

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

August 11, 2023

2023 #28

ABC Statement on Community Blood Centers Implementing Individual Donor Risk Assessments

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America's Blood Centers (ABC) issued a statement on Friday, August 11th regarding community blood centers implementing individual donor assessments in the wake of the U.S. Food and Drug Administration's final <u>guidance</u> on "Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of HIV Transmission by Blood and Blood Products."

The statement explains that "community blood centers across the country are actively working to implement the final guidance, with many already completing this work. Implementation of the guidance is a rigorous process that must be conducted with due diligence to uphold the safety of the blood supply." It encourages individuals "to contact their local blood center to learn [more about] the [implementation] timeline in their area."

ABC reiterated in the statement that "the deferral for individuals using PrEP and PEP medications remains in place. This deferral is not specific to any gender or sexual orientation and is based on the fact that these medications may prevent the detection of HIV by current screening tests used for blood donations. This precautionary measure ensures the safety and accuracy of blood donations."

The statement also explained that FDA guidance, resulting in revised donor eligibility criteria, can cause blood centers to "undertake extensive changes before welcoming impacted donors. This includes updating the Donor History Questionnaire (DHQ) that determines an individual's eligibility to donate; updating their Blood Establishment Computer Software (BECS) and validating the changes to ensure all information is entered to allow all blood products to be properly tracked and labeled; and updating center operations, including Standard Operating Procedures (SOPs). Blood center staff must be trained on these changes, and informational and educational materials must be updated to reflect the changes. The blood community is committed to upholding the safety and availability of the nation's blood supply."

The full <u>statement</u> is available on the ABC public website.

(Source: ABC Statement, 8/11/23) •





CBC (Dayton) Rebranding as Solvita



Community Blood Center (CBC)/Community Tissue Services (Dayton, Ohio) will become Solvita on September 1st. The new name is part of the organization rebranding as its mission is "to take life further. We are dedicated to helping our mact on the world. We act as the link between generous donors and patients in

donors make a lasting impact on the world. We act as the link between generous donors and patients in need, helping to make the sunshine brighter and hope grow stronger with each passing day," according to a letter announcing the change.

(Source: CBC Announcement, 8/9/23)

Vitalant Unveils Innovation Center

Vitalant held a ribbon-cutting <u>ceremony</u> this week to unveil the Vitalant Innovation Center. According to a news release from the organization, the Innovation Center is "the first of its kind in the U.S." and will serve as a facility "where innovative blood center equipment and processes can be tested outside of normal operations, advancing the science of transfusion medicine and research." The building, located in Denver, Colo. sitting adjacent to the Vitalant Research Institute and Vitalant's Denver blood center, "is nearly 5,000 square feet, including a 3,200-square-foot flexible lab space to pilot new technologies and



processes. The facility, primarily funded by a generous \$8 million Bonfils Blood Center Donor Advised Fund donation, has 19 full-time employees." Vitalant Chief Executive Officer Dave Green explained in the news release, "blood centers have an iconic history, emerging after World War II to meet the transfusion needs of patients. While modern blood services have changed tremendously over the last 80 years, there is an opportunity to pursue innovative services and lifesaving blood-derived products at a greater pace. The Vitalant Innovation Center represents our commitment to forging advancements in transfusion medicine to help save and sustain more lives." Susanne Marschner, PhD, vice president of research and scientific programs at Vitalant Innovation Center, added in the news release, "[t]he Innovation Center provides a much-needed 'sandbox' to advance cutting-edge developments and bring new products to Vitalant and the blood services industry. We also look forward to partnering with like-minded organizations to support their research and development needs with our capabilities." The Innovation Center includes "blood center process and equipment testing; cell sourcing; pre-clinical testing; clinical trial supply; [and a] biorepository with the capacity to securely store up to 1.5 million samples."

