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

ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2020 #41 **November 20, 2020**

INSIDE:

Please Note: The *ABC Newsletter* will not be published on November 27th. We will resume regular publication on December 4th. Thank you for your continued interest.

FDA Extends CCP EUA Implementation Period

The U.S. Food and Drug Administration (FDA) updated the guidance titled "Guidance for Industry: Investigational COVID-19 Convalescent Plasma (CCP)." It now reflects a 90-day extension being granted by the agency extending the administration of investigational convalescent plasma through February 28, 2021. It states, "FDA intends to exercise this discretion with respect to the investigational new drug (IND) application requirements for the collection, shipment, and administration of investigational convalescent plasma through February 28, 2021. This should provide blood establishments adequate time to develop the necessary procedures to manufacture COVID-19 convalescent plasma under the conditions of the [emergency use authorization], and if unable to develop such procedures, only administer investigational convalescent plasma under an IND."

As of March 1st, CCP units must be labeled as high or low titer as determined by the Ortho Vitros IgG test. America's Blood Centers (ABC), AABB, and the American Red Cross (ARC) previously requested an extension of enforcement discretion for CCP. In the joint letter, the organization's noted that the blood community has supported the national effort to collect and distribute CCP with federal partners and "to ensure continued patient access to treatment with CCP, we are requesting additional time for effective transition to the new EUA requirements. Specifically, additional time is required to meet the new labeling requirements for EUA CCP units as either high- or low-titer, as well as to distribute current stockpile units of investigational CCP. AABB, ABC and ARC, which collectively represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals, wish to ensure that CCP remains readily available to patients in need."

The full letter is available on the ABC public website.

(Sources: FDA Guidance, 11/16/20; ABC, AABB, ARC, Joint Letter, 11/2/20)

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!

ABC Submits Letter to CBER Regarding Bacterial Risk Control Strategies Final Guidance

America's Blood Centers (ABC) recently submitted a letter to U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) outlining concerns of ABC member blood centers regarding the March 31st implementation deadline for the "Bacterial Risk Control Strategies for Blood Collection Establishment and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion" final guidance. As a part of the association's ongoing advocacy efforts on behalf of its members, the letter requests that the agency:

- approve individual center variance requests to extend the timeline for guidance implementation for blood centers unable to meet the current deadline due to significant operational barriers;
- create an expedited process for approval of seven-day expiration and pathogen reduction technology licensure packages, including an initial timely review of less than one month leading to a variance or an interim licensure to allow blood centers to ship products in interstate commerce, thereby enabling them to continue to supply and resource share in interstate commerce and reduce the impact on platelet availability;
- since seven-day expiration licensure packages are for process revalidation, allow for a reduced burden of quality control (QC) data submission in association with licensure submissions (e.g. product data for two single, two double, and two triple (if applicable) products in lieu of the guidance's requirement for 2 months of consecutive QC data). This will save both time and financial resources for both the centers and the FDA;
- reduce the minimum platelet content requirement to 2.5×10^{11} to remove some barriers to the adoption of pathogen reduction and increase platelet availability;
- expedite the review of variance requests to supply and resource share low-yield platelets in interstate commerce, reducing the impact on platelet availability; and
- expedite the review of any applications for 14-day cold stored platelet products and other variances requests related to ensuring a sufficient platelet supply to meet hospital transfusion needs.

The full letter is available here.

Members are encouraged to contact Jill Evans, director of Regulatory Affairs, or Toni Mattoch, director of Quality Services, with any questions or concerns.

(Source: ABC Letter, 11/11/20)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors.

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

Evaluation of Donor Selection Criteria with Limited Scientific Evidence: TRANSPOSE. Findings of "TRANSPOSE (TRANSfusion and transplantation PrOtection and SElection of donors) were recently published in *Vox Sanguinis*. The authors note "[t]here is a significant reluctance of revising donor selection criteria (DSC)…currently no international agreement on carrying out such risk assessment." Their study "aimed to identify discrepancies between available scientific evidence and the current DSC across Europe and to propose new DSC that balances recipient and donor protection." From 2017-20, [38] stakeholders assessed "risks for whole blood donors and recipients of blood components…In total, 54 general DSC were proposed…Of these, three were considered to be general DSC and included pre-donation assessment, disability and autoimmune disease." The researchers state that "[f]our potential DSC (7.4 percent) were discussed but not included in the final DSC" The researchers state that "[t]hese included:

- "assessment of mental health;
- assessment of donor's fear of donation;
- history of anemia and symptoms of current anemia (blood donors); and
- previous vasovagal reactions or fainting."

