America's Blood Centers®
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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2023 #32 **September 8, 2023**

INSIDE:

Low-titer group O Experience in Military Ground Ambulances Studied

A paper published in *Transfusion* Medicine examines cold stored low-titer group O whole blood (LTOWB) being carried and used by the Israel Defense Forces Medical Corps (IDF-MC) ground ambulance teams. The authors explained that in 2022, "recognizing the benefits of early transfusion of whole blood, the IDF-MC deployed whole blood in ground ambulances for the first time in Israel." The paper not only describes the experiences from the field, but also "present a case-series of the first patients receiving LTOWB."

The authors noted that "the IDF-MC provides prehospital trauma care to both civilians and soldiers injured in military or civilian circumstances (i.e., road traffic collision, falls) occurring in proximity to IDF bases. The deployment of LTOWB in 2022 "to several ICU ambulances, replac[ed] the previous IDF-MC's standard fluid of choice for trauma resuscitation — freeze-dried plasma (FDP)." All intensive care unit ambulances carried two units of LTOWB that were replaced after being used or expired. A retrospective review of the IDF Trauma Registry (IDF-TR) was conducted by the authors to "identify cases of whole blood administration by ground ICU ambulance teams, between January and December 2022 [excluding] patients administered whole blood for the indication of traumatic cardiac arrest."

The LTOWB units were derived from "whole blood donations of male–only O Rh+ volunteer donors, with a volume of 450 ± 50 mL. All whole blood units are collected in CPDA-1, with a maximal expiration of 35-days. Each unit undergoes an automated screening procedure, and only units with a titer of Anti-A or Anti-B of <1:100 were classified as LTOWB during the study period…Currently, platelet-sparing leukocyte reduction is not utili[z]ed during unit processing as quality control tests performed during the validation of the filtration procedure revealed a significant reduction in the platelet content of the final LTOWB product. Units are supplied to the IDF ICU ambulance teams upon demand, to be used within 21 days from the time of collection. LTOWB units can be issued within three days after collection, due to preparation and transport times to the remote military units."

The study included seven cases of LTOWB being administered by ground ambulance teams. "Of the seven patients administered LTOWB for profound shock, six were males with a median age of 28 (IQR 19.5–42) years. Five of the patients were injured in military circumstances, all from gunshot wounds, while two sustained blunt injuries in civilian road traffic collisions…LTOWB was administered after a hypotensive measurement (≤90 mmHg) in two cases. In the remaining five cases, the indication for volume resuscitation was altered mental status, in the absence of

(continued on page 2)

LTOWB in Ground Ambulances (continued from page 1)

head injury or premedication with unmeasurable blood pressure. Whole blood was administered through intravenous access in 6 [of] 7 cases and was administered through a blood warmer in 5 [of] 7 cases. The median time from injury to LTOWB administration was 35 (IQR 28.5–40) minutes, and median time from injury to hospital arrival 53 (IQR 41.5–63) minutes. In only one case, a second unit of volume resuscitation (with the highest priority blood product available to the team) was indicated following reassessment and prior to hospital arrival. In this case, a unit of FDP was administered, as the team had only one unit of non-expired whole blood on hand. Additionally, 1g of IV tranexamic acid was administered in 6 [of] 7 cases. No adverse events were recorded after whole blood administration…All patients except one survived to discharge following ICU admission."

The authors concluded, "this small case series presents the initial experience of the IDF-MC in deploying LTOWB in ground ambulances, for the first time in Israel. This series demonstrates that administration of LTOWB by paramedic-lead ICU ambulance teams is feasible, and based on current evidence, could be safe and potentially improve outcomes of patients with severe traumatic h[e]morrhage. The hospital data of patients in this case-series demonstrates that they were indeed seriously wounded, suffered from severe bleeding, and that prehospital LTOWB transfusion was indeed indicated…Future studies are required to better characteri[z]e the indications, safety, and benefits of whole blood in resuscitating severely injured trauma patients in the prehospital setting."

Citation: Talmy, T., Malkin, M., Esterson, A. *et al*. "Low-titer group O whole blood in military ground ambulances: Lessons from the Israel Defense Forces initial experience." *Transfusion Medicine*. 2023. ♦

ABC Publishes Talking Points on Donor Diversity & Sickle Cell Disease

America's Blood Centers (ABC) issued talking points to member blood centers this week highlighting the need for blood donor diversity and its importance for sickle cell disease patients. The talking points are available in the ABC Member Resources Library and can be used in conversations with stakeholders, media interviews, public outreach campaigns, and any other relevant platforms.

