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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #18 **May 15, 2020**

INSIDE:

Please Note: The *ABC Newsletter* will not be published on May 22nd. We will resume regular publication on May 29th. Thank you for your continued interest.

ABC AABB, and ARC Send Joint Letters to CMS and HHS Regarding Blood Community's COVID-19 Response

CMS Letter. America's Blood Centers (ABC) joined AABB and the American Red Cross in sending a joint letter to the Centers for Medicare and Medicaid Services (CMS) regarding the reopening of facilities to provide non-emergent, non-COVID-19 healthcare. In the letter addressed to CMS Administrator Seema Verma, the organizations "commend" the agency for the development of recommendations that healthcare entities should consider as they begin providing non-emergent care to patients with non-COVID-19 needs, but urged the agency to revise the recommendations to facilitate the inclusion of blood centers as stakeholders in the non-emergent care planning processes of hospitals to ensure the availability of the country's blood needs.

"We request that CMS update these recommendations to recognize the need for hospitals to work with their blood supplier to ensure their blood inventory is sufficient to support the ever-changing requirements for blood, especially as resumption of elective surgeries and non-emergent care increase blood utilization. Maintaining a safe and adequate blood supply continues to be a critical public health objective. As a result of the COVID-19 pandemic, hospitals' blood utilization has significantly declined. Blood suppliers have altered their operations and collections have decreased due to the reduced utilization, social distancing, modified staffing structures, and cancelled blood drives. The blood supply chain remains fragile, as blood is a short-dated product collected from individual volunteer donors by community based-blood centers…Thus, while we recognize there is demand for elective and non-emergent healthcare services, it is essential that hospitals use information about the blood supply to inform their approach to resuming these activities.

Additionally, the three organizations also "encouraged" the agency support efforts to have hospitals "work with their blood suppliers, blood banks, and transfusion services to continually assess their blood inventory to ensure that it supports their changing utilization needs."

HHS Letter. ABC, AABB, and the American Red Cross also collaborated on a joint letter to the U.S. Department of Health and Human Services' (HHS) Office of Infectious Disease and HIV/AIDS Policy requesting funding reimbursement from the agency for COVID-19 convalescent plasma (CCP) collections by U.S. blood

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Blood Community Joint Letters to CMS & HHS (continued from page 1)

centers. "The Food and Drug Administration (FDA) is making CCP widely available to patients with COVID-19 through three investigational pathways:

- an expanded access protocol (EAP), which is being led by Mayo Clinic;
- a Single Patient Emergency Investigational New Drug (eIND); or
- other clinical trials.

"As explained in more detail under the executive summary, there are no current reimbursement pathways for CCP to be reimbursed outside of BARDA grants awarded to America's Blood Centers and the American Red Cross. Thus, hospitals and patients will need to absorb these costs. We respectfully submit this request for funding to establish a payment mechanism for CCP furnished to all patients, including patients who receive CCP under eIND, clinical trials, or the EAP (if not covered by BARDA) so that neither the patients, blood centers, or hospitals will be required to absorb the cost of the treatment."

FDA Updates Information for Blood Establishments Regarding COVID-19. The FDA made changes this week (May 11th) to the document entitled "Updated Information for Blood Establishments Regarding the Novel Coronavirus (COVID-19) Outbreak" (originally published on February 4th). The information was for consideration and neither prescriptive nor mandatory. The changes in the update for consideration include:

- Acknowledged that travel deferrals are not feasible.
- Changed suggested deferral period to 14 days from the original 28 for individuals…
    - who have been diagnosed or suspected of having symptomatic disease – 14 days after complete resolution of symptoms.
    - tested positive, but never developed symptoms – 14 days from positive test.
- Individuals who test positive for SARS-CoV-2 antibodies but who did not have prior diagnostic testing and never developed symptoms, can donate without waiting or performing a diagnostic test.
- Post-donation information considerations have changed from 28 days to 48 hours after donation.