They note that "no initial consensus could be reached for deferral periods for 28 (51.9 percent). These included after travel to West Nile virus and dengue virus endemic areas…Three areas (5.6 percent) with limited scientific evidence were identified:

- high-risk sexual behavior;
- allergy (blood products); and
- donation frequency (plasmapheresis)."

The authors explained that "there was also no consensus reached [regarding] iron supplementation in blood donors, despite strong scientific evidence…It was decided not to include local guidelines or legislation in the assessment of the DSC to allow for the proposed DSC to be based only on scientific evidence as much as possible…However, many participants had difficulty with this and directly opposed some of the proposed DSC as these would violate local legislation." The researchers state that changes "must be mandated by policymakers and competent authorities in the different countries as they are responsible for the legal framework in the respective member states…It was felt that [a] clearly defined international standardized risk assessment tool and DSC would provide a systematic approach to risk assessments, ensuring consistency." They also note that "where lack of strong scientific evidence hinders a standardized risk assessment, [the authors feel there is a] need to ensure that the precautionary principle is not excessively applied as a default solution to the detriment of the supply of safe Substances of Human Origin (SoHO)."

Citation: Mikkelsen, C., Mori, G., van Walraven, S. *et al*. How donor selection criteria can be evaluated with limited scientific evidence: lessons learned from the TRANSPOSE project. *Vox Sanguinis*. 2020. Doi: 10.1111/vox.13028.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

BRIEFLY NOTED

The Centers for Disease Control and Prevention (CDC) announced the next public health webinar in the blood disorder series titled "Overview of World Federation of Hemophilia (WFH) Treatment Guidelines, 3rd Edition." The webinar aims to:

- "[d]escribe the updated WFH Treatment Guidelines for three areas of hemophilia clinical practice: hemostatic agents, inhibitors, and prophylaxis;
- [d]iscuss the chronic care model and the evolution from acute, episodic, and reactive care towards longitudinal, preventive, and community-based integrative care; and

(continued on page 4)

BRIEFLY NOTED (continued from page 3)

- [l]ist examples of opportunities highlighted in the updated guidelines to improve the standard of diagnosis and care for people with hemophilia."

Registration is free and currently open as the webinar will take place on December 10th at 2 p.m. eastern. Speakers include:

- Steven Pipe, MD, chair of the Medical and Scientific Advisory Council, National Hemophilia Foundation;
- Margaret Ragni, MD, MPH, professor of Medicine at the University of Pittsburgh Department of Medicine, Division of Hematology/Oncology; and
- Manuel Carcao, MD, professor of Pediatrics at The Hospital for Sick Children Toronto, Canada.

(Source: CDC Announcement, 11/19/20)

Intellia Therapeutics, Inc. has received a grant from the Bill & Melinda Gates Foundation to develop "*in vivo* sickle cell disease (SCD) treatments using its CRISPR/Cas9 genome editing technology." Laura Sepp-Lorenzino, PhD, chief scientific officer, at Intellia stated in a news release, "[w]e are excited to receive funding from the Gates Foundation to take the first steps toward development of a potential in vivo non-viral CRISPR/Cas9-based cure for SCD. Genome editing offers multiple opportunities to treat SCD as shown by encouraging emerging clinical data. Our goal is to deliver on the already demonstrated promise of CRISPR/Cas9, but avoid the severe complications of bone marrow transplantation that may limit the usefulness of current approaches. Intellia's ambition is to use our non-viral in vivo platform to create an innovative treatment for blood disorders, that is scalable and can overcome the challenges inherent to ex vivo cell-based therapies for global diseases."

