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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2021 #3 **January 22, 2021**

INSIDE:

FDA Updates CCP Guidance

The U.S. Food and Drug Administration (FDA) updated the guidance titled "Investigational COVID-19 Convalescent Plasma Guidance for Industry." Updates to the guidance include that blood collectors "should not collect COVID-19 convalescent plasma from individuals who have received an investigational COVID-19 vaccine as a participant in a clinical trial, or received an authorized or licensed COVID-19 vaccine, unless they:

- had symptoms of COVID-19 and a positive test result from a diagnostic test approved, cleared, or authorized by FDA (i.e., individuals who meet the qualification for evidence of COVID-19 described in section III.B.1.a.1. above); and
- received the COVID-19 vaccine after diagnosis of COVID-19, and
- are within six months after complete resolution of COVID-19 symptoms.

These changes aim to ensure "that COVID-19 convalescent plasma collected from donors contains sufficient antibodies directly related to their immune response to COVID-19 infection. Administration of COVID-19 vaccines for the purpose of boosting immunity of convalescent plasma donors would need to be conducted within a clinical trial under IND [21 CFR Part 312]."

The agency also addresses enforcement discretion in the updated guidance by stating, "we recommend the measurement of neutralizing antibody titers when available. FDA intends to exercise this discretion with respect to the [individual new drug application] (IND) requirements for the collection, shipment, and administration of investigational convalescent plasma through May 31, 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."

America's Blood Centers (ABC) is continuing to review the guidance and will provide updates and clarifications to member blood centers regarding its ongoing outreach and advocacy efforts. For questions, please contact ABC Director of Regulatory Affairs Jill Evans.

(Source: FDA Guidance, 1/15/21)

FDA Updates Information for Blood Establishments During Pandemic

The U.S. Food and Drug Administration (FDA) updated its "Information for Blood Establishments Regarding the COVID-19 Pandemic and Blood Donation." The communication emphasizes that it is "imperative that healthy individuals continue to donate blood and blood components, including [s]ource [p]lasma." The agency reiterated general donor qualifications and included new information regarding the COVID-19 vaccine and blood donation:

- [i]ndividuals who received a nonreplicating, inactivated, or mRNA-based COVID-19 vaccine can donate without a waiting period;
- [i]ndividuals who received a live-attenuated viral COVID-19 vaccine, should refrain from donating blood for a short waiting period (e.g., 14 days) after receipt of the vaccine; and
- [i]ndividuals who are uncertain about which COVID-19 vaccine was administered, should refrain from donating for a short waiting period (e.g., 14 days) if it is possible that the individual received a live-attenuated viral vaccine.

For questions or comments, please contact America's Blood Centers Director of Regulatory Affairs Jill Evans.

(Source: FDA Announcement, 1/19/21)

UK CCP Trial Ends Recruitment

The RECOVERY trial, a national, randomized clinical trial in the United Kingdom (UK) that compared "convalescent plasma versus the usual care alone," has ended recruitment efforts. According to a statement, an independent data monitoring committee (DMC) did not see "convincing evidence that further recruitment [for the trial] would provide conclusive proof of worthwhile mortality benefit either overall or in any pre-specified subgroup." Dr Gail Miflin, chief medical officer for NHS Blood and Transplant (NHSBT), said in a statement "[t]hese preliminary results from RECOVERY are disappointing but show the value of this large clinical trial in determining how best to treat patients with COVID. Although today's results are preliminary, and we await the full results with interest, there is no doubt that this trial will provide a real answer to an important question. "We are enormously grateful to the tens of thousands of people who have given their time and donated plasma and to the hundreds of colleagues who have worked incredibly hard over many months. We can be incredibly proud of what we have achieved together. NHSBT has helped deliver the largest ever randomised control trial of convalescent plasma. This world leading trial could only be completed because of the immense professionalism, expertise, and hard work of NHSBT colleagues and partners."

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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.