These and other talking points available for member blood centers can always be accessed here.

(Source: ABC Donor Diversity Talking Points, 9/8/23) ♦

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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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REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) published a September 6th communication titled "Important Information for Human Cell, Tissue and Cellular and Tissue-based Product (HCT/P) Establishments Regarding Tuberculosis (TB) Outbreaks Linked to a Bone Matrix Product." Via the communication, the agency aimed to "increase [awareness] regarding the risk of transmission of *Mycobacterium tuberculosis* (Mtb) through the use of HCT/Ps in the U.S." The FDA indicated that it is investigatiing recent reports of Mtb. According to FDA, "[i]n 2021, a multi-state outbreak of Mtb in the U.S. was linked to transplantation of a bone allograft product and resulted in significant morbidity and mortality. A new, similar outbreak is currently under investigation." The agency noted that "routine screening measures are in place for evaluating clinical evidence of infection in HCT/P donors" and it provided recommendations in the form of risk mitigation strategies for public health and safety. The agency noted in the communication, "the HCT/P establishment's responsible person (21 CFR 1271.3(t)) must determine and document the eligibility of a cell or tissue donor (21 CFR 1271.50). The responsible person(s) who is(are) authorized to perform designated functions related to the donor eligibility determination, should have appropriate medical training and be qualified to review clinical evidence consistent with risks for sepsis and TB infection…Although a donor with latent tuberculosis infection (LTBI) may be asymptomatic, a person with TB disease may have a number of symptoms or signs that can mimic or overlap with other medical conditions…Based on our emerging awareness of Mtb transmission risks, establishments may wish to consider whether an HCT/P donor has ever had a diagnosis of TB, treatment for suspected TB, or a positive test for TB, [or whether a donor has] an increased risk for TB infection."

(Source: FDA Communication, 9/6/23)

RESEARCH IN BRIEF

Red Blood Cell Antibody Development During Massive Transfusions. The aim of a study published in *Blood Transfusion* "was to examine red blood cell (RBC) alloantibodies in the critical bleeding/massive transfusion (CB/MT) context." The authors explained that 2,585 "New Zealand (NZ) adults in the Australian and New Zealand Massive Transfusion Registry (ANZ-MTR), who received a MT during 2011-2019, were the subjects of this retrospective observational study…Of the patients, 2,395 (92.6 percent) had pre-MT testing recorded [and] 102 (4.2 percent) had evidence of [pre-existent] alloantibodies…Five of 1,329 (0.4 percent) showed evidence of anamnestic alloantibodies." The authors noted that there were 1,320 patients "who had testing during the d[ay] 8+ period [and] [o]f these, 95 (7.2 percent) patients showed evidence of new alloantibodies…In all, 830 had test results for all three time periods [and] 404 had pre-MT, and d[ay] 8+ results, but not [between] d[ays] 0-7…[T]hese 1,234 patients (47.7 percent) were considered to be those in whom it was possible to make judgements about all three RBC alloantibody types…Multivariable analysis by logistic regression showed that male sex, and the receipt of any RBC transfusions prior to MT, were, respectively, independently negatively (OR 0.56; CI 0.36, 0.88; p-value 0.01), or positively (OR 1.87; CI 1.21, 2.89; p-value 0.0005) associated with pre-existent alloantibodies." The researchers stated that, "[o]nly transfusion of any D-positive RBC to D-negative patients showed a positive association in both multivariable (OR 5.85; CI 1.78, 19.2; p-value 0.004), and univariate analysis…Antibodies of undetermined specificity (AUS) was the most common new alloantibody (36 patients)." The calculated relative and absolute immunogenicity were highest for Jk^a. "Thirteen patients had detectable anti-D…These included two where the result pattern may also have been consistent with new alloimmunization to the D-antigen." The study concluded that "the frequencies of RBC alloantibodies of any type appear to be low in CB/MT patients…Interestingly, the quantum of RBC transfused was not [associated with new alloantibody formation]. Nor was trauma as clinical context although, intriguingly, trauma seemed to be a predisposition."

Citation: Badami, K.G., Neal, C., Sparrow, R.L., *et al*. "Red blood cell alloantibodies in the context of critical bleeding and massive transfusion." *Blood Transfus*. 2023.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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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.