(Source: Intellia Therapeutics, Inc. News Release, 11/11/20)

COMMONWEALTH TRANSFUSION FOUNDATION

CALL FOR GRANT PROPOSALS

Commonwealth Transfusion Foundation (CTF) is a non-profit, private foundation whose mission is to inspire and champion research and education that optimizes clinical outcomes in transfusion medicine and assures a safe and sustainable blood supply for the U.S. Our current funding priorities include: Ensuring an adequate, post-pandemic blood supply; research on novel blood donor recruitment strategies; the role of blood centers in the battle against COVID-19; insight into the changing blood banking landscape; innovations in transfusion safety and patient blood management; better understanding of the supply chain and economics underpinning the blood industry; and promoting understanding and inclusion of cellular therapies in blood banking.

Interested parties should visit CTF's website (www.CTF.life) to learn more about our grants process and/or to begin the application process. Please pay special attention to what CTF does not fund. Applicants must apply through CTF's online portal beginning with a Letter of Inquiry (LOI) that briefly describes the proposal. If the LOI is approved, applicants may proceed to the full on-line application form. CTF has two grant cycles each year and the deadlines are December 20th and June 20th. For more information, feel free to contact us at info@CTF.life.

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

INSIDE ABC

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

Deadline Extended until December 2nd for 24th Annual *Awards of Excellence* Call for Nominations

ABC members are encouraged to nominate blood donation sponsors, corporations, and advocates for the 24th Annual *Awards of Excellence*. This program provides members with the opportunity to offer national recognition and showcase the best and brightest in the blood donation community. Additional details are available in MCN 20-093 for ABC member blood centers. The online submission form for each award is hyperlinked below. If your nomination is selected, you will be asked to upload a video of your award recipient being presented with the award (ABC will mail the award to the blood center). We will upload videos of all award winners to our website as part of national recognition of these individuals/organizations.

ABC members are permitted to submit up to three nominations per category. A full description of the awards is available.

We encourage member blood centers to take advantage of this opportunity to recognize your supporters by submitting your nominations before Wednesday, December 2nd, 2020. Nominations are currently being accepted for the following awards:

- ABC Outstanding Blood Drive of the Year
- Outstanding Public Relations Campaign
- Corporation of the Year Award
- Larry Frederick Award (jointly presented by ABC and ADRP)
- Thomas F. Zuck Lifetime Achievement Award (view a listing of past winners here).

Please contact Leslie Maundy with any questions about the *Awards of Excellence* or to receive a copy of the MCN.

(Source: MCN 20-093, 10/22/20)

ABC Develops New Membership Database and Resource Center

In a continued effort to provide value and services to ABC member blood centers, the association has launched a new membership platform that we encourage you to explore and use. This platform replaced the former Member website (please remove https://members.americasblood.org from your browser bookmarks) where members had grown accustomed to finding various member-only resources over the years.

Member blood centers can find the new system at https://login.americasblood.org which features a user-friendly interface and dashboard to help you quickly and efficiently navigate to relevant member resources and benefits. Start your visit on the Member Resources page and choose the area you would like to access. Additionally, to learn how to setup your profile, view this short how-to video. We encourage member feedback. If you are unable to access the platform with your current email address, please contact Member Services for assistance.

(continued on page 6)

INSIDE ABC (continued from page 5)

ABC Annual Meeting is Moving Virtual

The 59th ABC Annual Meeting, scheduled for March 8th—10th, 2021, will be held virtually. Although we will not be in-person, this meeting will provide plenty of opportunities to connect and explore industry trends through educational sessions and our annual Advocacy Day. This year challenged our industry in many ways, highlighting the need for community blood centers to come together to reflect on lessons learned and strategize ways to prioritize the important role of community blood centers within healthcare as we continue to discover ways to thrive moving forward.

The Preliminary Program will be released in the coming weeks.

INFECTIOUS DISEASE UPDATES

EBOLA

The World Health Organization (WHO) has declared the 11th outbreak of Ebola in the Democratic Republic of the Congo (DRC) officially over. The latest outbreak began this summer and lasted 42 days resulting in 119 confirmed cases with 55 deaths. "Overcoming one of the world's most dangerous pathogens in remote and hard to access communities demonstrates what is possible when science and solidarity come together," said Matshidiso Moeti, MD, regional director for WHO in Africa in an agency news release. "The technology used to keep the Ebola vaccine at super-cold temperatures will be helpful when bringing a COVID-19 vaccine to Africa. Tackling Ebola in parallel with COVID-19 hasn't been easy, but much of the expertise we've built in one disease is transferrable to another and underlines the importance of investing in emergency preparedness and building local capacity." U.S. Centers for Disease Control and Prevention (CDC) Director Robert Redfield, MD, added in an agency news release, "[t]his is a tremendous accomplishment, particularly in the midst of the COVID-19 pandemic. CDC congratulates the DRC Ministry of Health and partners who have worked tirelessly to overcome challenges and bring this Ebola outbreak to an end." In June, the 10th outbreak of Ebola, that lasted close to two years, was declared over with 3,470 confirmed cases and 2,287 confirmed deaths.

