

ABCNEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #19 May 29, 2020

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Study Set to Launch to Examine Percentage of Population with Antibodies for SARS-CoV-2

A collaboration of blood centers, testing laboratories, and research institutes has developed a seroprevalence survey that aims to measure the percentage of individuals with antibodies for SARS-CoV-2, the coronavirus that causes the disease COVID-19. The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) are providing funding for this initiative. It includes Vitalant Research Institute, Creative Testing Solutions along with the American Red Cross, Bloodworks Northwest, New York Blood Center, OneBlood, Vitalant, and other regional blood collection organizations that are partnering on the "National SARS-CoV-2 Seroincidence Studies in Blood Donors" survey which will include 25 metropolitan areas throughout the U.S.

"Public health officials need access to ongoing infection rate data in order to make the best decisions for their communities," said Dr. Michael Busch, director of Vitalant Research Institute in a <u>news release</u>. "By collaborating with government institutions and leveraging the diverse donor populations and testing systems in place to support our national blood supply, the blood banking community can provide these data relatively quickly. This allows us to monitor and respond to ongoing outbreaks and help evaluate the effectiveness of evolving policies to prevent future widespread transmissions."

The survey will be an 18-month nationwide with participating blood centers and testing laboratories "providing residual blood donation specimens from around the country that will be tested for the presence of SARS-CoV-2 antibodies using validated assays and confirmation algorithms."

Alicia Fry, MD, team lead for the CDC COVID-19 Epidemiology Task Force stated in the news release, "[t]his survey is the largest of its kind undertaken to date as part of the USG COVID-19 pandemic response and is part of CDC's efforts to better understand this new virus and help inform how we fight it." Dr. Fry added "it is because of established partnerships that CDC has with other federal agencies and blood organizations that we are able to rapidly put this survey into place to understand the total number of people who have been infected with SARS-CoV-2, including those infections that might have been missed." This seroprevalence survey expands on the ongoing NIH National Institute of Allergy and Infectious Diseases (NIAID) and National Heart, Lung, and Blood Institute (NHLBI) funded project which leverages the NHLBI REDS (Recipient Epidemiology and Donor Evaluation Study) SARS-CoV-2 "RESPONSE" Program.









OUR SPACE Ruth Sylvester MS, MT(ASCP)SBB, ABC's Director, Regulatory Services

Are You Prepared?

This is a year for the ages. Our lives have been turned upside down. Everything as we knew it has changed and will remain that way or somewhere in between for the time being at least. All of our focus has been on the coronavirus pandemic, but that does

not stop other disasters from happening. Michigan experienced historic flooding last week and the National Oceanic and Atmospheric Administration (NOAA) is predicting a busy hurricane season with the potential for 13-19 named storms with six to ten becoming hurricanes and three to five being classified as major. The Federal Emergency Management Agency (FEMA) has published guidance for emergency managers and public health officials on preparing for the 2020 hurricane season in the COVID-19 pandemic. Responding to disasters during a pandemic is a unique challenge. This is especially true for volunteers that provide the bulk of support during disaster response and to sheltering evacuees. How will your blood center's response to a disaster be different in light of COVID-19?

As with everything your organizations have and continue to do, thinking outside the box is a necessity, probably further outside the box than you ever imagined. There have been times when I was involved in disaster response exercises that I would "cry foul" when I was given an exercise input that I felt was unrealistic or too "worst case." I do not believe I will ever think something "cannot possibly happen" again. As we enter the hurricane season, we hope for a calm one, but should plan for much worse. Imagine the 2017 hurricane season with Harvey, Maria, and Nate or worse — a Katrina? How will you respond to a Pulse Nightclub or Las Vegas mass shooting during this pandemic? We cannot respond the way we have in the past. We will not be able to cease social distancing or enhanced infection control procedures because of a disaster.

Now is the time to think about your disaster plans and how you will activate them during a pandemic. It is chaotic enough responding to a disaster without having to figure out how to respond during a pandemic while a disaster is happening on your doorstep.

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Ruth Sylvester, MS, MT(ASCP)SBB Director of Regulatory Services

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare 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.

