology, both in practice and research. In my 50-year career, I've collaborated with people from France, England, Italy, Australia, Japan, Thailand, and West Africa. I'm looking forward to showing how ASH can help improve patient care and equity across the world. We at ASH are committed to addressing health care inequalities."

(Source: ASH News Release, 1/9/24)

GLOBAL NEWS

The World Health Organization (WHO) has published its Global Malaria Progr[am] Operational Strategy 2024-2030. The document outlines the, "priorities for the period 2024–2030 and the four strategic levers to control and eliminate malaria that are decisively within the progr[am]'s mandate:

- norms and standards;
- new tools and innovation;
- strategic information for impact; and
- leadership.

The strategy describes how the Global Malaria Progr[am] will also transform by collaborating more effectively with other progr[am]s, regional and country offices, and partners, guided by lessons learned from WHO's Thirteenth General Progr[am] of Work (GPW13) and the GPW14 priorities."

(Source: WHO Announcement, 4/23/24)

A report in *Cyber Daily* states that BlackSuit, "'a ransomware gang,' has taken responsibility for a damaging cyber-attack on Octapharma Plasma." The publication explained that, "BlackSuit has not shared any documents by way of proof but is claiming to have significantly sensitive data. [They posted a list of allegedly exfiltrated data [including:]

- data of donors (social security number (ssn), date of birth (dob), address);
- [deceased] donors' data (ssn, dob, address);
- [d]ata of donor cent[ers];
- [l]aboratory data;
- [f]inancial data (audits, reports, payments, contracts, etc.);
- [e]mployee data (passports, contracts, contacts, family details, medical examinations, etc.);
- [b]usiness data (contracts, contacts, planning, presentations, etc.); [and]
- [o]ther data taken from shares and personal folders."

The cyber-attack resulted in Octapharma closing donor centers on April 19th. The company began reopening centers this week. *Cyber Daily* added that Octapharma indicated that the closings were due to "network issues." Though a source told the news outlet that, "the incident was not due to a network issue but rather a cyber security incident. The source also suggested that BlackSuit was the culprit, but they were unaware if Octapharma had yet received any ransom demand."

(Source: *Cyber Daily*, "Exclusive: BlackSuit ransomware gang claims hack on Octapharma Plasma," 4/24/24)

COMPANY NEWS

The U.S. Food and Drug Administration (FDA) has approved a one-time gene therapy developed by **Pfizer Inc.** to treat adults with hemophilia B. According to a company news release, the agency approval took place today (April 26th). Fidanacogene elaparvovec-dzkt (BEQVEZ™) is specifically indicated for, "the treatment of adults with moderate to severe hemophilia B who currently use factor IX (FIX) prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes, and do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. BEQVEZ is a one-time treatment that is designed to enable people living with hemophilia B to produce FIX themselves rather than the current standard of care, which requires regular intravenous infusions of FIX that are often administered multiple times a

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week or multiple times a month." The gene therapy is also, "currently under review with the European Medicines Agency (EMA), and the treatment recently received regulatory approval in Canada."

(Source: Pfizer Inc. News Release, 4/26/24)

The FDA has cleared the **Becton, Dickson & Company** (BD) BD Vacutainer® K2EDTA Blood Collection Tubes according to an April 17th agency letter. In the 510(k) summary supporting document submitted by BD to the FDA, the company explained that it has removed the indication for use for blood donor screening "due to internal business decisions and not due to safety or performance concerns with the subject tubes…Results based on pre-determined acceptance criteria demonstrated the BD Vacutainer® K2EDTA Blood Collection Tubes are suitable for use in immunohematology testing…The BD Vacutainer® K2EDTA Blood Collection Tubes and the predicate devices have the same intended use and any differences in technological characteristics do not raise different questions of safety and effectiveness." BD also noted that the shelf-life of the BD Vacutainer® K2EDTA Blood Collection Tubes is 12-16 months which differs from the 15-24 months shelf-life of the predicate device (BD Vacutainer® Plus K2EDTA Tubes BK050036). The summary stated that the, "[d]ifferences in shelf-life are based on the data available at the time of submission for each tube configuration and do not raise different questions of safety or effectiveness."

(Source: FDA Announcement, 4/19/24)

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

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

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

ADRP The Association for Blood Donor Professionals

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).** Registration is open. 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.

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CALENDAR (continued from page 7)

May 29-30. **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.** More information is coming soon.

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 is coming soon.

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

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

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 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

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POSITIONS (continued from page 8)

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.

Immunohematology Reference Lab (IRL) Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Birmingham, AL. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The IRL Medical Technologist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. 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 Laboratory (IRL) Manager. LifeSouth Community Blood Centers is looking for a leader with a passion for making a difference to join our Immunohematology Reference Laboratory team in Atlanta, GA. This position is responsible for providing mentorship and leadership to laboratory staff. The IRL Manager is expected to provide onsite day-to-day supervision of testing personnel and reporting of test results under the direction of the Laboratory Director. This position is also responsible for performing laboratory procedures and reporting of test results, ensuring compliance with company policies and procedures, ensuring compliance with regulatory requirements from agencies such as CLIA, FDA, AABB, and HIPAA. 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 Laboratory CLS (San Diego Blood Bank). Under the direction of the department leadership, the Medical Laboratory Scientist I will assist the Immunohematology Reference Laboratory in daily operations according to cGMP compliant policies and Standard Operating Procedures implemented by the San Diego Blood Bank (SDBB). The ideal candidate will successfully complete/pass an initial training program resulting in the ability to provide guidance and expertise for the laboratory to meet the needs of SDBB customers, in

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POSITIONS (continued from page 9)

accordance with accepted standards and regulations. **Requirements:** Bachelor's degree, MLS/MT (ASCP)CM or equivalent experience, Clinical Laboratory Scientist (CLS). Certification as a Specialist in Blood Banking (SBB) preferred. For a full description of this job posting and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com).

Sr. Policy & Documentation Specialist (San Diego Blood Bank). The Senior Policy and Documentation Specialist proactivity guides and oversees policy management and technical documentation needs of San Diego Blood Bank. Creation, implementation, and maintenance of a document management system that can manage both internal and external controlled documents. This role provides relevant training on document control procedures and good documentation practices, assists Quality Assurance and Compliance Department in creating quality plans and procedures. The Sr. Policy & Documentation Specialist assists in the initiation, investigation and closure of product and process deviations/non-conformances. This position will author and revise policies, procedures, and manage document processes and systems to ensure control and availability of documentation to personnel. This role requires a bachelor's degree in a related field from an accredited college or university, or equivalent combination of education, training, and experience. Click here to view the job description and apply.

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.