(Sources: WHO News Release, 11/18/20, CDC News Release, 11/18/20)

WORD IN WASHINGTON

The National Institutes of Health (NIH) announced this week that an independent data and safety monitoring board (DSMB) "overseeing" the phase III trial of Moderna's investigational COVID-19 candidate has shared "promising interim results." The agency news release reveals that an interim analysis "of the data suggests that the vaccine is safe and effective at preventing symptomatic COVID-19 in adults. The interim analysis comprised 95 cases of symptomatic COVID-19 among volunteers. The DSMB reported that the candidate was safe and well-tolerated and noted a vaccine efficacy rate of 94.5 percent. The findings are statistically significant, meaning they are likely not due to chance. Ninety of the cases occurred in the placebo group and five occurred in the vaccinated group. There were 11 cases of severe COVID-19 out of the 95 total, all of which occurred in the placebo group." Moderna Chief Executive Officer Stéphane Bancel added in a company news release, "[t]his is a pivotal moment in the development of our COVID-19 vaccine candidate. Since early January, we have chased this virus with the intent to protect as many people around the world as possible. All along, we have known that each day matters. This

(continued on page 7)

WORD IN WASHINGTON (continued from page 6)

positive interim analysis from our Phase 3 study has given us the first clinical validation that our vaccine can prevent COVID-19 disease, including severe disease. This milestone is only possible because of the hard work and sacrifices of so many. I want to thank the thousands of participants in our Phase 1, Phase 2 and Phase 3 studies, and the staff at our clinical trial sites who have been on the front lines of the fight against the virus...We look forward to the next milestones of submitting for an emergency use authorization in the U.S., and regulatory filings in countries around the world, while we continue to collect data on the safety and efficacy of the vaccine in the COVE study. We remain committed to and focused on doing our part to help end the COVID-19 pandemic." U.S. Department of Health and Human Services (HHS) Secretary Alex Azar stated in an agency news release, "[t]he Moderna/NIH vaccine candidate is now the second vaccine to show the potential for very high efficacy in Phase 3 trials. Operation Warp Speed has provided about $2 billion in funding and operational support for development, manufacturing, and eventual potential delivery of the Moderna/NIH vaccine. This news is another stunning result of President Trump's leadership and his unwavering support for Operation Warp Speed, an incredible tribute to American scientists and innovators, and one more reminder that there is light at the end of the tunnel."

(Sources: NIH News Release, 11/16/20, Moderna News Release, 11/16/20, HHS News Release, 11/16/20)

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in HHS, has awarded DiaSorin $820,000 to develop a semiquantitative SARS-CoV-2 IgG assay. The test will "detect the presence" of SARS-CoV-2 antibodies individuals that have been "recently infected."

(Source: BARDA Announcement, 11/16/20) ♦

GLOBAL NEWS

Canadian lawmakers in the province of Alberta have passed three readings of the Voluntary Blood Donations Repeal Act, which would allow individuals in the province to receive payment for plasma donation, according to a report from *Global News*. "We want to allow the biopharmaceutical companies to access the product, which is plasma and they can then turn that into medications, which we, in turn, buyback," said Tany Yao, a member legislative assembly who also says he donates at Canadian Blood Services according to *Global News*. "I have faith in our society and in Canadians that Canadians will continue to donate their blood for the purposes of our public healthcare system." In 2018, Health Canada, the nation's regulatory authority, announced the publication of a report examining the country's self-sustainability of the immune globulin (Ig) supply in which an expert panel commissioned by the agency applied an "evidence-based assessment" exploring the impact of commercial expansion of the plasma industry on the Canadian blood supply...The findings of that report determined that a crisis did not exist in the "medium term" as supply can meet demand though efficiencies could be improved to collect more plasma and increase utilization. Currently, commercial plasma collection does not adversely impact Canada's whole blood supply (though continued monitoring was recommended), and Ig and other plasma products remain "very safe" demonstrating "effective regulation and oversight." Canadian Blood Services has plans to open three voluntary plasma donation sites as part of a pilot to help mitigate any shortages. Opponents of the Voluntary Blood Donations Repeal Act, such as the United Nurses of Alberta (UNA), feel that "[t]he pay for plasma collectors have a global market and the products will go to the highest bidder," according to UNA President Heather Smith reported *Global News*. "The government is putting its ideology and desire to support profiteers above what is actually safe for Albertans and Canadians." Paid plasma is currently permitted in Saskatoon and Moncton according to the *Global News*.