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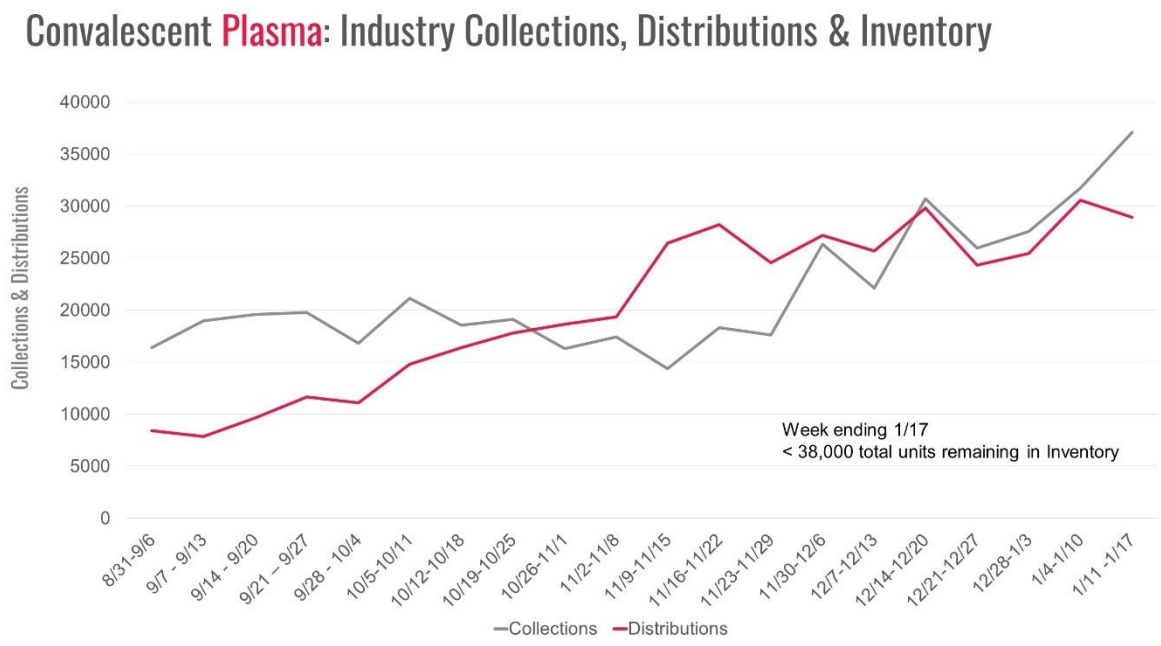
UK RECOVERY Trial (continued from page 2)

Martin Landray, professor of Medicine and Epidemiology at the Nuffield Department of Population Health, University of Oxford, and joint chief investigator for the trial added in the statement "[t]here has been substantial international interest in the role of convalescent plasma as a possible treatment for patients hospitali[z]ed with COVID-19. The results announced today are preliminary and follow-up of patients is ongoing. Once again, the RECOVERY trial is demonstrating the value of large randomised trials to properly assess the role of potential treatments. At this very challenging time, we are incredibly grateful to the hard work of NHS staff and huge contribution made by patients across the whole country."

Peter Horby, professor of Emerging Infectious Diseases in the Nuffield Department of Medicine, University of Oxford, and joint chief investigator for the RECOVERY trial, also said in the statement, "[t]his is the largest ever trial of convalescent plasma and it was only possible thanks to the generous donation of plasma by recovered patients and the willingness of current patients to contribute to advancing medical care. We owe them all a great debt of gratitude. Whilst the overall result is negative, we need to await the full results before we can understand whether convalescent plasma has any role in particular patient subgroups."

(Source: RECOVERY Trial Statement, 1/15/21)

COVID-19 Convalescent Plasma Updates



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!

REGULATORY NEWS

This week, the U.S. Food and Drug Administration (FDA) published a final guidance for the industry titled "Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency." The agency stated that the agency is, "issuing this guidance to provide manufacturers of licensed and investigational cellular therapy and gene therapy (CGT) products with risk-based recommendations to minimize potential transmission of the novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This guidance is intended to supplement the recommendations to drug and biological product manufacturers provided in FDA's "Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing; Guidance for Industry" issued in June 2020 (Ref. 1) (June 2020 GMP Guidance). The recommendations in this guidance specifically consider the source material (cells and/or tissues) recovered from donors and how the CGT product will be manufactured (e.g., cell expansion in culture, viral reduction steps, formulation)."