America's Blood Centers

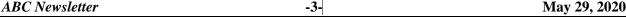
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ABC AABB, and ARC Issue Joint Statement Encouraging Blood Donation

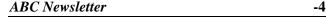
America's Blood Centers, AABB, and the American Red Cross published a joint <u>statement</u> raising awareness of the need for blood donors as states around the country relax "stay at home orders," leading to increases in both elective surgeries and the demand for blood as the summer months arrive, a time when blood donations typically declines. The organizations state, "Now, throughout the country, blood centers are reporting inventories falling to their lowest levels since the early stages of the pandemic as the nation's hospitals resume elective surgeries. In addition, blood drives continue to be canceled, as many businesses, high schools and community organizations remain closed, and social distancing measures have limited blood centers' ability to collect blood at pre-pandemic levels. The availability of an adequate blood supply is a key aspect of ensuring optimal treatment for all patients and must be replenished to help prevent shortages during the coming weeks and months."

It continues by adding that, "AABB, America's Blood Centers, and the American Red Cross are joining together to urge eligible individuals to make an appointment to donate now. Blood will continue to be needed throughout the summer and beyond. Making and keeping an appointment to donate blood is the best way to help ensure the continued stability of the blood supply."

(America's Blood Centers, AABB, American Red Cross Joint Statement, 5/28/20)

RESEARCH IN BRIEF

International Forum on Hospital Transfusion Services' Response to COVID-19. A recent paper in Vox Sanguinis surveyed centers in 12 countries to examine the response of hospital transfusion services to the COVID-19 pandemic. It notes that, "[t]he transfusion community has faced epidemics and pandemics before, but little has been published about the preparations made by hospital-based transfusion services for handling samples and performing pretransfusion testing on patients who are affected by the disease." Each of the transfusion services surveyed "indicated that [they] accepted samples from patients with confirmed or suspected coronavirus infections," although two (Israel and Korea) had COVID-19 written on the sample label. In Spain, the transfusion service disinfected the samples with hypochlorite and ultraviolet (UV) irradiation. Regarding personal protective equipment (PPE), in Israel lab workers wore "double gloves, goggles an N95 respirator and gown when testing samples [from COVID-19 patients]; and prior to receiving the biosafety cabinet, samples from these patients were not accepted for pre-transfusion testing. Instead, group O red blood cells (RBCs) and group AB plasma would have been issued to these patients." The transfusion service also made sure "[c]oolers [holding blood] always remained outside of the patient's room. RBCs that were taken into a patient with known or suspected coronavirus' room, but not transfused, were discarded if they were returned to the blood bank." Several countries reported that the coolers were disinfected upon return. The American and Italian respondents wiped down the returned RBCs and they were restocked. "Many of the [transfusion services surveyed] indicated that they had a pre-existing plan for handling samples from patients with novel pathogens...Both the American and Italian respondents indicated that they did not have a specific plan for dealing with novel pathogens because standard universal precautions were always being used for all samples." A majority of the reporting countries "noticed reductions in transfusions...of around 30 percent for RBCs, 20-47 percent for platelets, and about 40 percent for plasma." The hospital transfusion service reporting from Canada "also expect[ed] a shortage of plasma fractionation products such as [intravenous immunoglobulin] IVIg in the long term." Most of the respondents reported "cancelled elective surgeries thereby helping to preserve their blood product inventories. Others, such as the respondents from U.S., Brazil, Australia, and Canada held information campaigns to remind clinicians about appropriate transfusion thresholds and transfusing a single RBC unit at a time." Most of those surveyed had begun providing convalescent plasma with Israel and Brazil using pathogen reduction









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RESEARCH IN BRIEF (continued on page 3)

technology. "[The article concluded that] among countries with different levels of people affected by the SAR-CoV-2 pandemic, the hospital blood banks/transfusion departments have reacted differently to the pandemic."

Citation: Yazer, M.H., Pagano, M.B., Cho, D., et al. International Forum on Hospital Transfusion Services' Response to COVID-19. Vox Sanguinis. 2020. Doi:10.1111/vox.12943.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

WORD IN WASHINGTON

Reps. Joe Cunningham (D-S.C.), Mario Diaz-Balart (R-Fla.), and Senator Amy Klobuchar (D-Minn.) sent a letter to the heads of the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration encouraging them of the need to raise awareness for the importance for individuals recovered from COVID-19 to donate convalescent plasma as potential therapy for critically ill COVID-19 patients. "Given the unprecedented scale and nature of this outbreak, is it critically important that we support the development of safe and science-based treatments. In some cases, clinicians and investigators rely on plasma donations by people who have recovered to develop these treatments," stated the lawmakers in the letter. They added, "We understand that FDA and CDC have taken initial steps to encourage plasma donation by partnering with outside organizations, issuing guidance on plasma collection, and developing an informational webpage. We encourage FDA and CDC to take additional steps to effectively share these resources with the public, people who have recovered from coronavirus, and hospitals and health systems caring for patients with the virus."