(Source: *Global News*, Paying for blood and plasma in Alberta? Bill allowing it passes in the legislature, 11/17/20) ♦

COMPANY NEWS

Pfizer and **BioNTech SE** announced this week that their final efficacy analysis from the phase III clinical trial of a COVID-19 vaccine candidate revealed that "all of the study's primary efficacy endpoints" were met. A 95 percent efficacy rate is being reported by the companies according to the news release, "in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose." Pfizer Chairman and Chief Executive Officer (CEO) Albert Bourla, PhD added in the news release, "[t]he study results mark an important step in this historic eight-month journey to bring forward a vaccine capable of helping to end this devastating pandemic. We continue to move at the speed of science to compile all the data collected thus far and share with regulators around the world. With hundreds of thousands of people around the globe infected every day, we urgently need to get a safe and effective vaccine to the world." The companies note that the Independent Data Monitoring Committee has not identified any "serious safety concerns" for the vaccine candidate to date. "We are grateful that the first global trial to reach the final efficacy analysis mark indicates that a high rate of protection against COVID-19 can be achieved very fast after the first 30 µg dose," said Ugur Sahin, MD, CEO and co-founder of BioNTech in the news release. "Our objective from the very beginning was to design and develop a vaccine that would generate rapid and potent protection against COVID-19 with a benign tolerability profile across all ages. We believe we have achieved this with our vaccine candidate BNT162b2 in all age groups studied so far and look forward to sharing further details with the regulatory authorities." Pfizer and BioNTech SE shared that, "[t]he first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol, of which 162 cases of COVID-19 were observed in the placebo group versus 8 cases in the BNT162b2 group. Efficacy was consistent across age, gender, race and ethnicity demographics. The observed efficacy in adults over 65 years of age was over 94 percent." Additionally, the news release states that 10 severe cases of COVID-19 "were observed" in the trial with nine "occurring in the placebo group and one in the vaccinated group."

(Source: Pfizer & BioNTech SE Joint News Release, 11/18/20)

Siemens Healthineers received a CE mark for its SARS CoV-2 IgG quantitative test, a designation that allows it to be sold in the European Economic Area (EEA). "At the onset of the pandemic, the scientific community had to learn about COVID-19 and how our immune systems would respond. We targeted the spike protein for our antibody tests, anticipating antibodies to this protein would eventually prove to be neutralizing," said Deepak Nath, PhD, president of Laboratory Diagnostics at Siemens Healthineers in a company new release. "Adequate data is available now to confirm the spike protein antibodies are indeed neutralizing, especially those against the spike receptor binding domain. Healthcare providers can feel confident that our test will help them determine whether a patient's immune system is producing the right antibodies to stop or prevent COVID-19 infection." The test "demonstrates the ability to detect neutralizing antibodies and reports quantitative results measuring the amount of neutralizing antibodies present in an individual's blood sample." The CE mark specifies that the qualitative test has been "assessed to meet high safety, health, and environmental protection requirements," according to the European Commission. Siemens Healthineers has applied for emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA).

(Source: Siemens Healthineers News Release, 11/18/20)

Upcoming ABC Webinars – Don't Miss Out!

- **ABC SMT Journal Club Webinar** – December 3rd from 12 – 1 p.m. (ET). More details available in MCN 20-102. Contact Toni Mattoch for questions.

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) 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.)*

2021

Mar 8-10. **ABC Annual Meeting (Virtual).** More details coming soon.