Additional information is available of the FDA's website.

(Source FDA Guidance 1/19/21)

BRIEFLY NOTED

The BEST Collaborative has issued the call for applications for the Scott Murphy Memorial Award Lecture according to a recent announcement. The Scott Murphy Memorial Lecture was established in 2007 in recognition of the tremendous contribution of the late Dr. Scott Murphy, a past chair of the BEST Collaborative, made to the field of transfusion medicine and to the science of platelet storage. The BEST Collaborative is encouraging junior faculty involved in the broadly understood field of transfusion medicine to apply for this unique award. The recipient of the next award will be invited to present during the BEST Virtual Meeting and to network with BEST members. A list of prior award recipients and their presentation titles can be found here. Online applications must be submitted by January 25th. The award recipient will present a lecture during the 61st BEST Main Meeting. The lecture should be no more than 30 minutes, followed by 10-15 minutes of question and answer. The award recipient will also be welcome to attend the entire BEST multi-day meeting as desired. BEST will provide a $500 honorarium.

(Source: BEST Collaborative Announcement, 1/18/21)

PEOPLE

Claudine Van Gonka has been named the Director of Community Relations and Marketing at San Diego Blood Bank. She joined the blood bank in 2004 and has been a key member of the organization's fundraising, special events, communications, and public relation efforts throughout her tenure. In her new role, Ms. Van Gonka and her team will be responsible for the planning, development, and implementation of the blood bank's marketing strategies and public relations activities. Prior to joining San Diego Blood Bank, she worked in radio as a promotion director, while also co-hosting a morning show.

(Source: San Diego Blood Bank Announcement, 1/18/21)

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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.

Annual Meeting Registration Opens

Registration is now open for the 59th America's Blood Centers Annual Meeting, which will be a virtual event March 8th–12th. Last year's meeting demonstrated the power of coming together as an industry to collaborate on strategies for the future of the blood industry. It is essential now more than ever, to bring executive, operational, and medical leadership together to focus on key issues which will ultimately impact blood center bottom-lines. The meeting will also feature a virtual Advocacy Day as member blood centers will have the opportunity to let their voices be heard with Congress. A preliminary schedule is available here.

ADRP Webinar: Creating a Culture of Resilience

Register today for the Wednesday, February 10th ADRP webinar titled "Creating a Culture of Resilience." This webinar will take place at 1 p.m. EST and will describe how Versiti developed their culture over the years with a focus on resiliency which has been a critical part of improving staff engagement and overall performance. Anne Krueger, director of Organ and Tissue Donation at Versiti will share the foundations of their resiliency culture, specific programs developed along the way, measurable impact, and plans for future expansion of the resiliency program.

ADRP subscribers may register for free and non-subscribers can participate for $25.

(ADRP Announcement, 1/20/21) ♦

New Video Added to National Blood Donor Month Resources

With National Blood Donor Month, the annual celebration thanking blood donors while raising awareness of the constant need of blood to ensure availability of the nation's blood supply, now underway, ADRP, an International Division of America's Blood Centers, has developed several resources as part of a toolkit for blood centers to use. We encourage you to take advantage of these resources throughout the month of January to promote National Blood Donor Month which include:

- a new video;
- a recently released podcast featuring ADRP President-elect Theresa Pina (beginning at the 9 minute and 30 second mark);
- a template news release;
- social media graphics, sized for Twitter, Instagram, and Facebook;
- sample social media posts; and
- an updated National Blood Donor Month logo.

Additional resources will be added as they become available.

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INSIDE ABC (continued from page 5)

ABC Employee Turnover and Retention Survey Deadline Extended

America's Blood Centers (ABC) extended the deadline to participate in the Employee Turnover and Retention Survey for calendar years 2018 and 2019 to January 29th. ABC hopes to achieve a 100 percent response rate this year. Member blood centers are encouraged to participate in this survey to ensure that this will be a valuable tool for the entire ABC membership. Survey results will be reported in aggregate and made available to participating member blood centers.

