America's Blood Centers®
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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2020 #30 **August 28, 2020**

INSIDE:

EUA Granted for Convalescent Plasma

The U.S. Food and Drug Administration (FDA) announced this week that it has issued emergency use authorization (EUA) for convalescent plasma from recovered COVID-19 patients to be used to treat hospitalized COVID-19 patients. The agency also published its decision memorandum to summarize the existing data used in the decision-making process in providing convalescent plasma with the EUA designation. "I am committed to releasing safe and potentially helpful treatments for COVID-19 as quickly as possible in order to save lives," said FDA Commissioner Stephen Hahn, MD in an agency news release. "We're encouraged by the early promising data that we've seen about convalescent plasma. The data from studies conducted this year shows that plasma from patients who've recovered from COVID-19 has the potential to help treat those who are suffering from the effects of getting this terrible virus. At the same time, we will continue to work with researchers to continue randomized clinical trials to study the safety and effectiveness of convalescent plasma in treating patients infected with the novel coronavirus."

America's Blood Centers issued a statement supporting the FDA's decision. "As is expected with an EUA status, clinical trials are ongoing to gather additional data. We remain supportive of these ongoing clinical trials. The need for CCP for patients remains, including those enrolled in clinical trials, to ensure every patient in need is able to receive this promising therapy. We urge all eligible individuals who have fully recovered from COVID-19 to donate at your local blood center."

The agency also held a call with industry blood centers and industry stakeholders in which it answered questions and provided clarification for the blood community including that:

- per the EUA, units should be tested by the Ortho VITROS SARS-CoV-2 IgG test and found to have a signal-to-cutoff (S/C) value of 12 or greater to qualify as high-titer COVID-19 convalescent plasma. Blood establishments can approach the FDA to discuss alternative assays that they are using that they feel are comparable to the Ortho test;
- FDA anticipates that the implementation timeline will require a transition of a period of a "few months" in which the agency will allow the use of investigational convalescent plasma, even with the Expanded Access Protocol (EAP) ending as of August 28th. These investigational units will still be permitted, even if they have not been tittered. Additional communication is forthcoming from the agency regarding this;
- convalescent plasma can be collected by apheresis more frequently than every 14 days at the discretion of the blood establishment's medical director;

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FDA Grants Convalescent Plasma EUA (continued from page 1)

- due to concerns about contamination and being considered "manufacturing," pooling cannot be done at this time to create additional high-titer inventory;
- as part of the EUA, products have to be labeled as high-or low-titer to meet conditions specified in the EUA;
- the agency does anticipate providing a pathway for convalescent plasma to be used as an investigational product that would not require an investigational new drug application (IND); and
- EUA convalescent plasma can be shipped across state lines.

U.S. Department of Health and Human Services Secretary Alex Azar stated, "the FDA's emergency authorization for convalescent plasma is a milestone achievement in President Trump's efforts to save lives from COVID-19. The Trump Administration recognized the potential of convalescent plasma early on. Months ago, the FDA, BARDA, and private partners began work on making this product available across the country while continuing to evaluate data through clinical trials. Our work on convalescent plasma has delivered broader access to the product than is available in any other country and reached more than 70,000 American patients so far. We are deeply grateful to Americans who have already donated and encourage individuals who have recovered from COVID-19 to consider donating convalescent plasma."

Additional information is available here.

(Sources: FDA News Release, 8/23/20, FDA EUA, 8/23/20; MCN 20-078, 8/23/20)

ABC Provides Statement at HHS ACBTSA

The HHS Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) held a virtual meeting this week to discuss "recommendations to improve the blood community's response to future public health emergencies" and to "analyze strengths and weaknesses from the COVID-19 response on the blood community and blood supply." The multi-day meeting will be covered in more detail in next week's *ABC Newsletter*.

America's Blood Centers (ABC) did address the committee on behalf of its members blood centers and submitted written comments that highlighted the benefits of:

- national messaging from the Administration and federal regulators encouraging blood and plasma donation;
- the coordination and flexibility of the FDA;
- disaster coordination and collaboration among the public and private sector; and
- the response of community blood centers to the pandemic producing and distributing more than 125,000 units of convalescent plasma.