(Source: Vitalant News Release, 8/10/23)

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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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ABC Joins Coalition Supporting Congressional Workforce Legislation

America's Blood Centers (ABC) joined the <u>Tomorrow's Workforce Coalition</u> in support of the "Freedom to Invest in Tomorrow's Workforce Act (<u>S. 722</u> and <u>H.R. 1477</u>)." The coalition includes more than 500 trade associations, professional societies, businesses, and employers and is being led by the American Society of Association Executives (ASAE) and Professional Certification Coalition (PCC). According to an ASAE news release, the "bipartisan, bicameral 'Freedom to Invest in Tomorrow's Workforce Act' would expand qualified expenses under 529 savings plans to include postsecondary training and credentialing, such as licenses and professional certifications. The bill would provide valuable tax-advantaged resources for families, students, and workers — with or without a college degree—who pursue career growth, midcareer changes or pathways that diverge from a typical academic route."

(Source: ASAE News Release, 7/27/23) •

RESEARCH IN BRIEF

Donor Characteristics Affect Hemolysis of Stored Red Blood Cells. The aim of a study in Vox Sanguinis was to "determine the association of blood donor characteristics with in vitro h[e]molysis in packed red blood cells (PRBCs) during storage." The authors explained that "[a] total of 109 blood donors were selected [three were excluded]...A pre-donation sample was taken from the enrolled study subjects...Whole blood was collected in blood bags containing citrate phosphate dextrose adenine (CPDA-1) anticoagulant...Samples were tested on days 1, 21 and 35 of storage." The researchers noted that "[s]ignificantly higher mean potassium values were observed in PRBCs from male donors than female donors on all days of storage (p-value: 0.05 day 35) and donors with higher serum uric acid (UA) values (>6 mg/dL) than donors with UA values ≤6 mg/dL on day 35 of storage (p-value: 0.03)...Median lactate dehydrogenase (LDH) values of PRBCs were significantly higher in male donors on day 21 (p-value: 0.05) of storage...PRBCs from first-time donors had higher median LDH values on day one of storage while over the storage period, the values were greater in frequent donors with a significant difference on day 21 of storage (p-value: 0.006)...PRBCs from overweight donors had higher median LDH values and the difference was significant on day 21 (p-value: 0.003)...Plasma Hb values were also significantly higher in first-time donors as compared with frequent donors on day 35 (p-value: 0.02) of storage." The study found that "[m]ean storage h[e]molysis was significantly higher in PRBCs from female donors on day 35 (p-value: 0.002)...It was also higher in PRBCs from healthy weight donors as compared with overweight donors and the difference was statistically significant on day 21 of storage (p-value: 0.02)...Over the storage period, mean h[e]molysis was observed to be higher in PRBCs from blood donors with lower UA levels (≤6 mg/dL) and the difference was statistically significant by the end of the storage period (p-value: 0.03)...Multiple regression analys[es] [showed a] statistically significant positive association between donor UA levels and LDH levels of PRBCs (β coefficient: 715.52, p-value: 0.003)." The authors concluded that "donor characteristics do have an impact on in vitro h[e]molysis of PRBCs during storage."

Citation: Dhawan, B., Mittal, K., Kaur, P., Jaswal, S., Tahlan, A., Kaur, R., et al. "Association of blood donor characteristics and in vitro haemolysis of packed red blood cell concentrates during storage." Vox Sang. 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.

Register for the ABC Quality Forum Webinar

America's Blood Centers (ABC) will host its next Quality Forum Webinar on August 24th from 2-3 p.m. EDT. Registration is required for this event and a link is available to ABC members in MCN 23-071. The webinar will feature Kendra Reynolds, director of Quality and Regulatory Affairs at Innovative Blood Resources, presenting the basics of using the U.S. Food and Drug Administration's electronic submission process and providing helpful hints from her experiences using the system. Following the presentation, the audience will have an opportunity to ask questions and/or discuss their own experiences with the electronic submission process. Please contact us with questions.