(Source: Rep. Joe Cunningham Announcement, 5/13/20)



Sen. Tom Carper (D-Del.) recently donated blood at the Blood Bank of Delmarva (BBD), a division of New York Blood Center, Inc. He is a repeat blood donor who has donated frequently enough to achieve multi-gallon status at BBD. Sen. Carper has long been an advocate of blood donation and began donating at BBD in the 1990s.

(BBD Announcement, 5/26/20) •

PEOPLE

Sandya R. Panch, MD, MPH has been announced as the 24th recipient of the Biomedical Excellence for Safer Transfusion (BEST) Collaborative Scott Murphy Memorial Award Lectureship. She currently serves as the Assistant Research Physician/Medical Director at the Center for Cellular Engineering within the Department of Transfusion Medicine at the National Institutes of Health's Clinical Center. Dr. Panch will deliver a lecture on "Engineering blood cells for improved transfusion, transplantation, and immunotherapies: Studies in mice, macaques and (wo)men" during the 59th Meeting of BEST, which will be held virtually on June 19th after previously be scheduled for an April 24th in-person meeting in Warsaw. Poland.



(Source: BEST News Release, 5/21/20)



INSIDE ABC

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

ADRP COVID-19 Forum Webinar: Antibody Testing

Register today for the Thursday, June 4th ADRP webinar entitled "COVID-19 Forum: Antibody Testing." This webinar will take place at 1 p.m. EDT and will feature discussions on antibody testing and its implications for blood centers. America's Blood Centers Chief Medical Officer Rita Reik, MD and The Blood Connection, Inc. Director of Marketing and Public Relations, Heather Moulder will review the current state of antibody testing, while examining considerations for marketing it. The event will also include a question and answer session for attendees. ADRP subscribers may register for free and non-subscribers can participate for \$25.

(ADRP Announcement, 5/29/20)

ABC Webinar: Facebook Blood Donation Tool Training & New Features Update

As a strategic partner in prioritizing and raising awareness of the need for individuals to donate blood, Facebook is launching new features to their Blood Donation Tool. Facebook will be hosting a training webinar for ABC Member blood centers to introduce these updates and provide a refresher on using the tool. Please mark your calendars as the webinar will now take place on **Thursday, June 9th from 1 – 1:45 pm EDT.** Attendees will have the opportunity to have questions answered regarding the functionality and use of the blood donation tool developed by Facebook that was launched nationwide in December (see MCN 19-087). An email was disseminated to ABC members earlier this week that included a meeting invite and call instructions for joining the webinar. If you did not receive it and are interested in attending please contact us.

2020 ABC MD Workshop and Summer Summit is Going Virtual

After careful consideration, America's Blood Centers (ABC) has decided to transition the 2020 ABC Medical Directors Workshop and Summer Summit to a virtual event. We believe this ensures the safety of our attendees and staff while continuing to offer opportunities to network and discuss the most pressing issues facing the industry. ABC is currently evaluating platforms and adjusting the program to reflect the new format and will have additional details in the coming weeks and months. Thank you for your patience during this process, and for your continued support of ABC.

(Source: MCN 20-053, 5/4/20)



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MEMBER NEWS

LifeSouth Community Blood Centers recently announced a partnership with Emory University for a clinical trial collecting convalescent plasma from recovered COVID-19 patients to be used as a potential therapy to treat critically ill patients with the disease. "LifeSouth is honored to partner with Emory Healthcare to encourage those who have recovered from COVID-19 to donate convalescent plasma and provide this lifesaving donation to Emory to help patients fighting this devastating virus," said LifeSouth Community Blood Centers Vice President of Medical Services, Chris Lough, MD in the announcement. "As other treatments are developed, convalescent plasma may be the only current option to care for critically ill COVID-19 patients. Therefore, it is essential that we work with our communities to make this resource available for patients in need while work continues other potential therapies."