The comments also describe "weaknesses" that could threaten the safety and availability of the blood supply including:

- the need for national disaster plans and increased stakeholder involvement;
- coordination among local, regional, and national stakeholders;
- supply chain preparedness; and
- financial stability.

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ABC ACBTSA Statement (continued from page 2)

ABC recommended:

- the continuous recruitment of donors "must be explored in greater depth with social science research required to best understand a path forward. ABC also believes that a public-private partnership is necessary to amplify the reach of a public awareness campaign to expand the donor pool to ensure blood is available to patients in need. We witnessed first-hand the success of messaging by federal officials for donations and the power of public-private partnerships in convalescent plasma. These efforts must be institutionalized to ensure a viable blood supply moving forward;"
- creation of a national, near real-time monitoring system for the U.S. blood supply is "essential to develop a similar national blood supply data system which includes all units of available blood components in the U.S and blood usage patterns. Failure of hospitals to report current inventories and blood utilization patterns caused a significant blind spot in the ability of blood centers to plan for the pandemic. A national database, with reporting requirements linked to financial support, would allow for maintenance of real and virtual blood product inventories that could be maintained, rapidly identified, and deployed in the event of a disaster of any size and scope;"
- development and funding of a comprehensive national disaster plan for the blood supply that includes "a number of measures to ensure blood centers already have in place and practice their disaster procedures. Alternative collection procedures should be developed by FDA to allow blood centers to establish Standard Operating Procedures that can be implemented easily during a disaster to ensure sufficient collections. For instance, FDA should consider and publish other potential donor qualification modifications they would allow in future emergencies so the industry can be better prepared; and"
- a revised approval and funding pathway for novel products, tests, and technology. "FDA should be prepared for such a product during a future pandemic by having a plan in place for atypical therapeutics development requiring a condensed timeframe. In addition, there is a need for a more rapid FDA approval process for new products and technologies (e.g. CCP, cold stored platelets, and pathogen reduction for whole blood) to speed innovative products to market…A more centralized role by the federal government could alleviate many of these challenges and better prepare the country for the next pandemic. A study of the potential for pathogen reduction of the entire blood supply should be a national priority."

The full comments are available on the ABC website.

(Source: ABC Comments, 8/27/20)

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.

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HHS OCR Revises Guidance on HIPAA and Contacting Former COVID-19 Patients about Convalescent Plasma Donation

The U.S. Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has updated its guidance regarding the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and health providers (e.g., hospitals, pharmacies, laboratories) contacting recovered COVID-19 patients about becoming potential convalescent plasma donors. Health plans have now been added to the guidance. "Generally, a covered healthcare provider (e.g., a hospital, pharmacy, or laboratory) or health plan may use [protected health information] to identify individuals who have recovered from COVID-19 to provide them with information about how they can donate their plasma containing antibodies to SARS-CoV-2 (the virus that causes COVID-19) for use in potentially treating patients with COVID-19."

OCR also "emphasized that, without individuals' authorization, the providers and health plans cannot receive any payment from, or on behalf of, a plasma donation center in exchange for such communications with recovered individuals." Roger Severino, director of OCR, added in a news release that, "[i]n response to the President's call for Americans who have recovered from COVID-19 to donate their plasma, OCR clarified how HIPAA permits health plans to contact their beneficiaries about plasma donation opportunities. We will continue to use every tool at our disposal to beat this virus and keep Americans healthy."

(Sources: HHS OCR Guidance, 8/24/20; HHS OCR News Release, 8/24/20)