(Source: MCN 23-071, 8/9/23)

UPCOMING ADRP Webinar: Spanish Donor Recruitment

<u>Register</u> today for the ADRP <u>webinar</u> titled "Spanish Donor Recruitment." This webinar will take place Wednesday, August 30th at 1 p.m. EDT and attendees will hear how their peers use creative marketing, donor service training, and translation services to create better experiences for their Spanish-speaking donors. Speakers include:

- Ramona Moise, director of Marketing at Gulf Coast Regional Blood Center;
- Liz Parker, training manager, Donor Services at Versiti; and
- Clinton McCoy, director of Mobile Donor Recruitment and Regional Operations at Carter Blood-Care.

The webinar is free for ADRP members. Non-members may register for \$25 and \$50 for industry partners. Please contact us with questions.

(Source: ADRP Announcement, 8/2/23)

July **Blood Bulletin** Available

America's Blood Centers (ABC) has published the July 2023 edition of the <u>Blood Bulletin</u>. The issue, titled "Individual Donor Risk Assessment and Blood Safety," is available in <u>PDF</u> or <u>MS Word</u>. The article was written by Louis Katz, MD, Chief Medical Officer Emeritus at ImpactLife; Daniela Hermelin, MD, Chief Medical Officer at ImpactLife; Kip Kuttner, DO, Vice President and Medical Director at Miller-Keystone Blood Center; Richard Gammon, MD, Medical Director at OneBlood; Debra Smith, MD, PhD, Medical Director at Carter BloodCare; Courtney Hopkins, DO, Senior Medical Officer at Vitalant; Nancy Van Buren, MD, Medical Director at Innovative Blood Resources and Community Blood Center of Kansas City, divisions of New York Blood Center; and Jed Gorlin, MD, MBA, Chief Medical Officer at America's Blood Centers. <u>Blood Bulletin</u> is a quarterly publication reviewed and edited by ABC's Scientific, Medical, and Technical (SMT) Publications Committee. An archive of Blood Bulletin issues prior to 2022 are available exclusively to ABC members here.

(Source: MCN 23-066, 7/17/23)

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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.

INFECTIOUS DISEASES UPDATE

SARS CoV-2

The World Health Organization (WHO) has "classified the EG.5 coronavirus strain circulating in the United States and China as a 'variant of interest.'" According to a report in *Reuters*, the WHO stated "[c]ollectively, available evidence does not suggest that EG.5 has additional public health risks relative to the other currently circulating Omicron descendent lineages. A more comprehensive evaluation of the risk posed by EG.5 was needed." The news publication added that "[t]he fast-spreading variant, the most prevalent in the U.S. with an estimated more than 17 percent of cases, has [caused] upticks in the virus across the country and also has been detected in China, South Korea, Japan and Canada, among other countries."

(Source: Reuters, WHO classifies EG.5 as COVID-19 "variant of interest," 8/9/23)

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

- **ABC Quality Forum Webinar** Aug. 24. More information available to ABC Members, including a link to registration, in MCN 23-071.
- ADRP: The Association for Blood Donor Professionals Spanish Donor Recruitment Webinar Aug 30. Registration is open. More information available here.
- ADRP Masterclass: Change Is Good The Journey of Donor Eligibility Sept. 20-21. Registration is open. More information available here.





GLOBAL NEWS

ABC Newsletter

The United Nations Office for Project Services (UNOPS) announced that it has provided \$3 million in funding to support the development of a fully functioning blood bank in Somalia. According to a news release from UNOPS, the blood bank will be able to "store up to 10,000 units of donated blood and [will be] equipped with state-of-the-art technology allowing the facility to screen, prepare and securely store blood and blood products. The facility will provide a dependable supply of blood products, particularly during emergencies arising from trauma, postpartum complications, conflict-related injuries, and other health-related conditions." The facility will be in Mogadishu, the nation's capital.