The full document is available on the FDA website.

(Source: ABC, AABB, American Red Cross Joint Letter to CMS, 5/13/20, ABC, AABB, American Red Cross Joint Letter to HHS, 5/5/20; FDA Announcement, 5/11/20) ♦

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

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
Chief Executive Officer: Kate Fry
Chief Medical Officer: Rita Reik
Editor: Mack Benton
Subscriptions Manager: Leslie Maundy
Annual Subscription Rate: $390

Send subscription queries to
memberservices@americasblood.org
America's Blood Centers
1717 K St. NW, Suite 900, Washington, DC 20006
Phone: (202) 393-5725
Send news tips to newsletter@americasblood.org.

RESEARCH IN BRIEF

The Role of Antibody Testing for SARS-CoV-2. "While molecular testing of respiratory tract sample(s) to detect SARS-CoV-2 RNA remains the preferred diagnostic test for assessment of symptomatic patients [with] COVID-19," a recent manuscript published in the *Journal of Clinical Microbiology* noted that there is "increasing interest for use of serologic assays to detect [IgG] antibodies against SARS-CoV-2." The authors note "[IgG] is associated with viral neutralizing activity, which is likely essential for recovery from COVID-19" while adding that "[p]reliminary data suggest that IgG developed against different SARS-CoV-2 antigens becomes detectable…after at least 8 days post-symptom onset (PSO), with over 90 percent …seropositive after day 14 of illness." The paper recognizes that"[i]nitial studies suggest fairly high specificity (>95 percent) for IgG-based SARS-CoV-2 serologic assays against commonly circulating coronaviruses and other infectious pathogens" though "[c]urrently, all available IgG serologic assays for SARS-CoV-2 are either qualitative or semi-quantitative in design." The authors address concerns regarding antibody tests available at the time of publication: "a negative result may indicate either no prior exposure or, for samples collected too soon after illness onset or from immunosuppressed patients, the absence of an as of yet detectable immune response. In contrast, a positive SARS-CoV-2 IgG result implies infection with the virus at some point in the recent or remote past." It should be noted that "the presence of SARS-CoV-2 IgG does not equate to protective immunity against re-infection nor does it indicate whether a patient has stopped shedding virus." The paper identifies scenarios in which "SARS-CoV-2 serologic testing, specifically IgG based assays, may be useful" such as:

- "[to screen] recovered COVID-19 patients for convalescent plasma therapy;" and
- "[for] SARS-CoV-2 seroprevalence studies."

It also states that [s]erologic testing to detect IgG-class antibodies against SARS-CoV-2 will play an essential role in determining the true prevalence of this virus." The authors also note that "monitoring immune responses to ...[s]erologic testing for SARS-CoV-2 will play an important role for pre-screening individuals prior to admission into vaccine clinical trials, and to monitor the temporal immune responses in vaccine recipients and ultimately help to define vaccine efficacy." They continue by stating that the "use of anti-SARS-CoV-2 antibody tests performed at a population-level to guide return-to-work decisions or to 're-start the economy' is a topic of widespread discussion at the local, state and national levels" and acknowledge that while it "is an intriguing concept, with mass serologic screening potentially achievable at a national scale," the authors caution that "we must remain cognizant of the current challenges and limitations of such an approach."

Citation: Theel, E.S., Slev, P., Wheeler, S., *et al.* The Role of Antibody Testing for SARS-CoV-2: Is There One? *J. Clin. Microbiol*. 2020. Doi:10.1128/JCM.00797-20.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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.