RESEARCH IN BRIEF

COVID-19 Convalescent Plasma Reduces Mortality. A "prospective, propensity score-matched study assessing the efficacy of COVID-19 convalescent plasma (CCP) transfusion vs. standard of care as treatment for severe and/or critical COVID-19 disease" was recently published in *The American Journal of Pathology*. The "results of an interim analysis" were reported as eight hospitals analyzed data from March 28th through July 6th. Eligible patients "had severe and/or life-threatening COVID-19 disease" and "were transfused with one or two units of CCP." The study "conducted a one-to-many nearest neighbor propensity score matching without replacement using an initial ratio of case: control = 1:3 and caliper of 1 between patients having plasma transfusion (cases) vs. patients who did not have plasma transfusion (controls)…A secondary propensity score matching the ratio of case: control of either 1:2 or 1:1 and caliper <1 was conducted based on the ventilation status at Day 0, which was defined as the day of transfusion for cases and the corresponding day in the hospitalization course for controls." The researchers identified "pre-specified sub-groups of transfused patients…and matched [them] with available controls: patients transfused with plasma within 72 hours (h) of admission; patients who were transfused >72 h after admission; and patients transfused within 72 h of admission with an anti- receptor binding domain (RBD) IgG titer >1:1350." The study found that "[t]he primary outcome [was] mortality within 28 days post-Day 0…After secondary [propensity score] matching, there were 136 transfused patients matched to 251 controls." The researchers saw "[a] decreased probability of death within 28 days post-Day 0 in the transfused cohort relative to propensity score-matched controls, although the difference did not reach statistical significance…The decreased mortality was improved and reached significance (P = 0.047) when only patients who received a plasma transfusion with an anti-RBD IgG titer of >1:1350 within 72 h of hospital admission were considered." Higher mortality was associated "[with] advanced age, hypertension, diabetes, chronic kidney disease, coronary disease, higher interleukin-6, higher d-dimer, and use of any steroid, ribavirin, or tocilizumab." The authors concluded that "this interim propensity score-matched analysis suggests that transfusion of high anti-RBD IgG titer CCP early in hospitalization reduces mortality in COVID-19 patients."

Citation: Salazar, E., Christensen, P.A., Graviss, E.A., *et al*. Treatment of COVID-19 Patients with Convalescent Plasma Reveals a Signal of Significantly Decreased Mortality. *The American Journal of Pathology*. 2020. Doi: 10.1016/j.ajpath.2020.08.001.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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INSIDE ABC

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

August *Blood Bulletin* Now Available

ABC's Scientific, Medical, and Technical (SMT) Publications Committee, has published the August 2020 Issue (PDF or MS Word versions) of the *Blood Bulletin*, titled "An Overview of Approved CAR-T Cell Therapeutics."

The article was written by Minh-Ha Tran, DO, Clinical Professor at University of California Irvine, School of Medicine; Cham Nguyen, PharmD, Pharmacy Specialist Oncology, University of California Irvine, Department of Pharmacy; and Deepa Jeyakumar, MD Assistant Clinical Professor, University of California Irvine School of Medicine. *Blood Bulletin* is reviewed and edited by ABC's SMT Publications Committee.

ABC publishes the *Blood Bulletin* for use by member blood centers in their educational programs as a value-added service for hospital customers. Current and previous issues can be accessed at any time on the ABC member website.

Please note: The MS Word version may not display properly for users with older versions of MS Word. For those individuals, we recommend viewing and using the PDF version of this publication instead.

(Source: MCN 20-075, 8/24/20)

ADRP Digital Marketing Solutions Virtual Master Class Begins in Less Than 3 Weeks

Registration is now open for the upcoming Digital Marketing Solutions Virtual Master Class. This series of three single-day events will occur over the course of three weeks and has been designed to move beyond the basics and build upon the skills needed to excel at your job while providing participants with the latest tools and trends to incorporate into their current business plans.

ADRP has scheduled more than 15 speakers from blood centers of all sizes as well as digital marketing subject-matter experts from Facebook and Google. This will be a hands-on experience, rather than solely lectures, featuring activities designed to engage attendees equipping them with the necessary resources to strategize a plan that can be implemented immediately.

Individuals and teams within the communications, marketing, and public relations departments at your blood centers are encouraged to register today for the Digital Marketing Solutions Master Class to drive tangible results for both your existing and future digital marketing efforts.

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has published a guidance titled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood products." It updates the April 2020 guidance with changes including:

- "revised Section III to update the recommended deferral for individuals who had sex with a person who has exchanged sex for money or drugs and individuals who had sex with a person who has engaged in non-prescription injection drug use; and
- other minor editorial changes."