About the Survey

- Data Collection Period: December 16 to January 29, 2021.
- Please submit only one (1) survey per member blood center.
- Before you begin, preview all of the survey questions (see pages 2-19 of the MCN attachment) or use the questionnaire as a data collection tool.
- Survey completion times will vary based upon your system's reporting capabilities.
- You can log in and out and revise your answers. Please Note: It is very important that you click the "save and continue survey later" option on the top of every page after adding or updating an answer to ensure the data is captured.
- You will have an opportunity to review, edit, and print your responses prior to submitting your survey.

Survey Definitions

- FTE: Employees who are scheduled to work 40 hours per week are 1.0 FTE. Employees scheduled to work 20 hours per week are 0.5 FTEs.
- Turnover Calculation: the Society for Human Resource Management recommends using the average number of FTEs for the year.

ABC members can find more information in MCN 20-113. Please contact Member Services to obtain a copy of the MCN or links to the survey.

(Source: MCN 20-113, 12/16/20)

WORD IN WASHINGTON

Janet Woodcock, MD, has been named Acting Commissioner of U.S. Food and Drug Administration. She has worked at the agency since 1986 and currently serves as the Director of FDA's Center for Drug Evaluation and Research.

(Source: *New York Times,* Hahn Leaves F.D.A.; Woodcock Named Acting Commissioner, 1/20/21)

The Office of the Assistant Secretary for Health recently announced that RADM Felicia Collins, MD, MPH will be serving as Acting Assistant Secretary for Health (ASH) until the new administration places its appointees. Additionally, Elisabeth Handley will serve as the Acting Principal Deputy Assistant Secretary for Health. President Biden has nominated Dr. Rachel Levine to fill the role of ASH if confirmed by the Senate.

(Source: OASH Communication, 1/20/21)

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WORD IN WASHINGTON (continued from page 6)

Liz Richter has been named the Acting Administrator of the Centers for Medicare and Medicaid Services (CMS). She has been with the agency since 1990 and has been serving as deputy director of the Center for Medicare since 2007.

(Source: CMS Announcement, 1/20/20)

COMPANY NEWS

Grifols is beginning a clinical trial in Spain to assess the safety and efficacy of a COVID-19 hyperimmune globulin therapy made from Grifols immunoglobulin Gamunex®-C and the antibodies from convalescent plasma donors who have recovered from COVID-19. According to the company news release, the therapy "would provide immediate post-exposure protection against the virus and would be especially useful as a complement to the vaccine in the early phase after vaccination." The trial is expected to begin in February with results potentially available by the spring of 2021. It will enroll an estimated 800 patients who are "asymptomatic but having tested positive for the virus in a diagnostic test, will participate in the clinical study, receiving subcutaneously Grifols' immunoglobulin rich with anti-SARS-CoV-2 antibodies." The study will be lead by Oriol Mitjà and Bonaventura Clotet from Germans Trias i Pujol Hospital in Barcelona. The researchers stated in the news release, "[t]his treatment based on immunoglobulins would provide a combination of polyclonal antibodies that, compared with monoclonal antibodies, offers a greater diversity that could improve the degree of protection against the virus…[it] is easy to refrigerate while its subcutaneous administration facilitates its distribution and use in any doctor's office, avoiding hospitalization. If the new therapy's efficacy is confirmed, it could be administered to people who test positive for the virus through PCR and antigen tests in hospitals and primary care offices."

(Source: Grifols News Release, 1/18/21)