New ADRP Resources Available: Toolkits for September Awareness Initiatives

ADRP, the Association for Blood Donor Professionals has developed three new toolkits to support efforts in raising awareness for upcoming recognition events during the month of September. Each toolkit aims to provide blood centers with resources that can be customized and tailored to fit their specific needs to assist with community engagement efforts. These resources include:

- Childhood Cancer Awareness Month Toolkit – includes social media graphics, draft press release, and more;
- Sickle Cell Disease Awareness Month Toolkit – includes social media graphics and community resources from the Sickle Cell Disease Coalition; and
- International Donor Recruitment Recognition Day Toolkit – includes social media graphics in English, French, and Spanish, a draft blog post, and more.

Contact info@adrp.org with questions or trouble accessing the toolkits.

Register for the ADRP Masterclass: Change is Good — The Journey of Donor Eligibility

Registration is open for ADRP's Masterclass, "Change is Good — The Journey of Donor Eligibility," taking place September 20th-21st. While navigating changes in donor eligibility can feel overwhelming at times, this virtual conference is designed to equip industry professionals with invaluable insights, strategies, and best practices to confidently address such challenges and turn them into opportunities. This Masterclass is about more than just implementing a single deferral change. Instead, attendees will hear from award-winning leaders from outside the blood community. These speakers will share insights into building a culture that helps your blood center be more adaptable to future changes, tips for managing challenging conversations on and offline, and cutting-edge strategies being embraced across other industries so they can thrive in a challenging environment. Participants will also get the latest industry data, hear best practices, and be a part of thought-provoking conversations with industry peers.

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:

- Not for Transfusion Labels (COLLECTIONS & DONOR SERVICES)
- Annual Temperature Verification of Coolers (COLLECTIONS & DONOR SERVICES)
- Post-donation Callback Instructions (MEDICAL ISSUES)

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

MEMBER NEWS

Inova Blood Services (Sterling, Va.) has officially joined America's Blood Centers (ABC). The organization has been approved for hospital-based blood center associate membership and is ABC's 50th member. Contact ABC's member services for additional information about hospital-associate membership.

Ozette Technologies Inc, is partnering with **Bloodworks Northwest** through its Bloodworks Bio division to "deeply profile and understand the immune systems of research donors to help drug developers engineer scalable "off-the-shelf" cell-based therapies and strengthen patients' immune systems in fighting cancer and autoimmune diseases," according to a report from *BioSpace*. "The collaboration will focus on redefining the role of blood centers in the evolving landscape of cell therapy research and development. By harnessing the analytical power of Ozette's single-cell profiling platform, a wide range of blood samples from healthy donors will be analyzed in detail to support biomedical research by Ozette's Immunology Lab. This groundbreaking approach will dramatically shorten the timeline for profiling blood components, transforming months of work into mere hours." Curt Bailey, MBA added in the article, "today, there is no gold standard for what makes a candidate a good donor for cell therapy products. Cultivating diverse donor immune cell samples continues to be a huge challenge in the industry. Through this partnership with Ozette, we will be able to develop fully characterized blood products to better inform our programs, accelerate the development of our products, and improve overall outcomes. This is a revolutionary step for the future of cell therapy."

(Source: *BioSpace*, "Ozette Technologies and Bloodworks Northwest Announce New Partnership to Deliver Insights Into Healthy Donor Immune Profiles to Help Advance New Therapeutics," 9/5/23)

WORD IN WASHINGTON

The U.S. Department of Labor (DoL) is proposing a rule that "would restore and extend overtime protections to 3.6 million salaried workers." According to the agency, the proposed rule would:

- "guarantee overtime pay for most salaried workers earning less than $1,059 per week, about $55,000 per year;
- give workers who are not exempt executive, administrative or professional employees valuable time back;
- prevent a future erosion of overtime protections and ensure greater predictability; [and]
- restore overtime protections for U.S. territories."

The proposed rule is titled "Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees" and was published in the *Federal Register* on September 8th with the 60-day comment period closing on November 7th.

(Sources: DoL News Release, 8/30/23; DoL Proposed Rule, 9/8/23)

GLOBAL NEWS

A report from *Ukrainska Pravda* stated the Ukrainian Ministry of Health "has adopted an order which will allow appropriately trained combat medics to administer blood transfusions at a pre-hospital stage." The publication stated in its report that, "the Health Ministry is expanding a special training progr[am] in the basics of transfusion therapy. On the training course, combat medics will acquire the skills required for blood transfusion. The new progr[am] corresponds to the North Atlantic Treaty Organization (NATO) standards.