(Source: UNOPS News Release, 8/9/23)

The World Health Organization (WHO) recently provided an <u>update</u> from a meeting of the Technical Advisory Group on Arbovirus (TAG). The TAG prioritized the following recommendations for upcoming years:

- "[t]he need for integrated data systems that are key to monitoring the transmission of known arboviruses, and early detection of the introduction of emerging arboviruses;
- [t]he development of preemptive vector control surveillance and interventions for implementation during inter-epidemic periods in urban settings;
- [a]lthough genomics plays an important role in arbovirus surveillance, it should not detract from basic diagnostic capacity building; access to genomics will however be pivotal to strengthen molecular diagnostic target matching and to determine genotype circulation associated with vector transmissibility and disease severity;
- [t]he development of innovative platforms for partner engagement that seek to strengthen community engagement and resilience to arboviruses; [and]
- [t]he development of an inventory of partners working on arboviruses to expand partnerships for the next steps of the WHO's Global Arbovirus Initiative implementation."

(Source: WHO News Release, 8/2/23) •

COMPANY NEWS

The **Association for the Advancement of Blood & Biotherapies** (AABB) has <u>developed</u> a 60-minute training course to assist blood centers with the implementation of individual donor assessments in the wake of blood donation policy shifts. This course is free and:

- "explor[es] techniques to respond to challenging conversations and de-escalate conflict;
- [includes a] toolset of key messages and phrases to enable sex-positive, respectful verbal and non-verbal communication with potential donors;
- identif[ies] approaches to create a welcoming experience that leads to long-standing relationships with donors."

(Source: AABB Announcement, 8/7/23)

Bavarian Nordic recently <u>reported</u> data from a phase III randomized clinical trial of its investigational virus-like particle (VLP)-based chikungunya virus vaccine candidate. According to a company news release, "[a] total of 3,254 participants [ages 12 to 64] were enrolled and randomized to receive either a single intramuscular injection of [the investigational vaccine], or placebo. The results up to day 22 post vaccination showed that [the investigational vaccine] was highly immunogenic in healthy adolescents and adults,

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COMPANY NEWS (continued from page 6)

as demonstrated by the strong induction of chikungunya neutralizing antibodies in 98 percent of vaccinees in the active group. The strong neutralizing antibody tit[ers] were equal to, or exceeded the threshold agreed with authorities as a marker of seroprotection, meeting primary objectives of the study. [The investigational vaccine] induced significant neutralizing antibodies in 97 percent of the subjects at two weeks post vaccination, confirming a rapid onset of protective levels of immunity. These responses were robust and durable, as 86 percent of the subjects had seroprotective levels of neutralizing antibodies six months post vaccination. [The investigational vaccine] was well-tolerated in this adolescent and adult population and adverse events were mainly mild or moderate in nature." The company anticipates submitting a biologics license application (BLA) to the U.S. Food and Drug Administration and a marketing authorization application (MMA) to the European Medicines Agency next year.

(Source: Bavarian Nordic News Release, 8/6/23)

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

Aug. 14-16. National Heart, Lung, and Blood Institute (NHLBI) Annual Sickle Cell Disease Research Meeting (Hybrid). Registration is open. More information available here.

Aug. 11. **America's Blood Centers (ABC) Quality Forum.** More information available to ABC Members, including a link to registration, in MCN 23-071.

Aug 30. ADRP Webinar: Spanish Donor Recruitment. Registration is open. More information available here.

Aug. 30. U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Officer of Therapeutic Products (OTP) Town Hall: Nonclinical Assessment of Cell and Gene Therapy Products (Virtual). More information available here.

Sept. 7-9. European Blood Alliance European Conference on Donor Health and Management. Vienna, Austria. Registration is open. More information available here.

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.

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

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<u>CALENDAR</u> (continued from page 7)

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 15-17. 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

POSITIONS

Transfusion Lab Supervisors Needed! Join Florida's leading blood bank, OneBlood, as a Lab Supervisor working inside one of the largest hospitals in Tampa, FL. Bring your leadership, technical expertise, and management experience to support the transfusion testing procedures on patient and/or donor samples. Qualified candidates should possess three (3) or more years' experience in a clinical laboratory, preferably blood banking environment, including one (1) or more years' experience in supervision and management experience, as well as a valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking; Supervisor license strongly preferred. To apply and view a complete Job Description of this position, visit www.oneblood.org/careers. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Manager of Technical Services. The Blood Connection is seeking a proactive and results-driven Manager of Technical Services to oversee and manage the daily operations within our technical departments which include Hospital Services, Biologics Processing, and Reference Laboratory. This position requires an understanding of laboratory operations, including specialist (SBB) skills, and involves supervising staff while performing essential functions within the laboratory. The ideal candidate will hold their SBB and have a background in the Reference Laboratory. This role is based in Morrisville, NC. Prospective candidates may be eligible for relocation assistance. How to apply: Manager of Technical Services Application.