(Source: FDA Guidance, 8/27/20)

The FDA updated its April guidance titled "Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components. According to the agency, changes include:

- revised terminology used to describe familial prion diseases;
- updated information on the National Hormone and Pituitary Program in the U.S.; and
- provided clarification of the recommendation to permanently defer individual who have received cadaveric pituitary human growth hormone (Section IV. and the Appendix).

vCJD, the human form of Bovine Spongiform Encephalopathy (BSE), is a fatal, progressive neurological condition that was first identified in the U.K. in 1996. It is generally transmitted by eating the beef of animals affected, though a few cases have been found to result from blood transfusion from donors that appeared healthy at the time of donation but later developed vCJD. As a result, the FDA has recognized vCJD as a relevant transfusion-transmitted infection. Since no licensed screening test for vCJD exists, the FDA implemented geographical deferrals for blood donors depending on time in areas considered at risk for vCJD transmission in 1999.

(Source: FDA Guidance, 8/26/20)

The U.S. Department of Health and Human Services has determined that FDA will not require premarket review of laboratory developed tests (LDTs). Those seeking approval or clearance, or an emergency use authorization (EUA) for an LDT may voluntarily submit a premarket approval application, premarket notification, or an EUA request. Those opting to use LDTs in their laboratories without premarket review or authorization are still subjected to regulation by the Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments of 1988 and its implementing regulations (42 CFR pt. 493).

(Source: HHS Announcement, 8/19/20)

PEOPLE

Krystalyn E. Hudson, PhD has been announced as the 25th recipient of the Biomedical Excellence for Safer Transfusion (BEST) Collaborative Scott Murphy Memorial Award Lectureship. She currently serves as an assistant professor in the Department of Pathology and Cell Biology at Columbia University. Dr. Hudson will deliver a lecture on "Tolerance and Autoimmunity to Red Blood Cells" during the 60th Meeting of BEST, which will be held virtually on November 6th after previously being scheduled for September 30th-October 1st in Washington, D.C.

(Source: BEST News Release, 8/24/20)

MEMBER NEWS

New York Blood Center announced the findings of an independent study that tested the sensitivity and specificity of the Clungene® SARS-CoV-2 IgG/IgM Rapid Serology Test which "produces rapid results in 15 minutes from a finger prick of whole blood, serum or plasma." The study performed by the blood center's Lindsley F. Kimball Research Institute (LFKRI) determined that "IgG results are consistent with the manufacturer's 97.4 percent clinical performance data which showed positive IgG agreement with known positive RT-PCR test," according to a news release. The IgM results are consistent with recently published data which shows that IgM can persist more than 23 days after symptom onset and can be earlier, synchronous or later than IgG." Larry Luchsinger, assistant member of the LFKRI added in the news release, "[h]aving the ability to accurately identify the presence of antibodies is the first step in understanding individual immune response to COVID-19 and evaluating future risk for exposure. This is critical for creating informed public health policies and charting a path forward for our communities."

The National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) awarded a grant to New York Blood Center's LFKRI's Karina Yazdanbakhsh, PhD for a sickle cell research program "studying the consequences of transfusions in patients with sickle cell disease and developing strategies to optimize transfusion management for this patient group." In a news release announcing the grant, Dr. Yazdanbakhsh stated, "The grant provides us with a unique opportunity to understand at the molecular level how transfusions can switch these key immune cells and bone marrow cells to function normally and to discover new transfusion protocols and combination therapies to reverse the hemolytic insult in sickle cell disease. Transfusions decrease the risk of stroke in sickle cell disease by 90 percent. However, many indications for transfusion in sickle cell disease remain controversial partly due to our limited understanding of the complex biological processes that lead to disease complications in sickle cell disease despite the common single mutation and in part because of paucity of data on how transfusions improve or prevent sickle cell complications. The Program Project aims to fill these gaps in our knowledge to advance our understanding of transfusion outcomes, focusing on the role of hemolysis, with the goal to develop novel approaches to improve transfusion efficacy for this patient population." New York Blood Center President and Chief Executive Officer (CEO) Christopher Hillyer, MD added, "[t]his hypothesis-driven approach to develop optimal transfusion management strategies to care for patients with sickle cell disease marries the capabilities of our outstanding basic science team with New York Blood Center's core expertise as innovators and leaders in transfusion medicine practice. We are proud of Dr. Yazdanbakhsh's outstanding work in the field and look forward to what she and her team will accomplish with this much-deserved research grant."