Eli Lilly and Company announced results from a randomized phase III BLAZE-2 COVID-19 prevention trial of its monoclonal antibody therapy Bamlanivimab (LY-CoV555). According to a company news release, the antibody therapy "significantly reduced the risk of contracting symptomatic COVID-19 among residents and staff of long-term care facilities." Eli Lilly Chief Scientific Officer and President of Lilly Research Laboratories Daniel Skovronsky, MD, PhD stated in the announcement, "[w]e are exceptionally pleased with these positive results, which showed bamlanivimab was able to help prevent COVID-19, substantially reducing symptomatic disease among nursing home residents, some of the most vulnerable members of our society. These data provide important additional clinical evidence regarding the use of bamlanivimab to fight COVID-19 and strengthen our conviction that monoclonal antibodies such as bamlanivimab can play a critical role in turning the tide of this pandemic. We're glad bamlanivimab is already available as a treatment for patients at high risk for progressing to severe COVID-19 illness or hospitalization, including those in nursing homes, and look forward to working with regulators to explore expanding the emergency use authorization to prevent the spread of COVID-19 in these facilities." The company added in the release, "[a]fter all participants reached eight weeks of follow-up, there was a significantly lower frequency of symptomatic COVID-19 (the primary endpoint) in the bamlanivimab treatment arm versus placebo (odds ratio 0.43, p=0.00021). Results for all key secondary endpoints also reached statistical significance in both the overall and resident populations. For the pre-specified subgroup of nursing home residents, there was also a significantly lower frequency of symptomatic COVID-19 in those treated with bamlanivimab versus placebo in this important population (odds ratio 0.20; p=0.00026). These results suggest that residents randomized to bamlanivimab have up to an 80 percent lower risk of contracting COVID-19 versus residents in the same facility randomized to placebo."

(Source: Eli Lilly and Company News Release, 1/21/21)

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COMPANY NEWS (continued from page 7)

Regeneron Pharmaceuticals, Inc. has reached agreement with the U.S. Department of Health and Human Services and U.S. Department of Defense (DoD) for the agencies to purchase up to an additional 1.25 million doses of Regeneron's monoclonal antibody therapy to treat COVID-19 in non-hospitalized patients. "COVID-19 continues to sicken hundreds of thousands of Americans every day and the people of Regeneron are committed to help," said Leonard S. Schleifer, MD., PhD., president and chief executive officer of Regeneron, in a company news release. "Tackling the COVID-19 pandemic will require a combination of public health measures, vaccines, and therapeutics. We are pleased to work with the U.S. government to supply our antibody cocktail as an important weapon in this fight." Under terms of the contract, the U.S. government will purchase "all finished doses" delivered by the end of June with a cap of 1.25 million doses.

(Source: Regeneron News Release, 1/12/21)

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 8-12. **ABC Annual Meeting (Virtual).** Registration now open.

Aug. 17-19. **2021 ADRP Conference, Kansas City, Mo.** More details coming soon.

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

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.

Oct. 16-19. **AABB Annual Meeting.** 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

Regional Operations Director (Baton Rouge, LA). LifeShare Blood Center is seeking an enthusiastic Operations Director to oversee regional blood collection and donor recruitment operations. Responsibilities include: develop and implement strategic and tactical plans for operations within the donation center and community-based activities; direct, develop and coach teams for achievement of established goals and KPI's; develop relationships with community leaders and groups to promote our mission and business needs; ensure operations adhere to standards and regulations governing the blood banking industry, including FDA, AABB, cGMP, and OSHA; and model LifeShare's mission and values, integrating them into daily decisions, behaviors, and actions. The ideal candidate has a bachelor's degree or equivalent experience and background in healthcare administration, business, or operations management,

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POSITIONS (continued from page 8)

including supervisory experience in the direction and coaching of other employees. S/he champions teamwork, communication and continuous improvement and has a passion for service to our community. Come be a part of the LifeShare team, "connecting donors and the lives they impact!" LifeShare offers a competitive salary, incentive bonus opportunities and a generous benefits package, including employer-paid medical, life and disability insurance; 401k with employer contributions and PTO. Click here to apply.

Director of Human Resources. The Blood Bank of Alaska is seeking a Director of Human Resources that will report to the CEO. The Director of Human Resources is responsible for the development and implementation of employee policies and procedures, benefit administration, and research related legal issues as requested by management. This person works closely with the leadership team to effectively plan and implement operational goals and objectives as assigned. Must be able to support the professional growth and development of employees across all levels of the organization. Candidate must be a strong leader with innovative ideas and deep experience to support the organization. The Director of Human Resources also serves in the capacity of Safety Officer; coordinating safety training as required including OSHA/cGMP, and other relevant annual required training(s). The incumbent for this role must possess excellent conceptual, communication, and analytical skills. Must understand general work flow processes. Must have excellent interactive skills necessary in communicating with co-workers. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply via our website at https://www.bloodbankofalaska.org/current-openings/.