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 Pub-Representatives, Relations, Marketing 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. www.msblood.com to apply online.

Fairbanks Center Manager. The Blood Bank of Alaska (BBA) is looking for a Fairbanks Center Manager. The Fairbanks Center Manager is responsible for oversight and coordination of the daily operational collection functions and related product processing workflow for the BBAF Center. Directs the activities of such team to facilitate reaching and exceeding goal. Oversight and partnership with BBA management team in planning, program formulation, and technical decision making with particular reference to the role, functions, and operation of the blood bank's technical areas. This position is fulltime exempt. The Blood Bank of Alaska offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life, and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, and a 401 (k) program are also available. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status, or any other legally protected status. Interested candidates please apply online at https://bloodbankofalaska.apscareerportal.com.

(continued on page 9)



POSITIONS (continued from page 8)

Director of Hospital Services and Manufacturing. The Blood Bank of Alaska is looking for a Director of Hospital Services and Manufacturing. The Director of Hospital Services and Manufacturing is responsible for ensuring alignment of teams with organizational goals and compliance with regulatory guidelines. Participates as a member of the blood bank's management team in planning, program formulation and decision making with reference to the role, functions and technical support of the manufacturing and distribution of blood products. Fosters and enhances customer hospital relations. This person ensures a dedicated focus on the production and distribution of quality products in a timely manner while providing the highest level of customer service. Also ensures all procedures are followed and promotes a positive work environment. This position is full-time exempt. The Blood Bank of Alaska offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life, and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays and a 401 (k) program are also available. A \$1,500 retention bonus will be paid after one year of service with the Blood Bank of Alaska. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status, or any other legally protected status. Interested candidates please apply online at https://bloodbankofalaska.apscareerportal.com.

Quality Systems Specialist and Technical Writer. The Blood Bank of Alaska is looking for a Quality Systems Specialist and Technical Writer. The person in this role is responsible for promoting organizational compliance with accrediting agency, state, and federal regulations. Managing the Blood Bank of Alaska's occurrence program which includes performing investigations for occurrences. The Quality Systems Specialist and Technical Writer writes, revises, edits, and approves Standard Operating Procedures (SOPs) along with assisting document owners in writing and revising SOPs. Assists in the management of the Blood Bank of Alaska's document control process and ensures consistency across departments when policies or procedures change. This position is full-time non-exempt. The Blood Bank of Alaska offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life, and short/long term disability programs to qualified employees. Educational assistance, paid annual leave and holidays, and a 401 (k) program are also available. A \$1,500 retention bonus will be paid after one year of service with the Blood Bank of Alaska. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status, or any other legally protected status. Interested candidates

please apply online at https://bloodbankofalaska.apsca-reerportal.com.

Laboratory Services Manager. The Blood Bank of Alaska is looking for a Laboratory Services Manager. Under the general direction of the Director of Laboratory Services, this person is responsible for oversight of daily laboratory operations ensuring that laboratory product QC and donor test results meet CLIA, AABB and FDA compliance standards/regulations for the manufacture of blood products. The Laboratory Services Manager is also responsible for oversight of laboratory personnel. This position is full-time exempt. The Blood Bank of Alaska offers competitive wages and an exceptional benefits plan. We offer medical, dental, vision, life, and short/long term disability programs to qualified employees. Educational assistance, paid annual leave, and holidays and a 401 (k) program are also available. A \$1,500 retention bonus will be paid after one year of service with the Blood Bank of Alaska. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status, or any other legally protected status. Interested candidates please apply online at https://bloodbankofalaska.apscareerportal.com.