June 25-26. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details available here.

May 11-13. **2021 ADRP Conference, Kansas City, Mo.** More details coming soon.

Aug. 4. **ABC Medical Directors Workshop, Cleveland, Ohio.** More details coming soon.

Aug. 5-6. **ABC Summer Summit, Cleveland, Ohio.** More details coming soon.

Sept. 15-17. **4th European Conference on Donor Health and Management, Hamburg, Germany.** More details available here.

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.

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

Director of Technical Services (N. Charleston, SC). At The Blood Connection, our mission is to support our healthcare partners with adequate, safe, cost-effective blood supplies and services. We desire to be the community blood provider of choice. Position Overview: The Director of Technical Services (CSC) is responsible for supervising and directing the daily operations of the Technical departments in the CSC division: Hospital Services, Component Manufacturing (Biologics Processing), if applicable, Immunohematology Reference Laboratory, as well as the HS couriers. Duties include: Developing and maintaining procedures; Supervising Reference Laboratory staff; Supervising Hospital Services staff; Supervising Component Manufacturing/Biologics Processing staff (if applicable); Performing bench work as needed; and Interfacing with hospital customers. This position requires general laboratory knowledge and skills as well as specialty (SBB) skills and is expected to perform tasks and well as supervise the performance of laboratory and other staff. Education Requirements: MT (ASCP) or equivalent. SBB strongly preferred. Licensure/Certification Requirements: Valid Driver's License. Experience Requirements: Previous supervisory experience required. Complete applications on https://thebloodconnection.org/about-us/careers/ for consideration.

QA Specialist. Stanford Blood Center is seeking a QA Specialist to work in the Technical Services Laboratory. Under the general supervision of the Operations Support Supervisor, the QA Specialist will perform the quality assurance duties of the Technical Services department by writing/revising department equipment and process validation plans, managing equipment preventative

(continued on page 10)

POSITIONS (continued from page 9)

maintenance program, manage training records, perform process and computer audits, write/revise procedures for regulatory compliance as necessary. Prepare training binders for new staff and monitor new and incumbent staff training is up to date. Ensure annual SOP and label review performed, review departmental records, help determine corrective actions for events by performing root cause analysis, and is involved in process improvement. Perform post-donation information follow-up that affects safety, purity, and quality of the product by quarantine/discard of units, notification of customers and tracking of recalls. Provide notification to hospitals, regulatory agencies and other customers of test results that affect patients/general population safety. For complete job description and to apply, please visit www.stanfordhealthcarecareers.com and reference req# 58277.

Laboratory Technician - Stanford Blood Center (Req# 57715). Stanford Blood Center is seeking a Laboratory Technician. Under the direction of the Laboratory Supervisor, prepares and labels blood components; monitors component inventory to assure proper levels are maintained; receives orders for blood products and issues, packs and ships blood components; processes deliveries of blood products into inventory and maintains accurate and detailed records of all work performed. Performs quality control on equipment and blood components, reviews quality control and maintains equipment as required. May be required to operate delivery vehicle for transport of blood products when necessary. Responds to blood storage alarms; cleans and disinfects areas and equipment according to laboratory policy and maintains a clean and organized work area. Answers telephones promptly; route calls or take messages as appropriate. Rotates beeper on-call for off hours emergency blood needs or equipment failure. This is not a research position. For complete job description and to apply, please visit www.stanfordhealthcarecareers.com and reference req# 57715.

Chief Clinical Officer (Central California Blood Center; Fresno, CA). The successful candidate will successfully navigate the ever-changing health care provider and blood industry landscapes to provide ever-increasing value to our clients. The Chief Clinical Officer (CCO) will provide clinical, scientific and leadership development for an independent community blood center to assure our expanding position as a national industry leader. The CCO will oversee blood component manufacturing, donor testing lab, innovative R&D programs, IRL, donor services and IT departments. The position will be responsible for developing strategies to ensure blood manufacturing operations are running efficiently and effectively to meet the needs of our hospitals and clients with a focus on ensuring regulatory compliance. The CCO is responsible for building and guiding a team of highly competent, high-achieving department leaders who will consistently exceed mission standards for cGMP, productivity and customer service. Please send inquiries to LChristiansen@donateblood.org.