PEOPLE

Jodi Minneman is retiring effective May 16th culminating her 37-year career of exemplary service to local, regional, and national blood banking organizations. She has served as the Chief Operating Officer of Blood Services for Community Blood Center (Dayton, Ohio), where she oversaw donor relations, collection services, and all laboratories including HLA, reference, molecular, stem cell, and donor testing. Ms. Minneman also held the positions of director of Quality Assurance, HLA technologist, assistant technical director, and processing laboratory supervisor during her tenure. Prior to joining Community Blood Center, she worked as a bench technologist at Stouder Memorial Hospital. Ms. Minneman is past president of the Ohio Association of Blood Banks and served on the boards of directors for America's Blood Centers, Group Services of America's Blood Centers (GSABC), and the Blood Group Alliance. She earned her B.S. in Medical Technology from Wright State University and was certified as a Medical Technologist with the American Society of Clinical Pathologists.

Susan Rossmann, MD, PhD has been selected as the Primary Non-Voting Industry Representative for the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research Blood Products Advisory Committee (BPAC). Dr. Rossmann is Gulf Coast Regional Blood Center's (Houston, Texas) Chief Medical Officer a past president of America's Blood Centers (ABC), and former chair of ABC's Scientific, Medical, and Technical Committee. Dr. Rossmann has also served as a faculty member at Baylor College and medical director of the Blood Bank and Microbiology Laboratory at Texas Children's Hospital

(Source: BPAC Announcement, 5/15/20)

WORD IN WASHINGTON

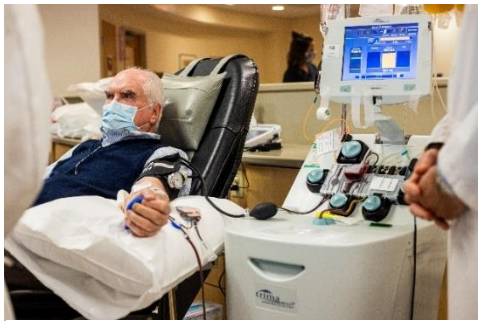

Photo courtesy of the University of Pittsburgh Medical Center

Rep. Mike Kelly (R-Penn.) who tested positive for COVID-19 in March and has since completely recovered donated COVID-19 convalescent plasma (CCP) at Vitalant on May 11th. "The coronavirus is a tough opponent for many who contract it," said Rep. Kelly in a news release. "At age 72 and a type two diabetic, I am in the category of people most vulnerable to COVID-19, so I am grateful to have defeated it. Thank you to my wife Victoria and the doctors at Butler Memorial Hospital for caring for me during my recovery. Thank you also to the great team at [the University of Pittsburgh Medical Center] for the work they are doing with convalescent plasma, which could save countless lives that would otherwise be lost to this disease." Additional photos and video of the donation are available here.

(Source: Rep. Mike Kelly News Release, 5/12/20)

ABC Calendar of Events

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

IN MEMORIAM

Ronald O. Gilcher, MD, FACP, former Oklahoma Blood Institute Chief Executive Officer, President, and Medical Director, has passed away. Dr. Gilcher's leadership at OBI spanned from 1979 to 2006. He will be remembered as "an undisputed international leader in blood transfusion, helped grow OBI into to a self- sufficient blood center and a national leader in blood safety testing and donor recruitment." Following the HIV epidemic, he instituted "key HIV testing" helping to "establish the standard" for blood centers across the country. Dr. Gilcher was instrumental in OBI becoming "the first blood center in the nation to offer cholesterol screening to all donors free of charge." Also, he played a pivotal role in the OBI's response to the Oklahoma City bombing in 1995. OBI named its North Lincoln donor center in honor of Dr. Gilcher in 2015. He is also the namesake of an annual ADRP, an international division of America's Blood Centers, award that recognizes a senior executive leader within a blood center who has made significant contributions to their own organization and the blood community.