(Source: *Ukrainska Pravda*, "Ukrainian government to allow blood transfusions by combat medics at pre-hospital stage," 9/5/23)

The European Commission (EC) has approved expanded use for Merck's Ebola vaccine. Now individuals ages one or older can receive the vaccine. According to a Merck News Release, the vaccine was previously authorized for use in the European Union (EU) for individuals 18 years of age or older. "The EC's decision follows the positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) received on July 20, 2023." The U.S. Food and Drug Administration approved the expanded indication in July 2023 for use of the vaccine in individuals ages one or older.

(Source: Merck News Release, 9/7/23)

COMPANY NEWS

Fresenius Kabi and the **Association for the Advancement of Blood & Biotherapies** (AABB) celebrated the 18th annual Blood Collectors Week 2023 September 3rd-9th. According to the organizations, the initiative honors "individuals who make blood collection possible, including phlebotomists, apheresis operators, medical directors, donor recruiters, technicians, and drivers [for their] vital role as the connection between blood donors and patients relying on blood for medical conditions." More the 250 collection sites across the U.S. were anticipated to take part in the year's celebration.

(Source: Fresenius Kabi News Release, 9/3/23)

A New Drug Submission (NDS) application for marketing approval submitted by **Valneva SE** to Health Canada for the company's investigational single-shot chikungunya vaccine candidate has been accepted for review. A Valneva SE news release stated that the regulatory review by Health Canada is expected to be completed by mid-2023. The company previously submitted a biologics license application (BLA) to the FDA for the investigational vaccine, which is currently under priority review by the agency. According to the news release, the regulatory submissions being reviewed by Health Canada and the FDA are based on "final pivotal phase III data in March 2022, final lot-to-lot consistency results in May 2022, and positive twelve-month persistence data in December 2022." Results from the clinical trial were published in the *Lancet* in June. Valneva SE also recently reported positive initial phase III safety data in adolescents for its investigational single-shot chikungunya vaccine candidate. According to the company news release, "[the vaccine] was generally safe and well tolerated in adolescents aged 12 to 17 years, regardless of previous chikungunya virus infection. 754 individuals were vaccinated in trial, and the present analysis includes safety data up to Day 29. An independent data and safety monitoring board (DSMB) has continuously evaluated safety data during the trial and has not identified any safety concerns. Overall, the adverse event profile is consistent with the profile observed in Valneva's pivotal phase III trial in adults. The majority of solicited adverse events observed following administration were mild or moderate and resolved within three days. Importantly, the initial data suggest a favorable safety profile in seropositive participants, confirming the observations following re-vaccination of individuals in [a] phase I trial [of the investigational vaccine]."

(Sources: Valneva SE News Releases, 8/29/23; 8/28/23)

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

- **ADRP Masterclass: Change Is Good – The Journey of Donor Eligibility** – Sept. 20-21. Registration is open. More information available here.

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

Sept. 17-20. **American Association of Tissue Banks Annual Meeting, National Harbor, Md.** Registration is open. More information available here.

Sept. 20-21. **ADRP Masterclass: Change Is Good – The Journey of Donor Eligibility (Virtual).** Registration is open. More information available here.

Sept. 20. **The Department of Transfusion Medicine, National Institutes of Health (NIH) Clinical Center, NIH, and the American Red Cross 42nd Annual Immunohematology and Blood Transfusion Symposium.** Registration is open. More information available here.

Oct. 9-11. **Advanced Medical Technology Association (AdvaMed) The MedTech Conference, Anaheim, Calif.** Registration is open. More information available here.

Oct. 14-17. **AABB Annual Meeting, Nashville, Tenn.** Registration is open. More information available here.

Oct. 18-20. **American Society for Clinical Pathology (ASCP), Long Beach, Calif.** More information 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. 18-21. **ISBT Regional Congress, Cape Town, South Africa.** Registration is open. More information available here.