(Source: LifeSouth Community Blood Centers Announcement, 5/11/20)

GLOBAL NEWS

German lawmakers continue to weigh the merits of the country's current 12-month blood donor deferral policy for men who have sex with other men. Two parties within the nation's parliament have previously submitted proposals that would "remove" or revise the 12-month deferral. According to a report from *DW Akademie*, some lawmakers feel that amendments made last month to the country's national Transfusion Act, "which states that restrictions should be checked in the event of new medical findings to determine whether they are necessary," does not go far enough in attempting to expand the pool of eligible blood donors for the country's blood supply. "[It] does not end discrimination against gay and bisexual men and transgender people when donating blood," said Green Party MP Sven Lehmann to *DW Akademie*. "The guidelines are completely arbitrary and enable a preconceived mistrust of homosexual men. This doesn't belong in modern society," he added. "This is an old stigma from the 1980s. But by now in 2020 we've come much further. Therefore, we need to assess the risk of the behavior of blood donors, but not the sexuality." In April, several companies including Microsoft and IKEA urged German government and medical officials to "ease restrictions" outlined in the MSM blood donor deferral.

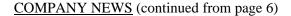
(Source: *DW Akademie*, German parliament debates relaxing blood donation rules for LGBT+ men, 5/27/20)

COMPANY NEWS

Haemonetics Corporation announced an agreement with the GPI Group to sell a portion of its blood donor management software solution assets. In a company news release, Haemonetics Global Blood Center President Chad Nikel <u>stated</u>, "We are committed to reshaping our portfolio for sustainable growth and this sale will enable us to focus on our core capabilities while delivering quality products and services where we bring distinct value. We will continue to invest across our business, execute our customer-centric strategies to strengthen our trajectory and develop innovative medical technologies that meaningfully advance healthcare." Through the transaction, which is expected to be finalized later this year, GPI Group will acquire "the intellectual property, customer contracts and certain other assets relating to ElDorado Donor®, Hemasphere®, Donor Doc®, Donor Doc Phlebotomy®, eDonor®, DonorSpace®, Surround™, and Safe-Trace® software products." GPI Group is an information technology (IT) company that specializes in IT solutions with the healthcare and social services sectors.

(Source: Haemonetics News Release, 5/28/20)





bioMérieux has received 510(k) <u>clearance</u> from the U.S. Food and Drug Administration (FDA) for its BACT/ALERT® BPA and BPN culture bottles for Large Volume Delayed Sampling (LVDS) of leukocyte-reduced apheresis platelets (LRAP) and leukocyte-reduced whole blood platelet concentrates (LRWBPC)." In a May 22nd news <u>release</u>, executive vice president and chief medical officer, Mark Miller, MD said, "[t]he FDA clearance for LVDS when using either of our two culture systems is an important step towards increasing patient safety and availability of precious life-saving platelets. As we continually face a shortage of blood products, especially now due to the COVID-19 pandemic, extending platelet shelf life with a single-step bacterial screening approach is critical and highly beneficial for patients in need." The clearance extends dating beyond day five and up to day seven for each of the following:

- Large volume delayed sampling (LVDS) of platelets no sooner than 48 hours after collection; or
- secondary culture no sooner than day four after platelet collection.

BACT/ALERT® Microbial Detection Systems are used to extend dating to five days for the following:

- Large volume, delayed sampling of platelets no sooner than 36 hours after collection; or
- secondary culture no sooner than day three after platelet collection.

(Source: bioMérieux News Release, 5/22/20; FDA Announcement, 5/20/20)

Cerus Corp. announced that it has submitted a pre-market approval supplement for a pathogen reduced cryoprecipitated fibrinogen complex with a five-day post-thaw storage to the FDA. "This is a major milestone in our corporate history," said Cerus President and Chief Executive Officer William 'Obi' Greenman, in a news <u>release</u>. "Pathogen-reduced cryoprecipitated fibrinogen complex is manufactured from FDA licensed INTERCEPT plasma. If approved by the FDA, it would be our first therapeutic product candidate. It is being developed specifically to provide a source of fibrinogen and other coagulation factors to treat patients with massive bleeding." Cerus previously received FDA breakthrough device designation for this potential therapy.

(Source: Cerus News Release, 5/26/20)

RESEARCH BRIEFS

America's Blood Centers welcomes contributions or briefs from guest authors for scientific/medical peer-reviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers. If you are interested in contributing a brief for potential publication please contact us here.

ABC Calendar of Events

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

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CALENDAR

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

2020

Aug. 28-29. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details available <u>here</u>.

Sept. 9. 10th Annual Symposium Red Cell Genotyping 2020: Visionary Solutions, Bethesda, Md. More details available here.

Sept. 10. **39th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** More details available <u>here</u>.

Sept. 23-25. 4th European Conference on Donor Health and Management, Hamburg, Germany. More details available here.