(OBI Announcement, 5/14/20)

MEMBER NEWS

San Diego Blood Bank (SDBB) has partnered with Genalyte to offer antibody testing on Genalyte's SARS-CoV-2 Multi-Antigen Serology Panel to the public. According to a news release, all testing will take place by appointment-only at SDBB locations and a temporary drive-thru testing site. "San Diego Blood Bank exists to save lives and support community health. Working with a trusted partner like Genalyte is an extension of our mission, and we are proud to provide greater access to COVID-19 antibody testing for our community," said SDBB Chief Medical Officer Mark Edmunds, MD in the news release. "The importance of aligning with a proven partner, able to deliver high-quality test results is essential in our efforts to place SDBB at the leading edge of transfusion medicine in the face of this pandemic." Genalyte Chief Executive Officer Cary Gunn added, "high-quality, extensive antibody testing is needed to provide essential feedback to physicians, health care providers, and to our community. "[The Genalyte] antibody panel allows us to test for IgM and IgG antibodies with overnight test results from our San Diego lab. This is important because IgG antibodies in particular typically remain long after a person has recovered and are believed to be a marker of sustained immunity, although the duration of immunity to SARS-CoV-2 needs further study. Determining a person or a population's level of exposure and potential immunity is not only essential to facilitate research to develop an understanding of the virus, but also to enable our city with the knowledge we need to safely return to daily activities."

(Source: Genalyte News Release, 5/7/20)

The Vitalant Research Institute (VRI), a division of **Vitalant**, is partnering with Takeda of the COVIg-19 Plasma Alliance, an international coalition of plasma organizations that are working to develop hyperimmune globulin (HIg) as a potential therapy for COVID-19 patients. According to a recent news release, Vitalant will use its San Francisco site to collect HIg. "Recovered COVID-19 patients who donate plasma create the momentum for finding a treatment," said VRI Director of Cell Sourcing and Specialized Collection Kadi Schroeder in a news release. "We encourage everyone eligible to join us in this journey. Their

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MEMBER NEWS (continued from page 5)

antibodies offer researchers the ability to study and create potential new medications that will have both short-term and long-term impact – which is critical when battling new infectious diseases."

(Source: VRI News Release, 5/7/20)

GLOBAL NEWS

The Brazilian Supreme Court has overturned the country's restrictions that prevented men who have sex with other men (MSM) from donating blood according to a report in *Reuters*. "Instead of the state enabling these people to promote good by donating blood, it unduly restricts solidarity based on prejudice and discrimination," wrote Supreme Court Minister Edson Fachin, one of seven Supreme Court justices that voted in favor of removing the MSM restriction. The court has been weighing the merits of the MSM policy since 2016 and finally reached a majority consensus among the court's 11 justices. A dissenting view from Minister Alexandre de Moraes, stated that "the waiting period was not discriminatory, but based on technical studies." Brazil becomes the latest country in growing list that has relaxed MSM regulations.

(Source: *Reuters*, Brazil's Supreme Court throws out rules that limit gay men donating blood, 5/10/20)

The World Health Organization's (WHO) International Health Regulations Emergency Committee regarding COVID-19 met for the third time to discuss and assess international safety measures and response efforts to the COVID-19 pandemic. Following the meeting, the WHO Director-General announced on May 1st that the COVID-19 pandemic "continues to constitute" a public health emergency of international concern (PHEIC). The recommendations of the committee are available on the WHO website and include strategies regarding:

- coordination, and collaboration;
- preparedness;
- surveillance;
- research and development; and
- risk communications and community engagement.

The committee will "reconvene" within three months at the latest to assess both the status and global response to the pandemic.

(Source: WHO Announcement, 5/1/20)

We Welcome Your Letters

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

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INSIDE ABC

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

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)

May 2020 Convalescent Plasma *Blood Bulletin* Updated

ABC's Scientific, Medical, and Technical (SMT) Publications Committee has revised the latest edition of *Blood Bulletin*, "COVID-19 Convalescent Plasma - a Potentially Effective Therapeutic Modality," to reflect an update to the U.S. Food and Drug Administration (FDA) "Investigational COVID-19 Convalescent Plasma" guidance on May 1st. The FDA now recommends complete resolution of symptoms at least 14 days before the donation, eliminating the need for a negative COVID-19 diagnostic test to donate between 14 and 28 days after symptom resolution.