Medical Director. Gulf Coast Regional Blood Center in Houston, TX seeks a Medical Director to provide medical and scientific direction in all areas of blood center operations, including an active program in cellular therapy. The Medical Director will work with the Chief Medical Officer to oversee medical aspects of blood donor qualification and collection, apheresis and other cellular therapy activities, an Immunohematology Reference Laboratory, and a donor testing laboratory that serves national clients. Consultation and communication with transfusion medicine physicians and other clinicians locally will be expected, and participation in national activities as appropriate. The candidate should hold an MD, DO, or equivalent degree and have or be eligible to acquire a Texas medical license. Qualification as a Clinical Pathologist with subspecialty qualification in Blood Banking and Transfusion Medicine or equivalent training would be expected. Experience in cellular therapy activities and blood center operations is desirable. As one of the largest community blood centers in the United States, we serve 26 counties across the Texas Gulf Coast, Brazos Valley and East Texas, and more than 170 hospitals and health care institutions. Gulf Coast Regional Blood Center is a non-profit organization and part of the Texas Medical Center, a large consortium of medical and research institutions. To apply, please visit https://jobs.giveblood.org/.

Medical Technologist (ASCP, MLS) (Erie, PA). The Community Blood Bank of NWPA & WNY is seeking a Medical Technologist for our Erie, PA location. The perspective candidate must have B.S. degree, ASCP certification, six years' experience in field. Component preparation and/or hematology experience desirable. Reports to Technical Director and Lab Supervisor, the position encompasses component preparation and modification of whole blood and required Quality Control/Blood component testing per FDA, Dept. of Health regulation and AABB guidelines. Must be adept in entering and retrieving data from the computer. Please visit http://fourhearts.org/careers to apply.

OneBlood is hiring multiple positions within the state of Florida to support our life saving mission. Bring your talent to one of these exciting career opportunities. **Therapeutics Apheresis RN (Ft. Lauderdale, FL - $5k Bonus Eligible).** Current and valid Florida RN license, current BLS CPR certification, and a valid and clear driver's license is required. Flexibility in scheduling needed to meet the needs of the department; travel within the tri-county market in the South Florida area is required. **Medical Technologist (Tallahassee, FL - $5k Bonus Eligible).** A valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking is required. Prior blood banking experience preferred. Multiple shifts available. **Compatibility Testing Lab Supervisor (Tallahassee, FL).** Bachelor's degree in medical technology, biological science, or related field and three plus years in a clinical laboratory, preferably in blood banking. Requires a current Florida Technologist license in Immunohematology or Blood Banking; FL Supervisor License preferred. OneBlood offers excellent benefits, including excellent shift differential pay for night and weekend schedules, Paid Time Off, Student Loan Repayment Program, a FREE medical coverage option, 403(b) Retirement Plan, company-paid annual CEU training & CE Broker account and MORE! To apply visit our OneBlood careers website at www.oneblood.org/careers.

Business Analyst (West Warwick, RI). Blood Centers of America, Inc. is seeking a Business Analyst. The position reports to the Director of Research & Innovation and

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POSITIONS (continued from page 9)

supports our Geospatial program by assisting members with donor optimization, marketing implementation and intelligence gathering. This position conducts data analysis, tracking and forecasting, projects and monitors member compliance and performs quality assurance on raw data sources. Strong written, verbal, and interpersonal communication skills, with the ability to work both independently and as part of a team are required. Effective analytical, planning, and organizational skills are necessary. Required PC skills: MS Office Suite; Social Media, Adobe Suite, ESRI Suite, Tableau, SQL are a plus. BS degree in a related field is required with one to two years of related experience. Blood Center experience is a plus. Based at the BCA headquarters in Rhode Island, the position requires travel 10-20% of the time (post Covid-19). Submit resumes to Jobs@bca.coop.

Chief Clinical Officer (Central California Blood Center). 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 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. MS, SBB preferred, strong and progressive blood industry leadership experience required. Please send inquiries to LChristiansen@donateblood.org. 🩸