Oct. 3-6. 2020 AABB Annual Meeting, Baltimore, Md. More information available here.

Nov. 22-24. **2020 ADRP Conference, Phoenix, Ariz.** More details 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 institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Outside Sales Representative/Event Planner (Fort Smith, AR). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational & religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: ate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range:

Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. **How to apply:** http://arkbi.org/careers/.

Blood Bank Technologist /Serologist I. Innovative Blood Resources is seeking a Blood Bank Technologist /Serologist I in St. Paul, MN! Join our team today and start making a difference in the community and saving lives! Precisely and accurately performs and interprets technical procedures to satisfy referrals and requests. Completes all ancillary duties including reporting of test results, sample processing, reagent preparation, and record keeping. Serves as consultant regarding resolution of patient testing, assists in development of new procedures, and participates in continuing education. Laboratory work includes donor testing, platelet management, proficiency surveys, reagent preparation, and serology. Requirements: Medical Technologist with ASCP certification or bachelor's degree in biological science with equivalent experience. Zero - 2 years of relevant technical and service-related experience. Blood banking experience preferred. Schedule: Three 12 hours shifts: Sun, Mon, Tues (3rd Shift -36 hours), Benefit Eligible

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POSITIONS (continued from page 8)

Position. View full job descriptions on <u>innovativeblood-resources.org/careers/</u>

East Coast Account Manager/Senior Product Specialist (Macopharma USA). Macopharma is a worldwide, leading and innovative Health Care Company specializing in the fields of Transfusion Medicine and Biotherapy. For more than 40 years, Macopharma has achieved continuous growth and success in these fields. In all our activities, we focus on the improvement of human health outcomes. This position is responsible for developing and maintaining relationships that lead to sales of blood bank filters, equipment, and related products. Travel is required three to four nights per week. Must live near a major airport in Eastern United States. Key responsibilities include: Develop and implement strategies to maintain and/or expand sales within an assigned territory; territory and account management to include forecast of product usage. Provides reports on the budget and sales activity for a given period of time. Interfaces with the customer on a regular basis to understand the customer's overall objectives and requirements. Provides post implementation support to assigned accounts / customers with the assistance of support staff. Serves as a point of escalation for issues or activities that the customer encounters during product utilization and ensures the resolution of customer problems/complaints. Prepares and conducts technical/product presentations and demonstrations. Participates in trade shows by representing the organization and sharing information on products. Required experience: Bachelor's degree from four-year college or university. Minimum five years' experience in the blood banking/medical device or related industry. Minimum three years proven sales success. Please send resumes with salary criteria to: roxane@macopharmausa.com. No phone calls.

Transfusion Lab Supervisor. Join Florida's leading blood bank, OneBlood, as a Lab Supervisor in Northwest Florida (Tallahassee, 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 five+ (5+) years 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.

Recruitment Director. Kentucky Blood Center (KBC) is seeking a dynamic professional to lead a team of Donor Recruitment Specialists who are responsible for growing

the donor base by promoting blood donation and recruiting organizations and community groups to sponsor blood drives. The individual will motivate and mentor the team, managing performance to established goals, and will provide continuing education and development opportunities. The position is responsible for the utilization of data analysis in developing and implementing effective recruitment strategies and in setting donation projections. The ideal candidate will possess exceptional interpersonal and marketing skills, and will be goal-oriented, a creative thinker and problem solver, and a team player driven by a desire to help others. They must proactively identify, build, and maintain strong strategic alliances for the advancement of KBC's mission. Some regular instate travel is required. Qualifications: Bachelor's degree in business, marketing/communications, or a related major. Minimum of 5 years of demonstrated success in sales/account management; 2 years of management experience. Excellent writing, public speaking/presentation, and interpersonal skills. MS Office proficiency; web-based applications, and internal software/systems. Valid Kentucky Driver's License. Click here to apply.

Director of Quality Assurance. Blood Assurance is seeking a Director of Quality Assurance to work in our downtown Chattanooga facility. The Director monitors the facility's compliance with all applicable standards and regulations and is responsible for the oversight of all activities relating to product quality. Determines appropriate Standard Operating Procedures (SOP's) exist for all manufacturing procedures and staff is appropriately qualified, trained, and competent. Evaluates reports of manufacturing errors and accidents, customer complaints, and variations from SOP's. Ensures records provide a complete and accurate history of all work performed. Audits all manufacturing systems to ensure compliance with applicable regulations and to identify opportunities for improvement. Determines new or revised processes are validated and equipment is appropriately qualified and validated. Qualified applicants should possess: Bachelor's degree with major in biological science or related field. Five years of experience in blood banking, biologics manufacturing or regulations and compliance. Extensive knowledge of AABB, FDA, CLIA, OSHA, and state Departments of Health requirements. Knowledge of quality control, SOP development, and auditing skills. Certification by American Society of Quality as a Certified Manager of Quality and Certified Quality Auditor desirable. Qualified candidates are encouraged to submit an online application at www.bloodassurance.org. Blood Assurance is an EOE and Tobacco Free Workplace.