ABC members can find PDF and MS Word versions of the revised *Blood Bulletin* and prior issues of the publication on the ABC member website.

(Source: MCN 20-050, 5/1/20)

COMPANY NEWS

Ortho Clinical Diagnostics has received the CE mark for its COVID-19 total antibody test. This clearance allows the test to be used in European countries. "Clinicians will now have invaluable information that may assist them to make decisions about the propriety of a patient returning to work," said Chockalingam Palaniappan, PhD., chief innovation officer at Ortho Clinical Diagnostics, in a company news release. "This is critical information for first responders, health care professionals and other essential personnel working with affected populations." The company reports 100 percent specificity and sensitivity with the test. Ortho received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the COVID-19 total antibody test in April.

(Source: Ortho Clinical Diagnostics News Release, 5/12/20)

Abbott announced that the FDA has issued EUA for its SARS-CoV-2 IgG lab-based serology blood test on the Alinity™ i system. "Having more options of highly reliable tests across our platforms will help healthcare workers and health officials as they conduct broad scale testing for COVID-19," said Abbott

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COMPANY NEWS (continued from page 7)

President and Chief Executive Officer Robert B. Ford in a news release. "Abbott is a leader in providing antibody testing at large scale on multiple systems, which is helping meet the needs of laboratories as they look to build testing capacity." The company previously received an EUA from the FDA and a CE Mark for use in European countries for its antibody test on the ARCHITECT system.

Abbott also responded to an FDA issued alert to the general public regarding potential inaccurate "false negative results" from the Abbott ID NOW point-of-care (POC) test for COVID-19 diagnosis. The FDA stated that the agency is, "still evaluating the information about inaccurate results and are in direct communications with Abbott about this important issue. We will continue to study the data available and are working with the company to create additional mechanisms for studying the test. This test can still be used and can correctly identify many positive cases in minutes. Negative results may need to be confirmed with a high-sensitivity authorized molecular test." In the company's response issued May 14th, Abbott stated, "[w]e're seeing studies being conducted to understand the role of ID NOW in ways that it was not designed to be used…It is our responsibility to provide healthcare professionals and the public with accurate information, and that's why we're doing the following:

- [f]urther clarifying our product information to provide better guidance to healthcare providers that negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Negative results should be presumed negative, but if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. We are also reinforcing proper sample collection and handling instructions. We are communicating this to our customers.
- Continuing to optimize this test as the world learns more about this virus. We're working to incorporate those learnings into the test as we do with all of our diagnostics tests."

(Abbott News Release, 5/11/20; FDA Alert, 5/14/20, Abbott Statement, 5/14/20)

The Advanced Medical Technology Association (AdvaMed) has published a medical technology compliance guidance for COVID-19 response. According to the May 8th announcement, the guidance entitled "Code of Ethics Compliance Guidance Related to the COVID-19 Response" aims to assist AdvaMed members and other medical technology organizations with the development and implementation of processes that foster timely decision-making, while "mitigat[ing] any related compliance risks." AdvaMed's Chief Operating Officer and General Counsel Christopher L. White, JD added in the announcement, [a]s MedTech companies supporting the public health response to COVID-19 work around the clock to produce essential medical products to help prevent, detect, and treat this disease, we must continue to do all we can to help ensure patients are provided both timely and ethical access to our equipment, knowledge, and trained personnel. The guidance complements AdvaMed's existing Code of Ethics, and addresses shared compliance concerns, experiences, and best practices developed by our member companies as they respond to the COVID 19 pandemic." The guidance addresses topics such as:

- contractual/legal obligations during a declared state of emergency;
- charitable donations including products, equipment, services, and/or financial support;
- volunteer activity by company personnel;
- virtual educational events; and
- other company processes.

(Source: AdvaMed Announcement, 5/8/20)

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 here.

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 here.

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

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

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POSITIONS (continued from page 9)

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 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 web-based 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 community-based, 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 self-motivated 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 excel-lent 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