(Source: New York Blood Center News Release, 8/26/20; News Release, 8/19/20)

Vitalant recently announced that its President and CEO David Green and the organization will join the CEO Action for Diversity & Inclusion™ coalition becoming the first CEO of a blood service provider to do so according to a news release. The CEO Action for Diversity & Inclusion™ coalition seeks to have executive leaders commit to advancing workplace diversity and inclusion with more than 1,000 CEOs currently pledged to support the initiative. "As a leader — and as a human being — I know we must constantly work to further racial justice and equality. Vitalant pledges to contribute to change in a sustained and meaningful way," said Mr. Green in the news release. "CEO Action for Diversity & Inclusion will help Vitalant further cultivate an inclusive and supportive work environment where employees can openly address challenges, present opportunities, and share perspectives. We know this will positively extend to the communities we serve." Vitalant Chief People Officer Peter Michaelson will also serve as a main coalition delegate with Mr. Green.

(Source: Vitalant News Release, 8/26/20) ♦

GLOBAL NEWS

Australian researchers announced preliminary results from a three-year trial aimed at reducing the incidence of dengue. As a part of the study, taking place in Indonesia which was chosen for the high prevalence of dengue in the region, investigators have been using genetically modified mosquitoes that are carriers of a bacterium known as *Wolbachia*. It prevents transmission of the mosquito-borne viruses. "Rates of dengue in these places were 77 percent lower, over several years, compared with areas that did not receive the mosquitoes," according to a report from *Nature*. "It will be important to scrutinize the full data, but 'a 77 percent reduction is really extraordinary', [said] Philipp McCall, a vector biologist at the Liverpool School of Tropical Medicine, [in the United Kingdom]. 'This does have huge promise.'" The trial was "coordinated" by the World Mosquito Program and began in 2016. "This a real breakthrough, a new hope for us, for the people and hopefully for the programme," said the co-leader of the trial Adi Utarini, a public health researcher at University of Gadjah Mada in Indonesia, *Nature* reported.

(Source: *Nature*, The mosquito strategy that could eliminate dengue, 8/27/20) ♦

COMPANY NEWS

Grifols has manufactured and delivered the initial batches of its SARS-CoV-2 hyperimmune globulin (HIG) candidate for clinical trials. According to a recent announcement, the HIG therapy derived from the convalescent plasma of received COVID-19 patients will be used in forthcoming clinical trials. "Grifols is grateful to all the plasma donors who through their generosity are now helping to develop a medicine, a hyperimmune globulin, whose concentrated antibodies will potentially provide others with passive immunity to overcome the disease," said Victor Grifols Deu, co-chief executive officer of Grifols, in a company news release. "All of us at Grifols are proud to devote our time, talent and energies to fight this health crisis." Grifols is collaborating with several federal agencies including the U.S. Food and Drug Administration, the National Institutes of Health, and the Biomedical Advanced Research Development Authority (BARDA). In June, the company announced that it had begun production on the HIG therapy. Grifols also has plans for an HIG clinical trial to take place in Europe.

(Source: Grifols News Release, 7/28/20) ♦

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.

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.)*

Aug. 28-29. **South Central Association of Blood Banks (SCABB) 2020 Annual Meeting & Exhibit Show (Virtual).** More details and registration available here.

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CALENDAR (continued from page 8)

Sept. 9. **10th Annual Symposium Red Cell Genotyping 2020: Visionary Solutions (Virtual attendance only).** More details available here.

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

Sept. 16, 23, 30. **ADRP Digital Marketing Solutions Virtual Master Class.** More details available here.

Oct. 3-5. **2020 AABB Annual Meeting (Virtual).** More information available here.

Oct. 27. **Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2020 (Virtual).** More information available here.

Nov. 22-24. **2020 ADRP Conference, Phoenix, Ariz.** More details available here.