Blood Collections Director of Quality/Projects. Kentucky Blood Center seeks a detail-oriented professional

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POSITIONS (continued from page 9)

to lead a team focused on Blood Collections quality initiatives, and to facilitate the management and implementation of special projects. Supervises the Donor/Patient Services Nurse and related processes, and reports to the Vice President, Donor Services. Responsibilities include department planning, budgeting, employee supervision and development, quality oversight. Provides technical assistance for automated Blood Collections procedures (apheresis platelets/plasma/red cells, double red cells), and special programs. Primary contact and lead for the Dendreon collection program. Guides interdepartmental collaboration fulfilling responsibilities, process improvement plans, and finding solutions. Oversees regulatory compliance, error management reporting, and procedural review and revision. Qualifications: BSN, and an active RN license required. Experience with good manufacturing practices, FDA, EU, and other regulated experience preferred. Experience with quality assurance, data analysis, and equipment/process validation highly desired. MSOffice proficiency; ability to effectively navigate other systems and webbased applications. Minimum two years of management experience required. Must be highly organized, reliable, and have outstanding interpersonal skills. Strong written and oral communication skills, solid work ethic, and a team player attitude are required. Qualified candidates must live in, or be willing to locate to, the Lexington, KY area. Click here to apply.

Director, Regulatory Affairs. America's Blood Centers (ABC), North America's largest network of communitybased, independent blood programs, is seeking a Director, Regulatory Affairs. The position will be actively involved and accountable for the development, implementation, execution and advancement of the ABC regulatory agenda before federal agencies and other stakeholders. In addition, the position will assist in the facilitation of member education, evaluation and coalescing of member input in the development of industry positions, data collection from internal and external sources, and primary and secondary research. The position will report directly to the Senior Director, Federal Government Affairs, providing strategic guidance on regulatory affairs and public policy issues pertaining to the nation's blood supply. A bachelor's degree is required for the position, which is based in Washington, D.C. This individual should: have a thorough understanding of the federal regulatory processes and landscape, particularly with the FDA; have knowledge of and experience in health policy; blood industry knowledge preferably (but not required); be able to collect, analyze, and synthesize information from varied sources; have strong critical thinking, analytical, and problem-solving skills; be selfmotivated and goal oriented; have the ability to multitask and determine priorities; be able to network and collaborate effectively with colleagues and volunteers; have strong communication skills - verbal, written, and presentation; and be able to travel, sometimes at short notice. ABC offers a salary commensurate with experience as well as an excellent benefit package including medical, dental, LTD, and 401k contribution. We are a hybrid virtual office that promotes a flexible work environment. This is a full-time staff position including benefits and a stipend for internet and telephone services. ABC prohibits discrimination and provides equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws. The full job description is available here. Interested applicants should send a cover letter and resume to careers@americasblood.org.

Sr. Account Manager- Donor Screening- (St. Louis, **MO).** The Opportunity: As we continue to grow, we are seeking a front-line resource responsible for providing technical and sales support to Donor Screening (DS), and Automation sales within a geographic territory or list of named accounts. Responsible for driving solution implementation, providing both proactive and reactive customer support, optimizing customer laboratory configuration, and contributing to ultimate retention and menu expansion of current customers by teaming with (DSAMs) and (DSM), as applicable. Reports to: Donor Screening, Manager. This remote position will be calling on customers in St. Louis, MO. The Responsibilities: Customer Retention and support, menu expansion, strategic planning and product implementation (Test of Record). The Individual: Clinical Background: Three to six years related experience in a clinical laboratory, Do-Screening, or equivalent experience. Industry/Domain Knowledge: Background in Donor Screening market knowledge for the purpose of understanding market forces impacting the business. Minimum Education: BS/BA Degree in Business, Life Science, or related field (or equivalent experience). Independent Worker. Strong Business Acumen. For more details, please visit here.