2024

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

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

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

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

Medical Director (Memorial Blood Centers). Memorial Blood Centers (MBC.ORG), a division of Innovative Blood Resources, now a major partner in the NYBC Enterprise, has been saving and sustaining lives since 1948, and we're seeking a Medical Director who will help further our efforts and expand our success. This challenging medical directorship serves as co-medical director at a nationally recognized Children's hospital transfusion service, a national quality leading safety net hospital that is the largest local level 1 trauma center (both adult and pediatric), and associate medical director for blood centers in Minnesota (Duluth and Twin Cities, Nebraska (Lincoln and Omaha) and Greater Kansas City (Kansas and Missouri). The role will provide medical support across the Enterprise and for the assigned blood centers and transfusion services. Memorial Blood Centers supplies blood and blood components, state-of-the-art laboratory services, and biomedical expertise to area healthcare partners, national blood centers, biotechnology companies, research institutions, and international clients. The blood centers in Minnesota, Nebraska and the Greater Kansas City area serve nearly 100 hospitals and more than a dozen air ambulances with life-saving blood. Ample opportunity for research and clinical publication as well as direct patient and donor involvement. Click here to apply: https://www.kleinhersh.com/positions/medical-director-2/.

Director, Public Relations and Marketing. Mississippi Blood Services (MBS) is seeking the right candidate for the highly visible position of Director of Public Relations & Marketing. We are looking for an individual with flexible skills who can oversee our Communications and Public Relations efforts to ensure we are able to collect and distribute the much-needed resource of blood donations! As the face of the company, the ideal candidate will be responsible for all aspects of Public Relations and Marketing, which includes recruitment of blood drives and telerecruitment. This individual will work with Public Relations, Marketing Representatives, Telerecruitment manager, and other managers to coordinate and organize ample daily collections of whole blood, double red cells, apheresis platelets, and plasma collections for the organization. They will also work in conjunction with other MBS management to set strategic goals and objectives for the company. Must have a bachelor's degree (BA) from a four-year college or university; three to five years' related experience; or equivalent combination of education and experience. Visit www.msblood.com to apply online.

Assistant Manager - Product Quality Control (Carter BloodCare). Principal Accountability: The Assistant Manager Product Quality Control reports to the Manager of Product Quality Control and will be responsible for all daily, routine departmental activities and operations, consulting with the Manager, as needed. This position will oversee strict fiscal adherence to the budget and other administrative activities for the department, as assigned by the Manager, Technical Director, or Medical Director. The Assistant Manager is able and willing to perform any departmental task, as needed, to ensure efficient workflow within the department. Education: Bachelor of Science Degree and Minimum MT/MLS ASCP, or equivalent, required. Experience: Working knowledge of Product Quality Control instrumentation and parameters associated with donor collections. Strong working knowledge of blood bank policies and procedures. Comprehensive problem-solving skills. Good written and verbal communication skills. Excellent interpersonal and conflict resolution skills. Very strong customer service practices. Advanced computer skills. Comprehensive knowledge of administrative functions, including budget activities. Effective organizational skills, to include the ability to organize and prioritize workload, attention to detail, and consistently follow through with a commitment to excellence. Equal Opportunity Employer:

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POSITIONS (continued from page 8)

Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job **Assistant Manager Product Quality Control.**

Quality Systems Director. Rock River Valley Blood Center, based in Rockford IL, is looking for a Quality Systems Director to oversee the strategic planning, development and execution of all quality systems and process improvement initiatives center wide. This includes business operations relating to blood collection, testing, manufacturing, distribution, document control, customer service, safety, risk management, training, internal and external audits/inspections. The position is responsible for ensuring the organization is in full compliance with all applicable federal and state regulations and professional contract requirements. The successful candidate is a self-starter who will lead and champion all quality initiatives from start to finish, taking an influential, collaborative, team-oriented and business friendly approach. Must possess strong leadership skills with advanced knowledge and business acumen in quality system concepts and process improvement. Must have advanced analytical and problem-solving skills; exceptional attention to detail; ability to prioritize tasks; effective communication skills both verbally and in writing. Strong skills in Microsoft Office applications. Qualifications include: five-plus years' experience in a progressive quality systems role within a highly regulated environment, three-plus years supervisory and leadership experience, previous experience interpreting and implementing regulatory/accrediting standards, bachelor's degree in health science, quality management or related field. M.T. or M.L.S. (ASCP) a plus. CMQ/OE and/or CQA (ASQ) highly preferred. Please visit our careers site online to apply https://www.rrvbc.org/careers/.

Purchasing Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Purchasing 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 Purchasing 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!