2021
Mar 8-10. **ABC Annual Meeting, Washington, D.C.** More details coming soon.

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

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

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Outside Sales Representative/Event Planner (Ardmore, Okla., USA). Account Consultants/Outside Sales Representatives must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, life insurance, long term disability, 401(k), paid time off, etc. How to apply: http://obi.org/careers/.

Chief Operations Officer (Shreveport, LA). LifeShare Blood Center is seeking an experienced Chief Operations Officer (COO) to plan, organize and direct all operations for its newly-formed division, LifeShare Plasma Services in accordance with our strategic goals and business plan, policies, SOPs, and applicable regulatory and accreditation guidelines. Primary areas of responsibility include collections, financial incentives, recruitment, manufacturing, distribution, quality, and other areas of operations. In leadership of the plasma operations team, the COO will model LifeShare's mission and values, integrating them into daily decisions, behaviors and actions. The ideal candidate holds a bachelor's degree in a health or business-related discipline; master's degree preferred; at

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POSITIONS (continued from page 9)

least 10 years of progressively responsible management experience, preferably in a clinical laboratory, blood or plasma center, or manufacturing center; and demonstrates a working knowledge of FDA regulations governing plasma centers, PPTA, OSHA, and cGMP for laboratory operations. Come be a part of the LifeShare team, "connecting donors and the lives they impact!" LifeShare offers a competitive salary and generous benefits package, including employer-paid medical, life and disability insurance; 401k with employer contributions and PTO. Click here to apply.

Quality Assurance Specialist (Bradenton, FL). SunCoast Blood Centers is accepting applications for a Quality Assurance Specialist to work at our Lakewood Ranch Head Quarters. This position performs duties in all areas of the quality assurance program, including, but not limited to error management, document control, lookback activities, and auditing. Other duties include: Acts as a liaison for external inspections. Conducts required annual staff trainings and maintains blood bank training files. Performs validations prior to implementation of new processes, equipment, or software version updates, and other duties as assigned. Qualified applications should possess a bachelor's degree in Medical Technology or equivalent experience. Prefer applicant to have MT licensure, but not required. Applicant must have three years blood center production or clinical laboratory experience plus two years medical administration or other medically related experience. To apply and view a complete Job Description of this position please visit https://www.scbb.org/careers.html. EOE. Applicant drug testing required.

Operations Manager. Blood Assurance is seeking an Operations Manager to manage our collection efforts in the greater Nashville, TN and surrounding areas. This position will be responsible for operational oversight of collection services for multiple collection teams in an assigned territory. Supervises staff in coordination with other department leaders and ensures compliance with all Standard Operating Procedures, FDA and AABB regulations. Monitors performance in the areas of productivity, proficiency and customer service. A bachelor's degree with some prior supervisory/ management experience in blood banking is required. Advanced skills in leadership, teamwork, analytics and communications are also required. Blood Assurance offers a competitive base wage with healthcare benefits and a 401K retirement plan. Qualified candidates are encouraged to submit an online employment application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.

Associate Medical Director. Blood Assurance is seeking an Associate Medical Director to work in our Nashville, TN facility. This position will assist the Medical Director with providing medical and professional guidance to employees of the company and to area medical professionals. Qualified applicants should possess: MD degree required; board certification or eligibility in pathology required (board certification must be secured within 1 year of hire); Transfusion Medicine board certification or eligibility preferred. Must be licensed to practice medicine in the states of our fixed facilities if required by that state (state licensure can be secured after hire). Minimum 5 years prior related experience; blood bank management and cellular therapy experience preferred. Advanced communications skills required, including ability to speak to groups; computer skills and ability to effectively interact with coworkers. Qualified candidates are encouraged to submit an online application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco Free Workplace.

Transfusion Lab Manager (Recruitment Bonus Eligible!!). Join Florida's leading blood bank, OneBlood, as a Lab Manager 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 plus years in a clinical laboratory, preferably blood banking environment, Valid and current Florida Clinical Laboratory Supervisor license in Immunohematology or Blood Banking required. SBB certification 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.

Medical Apheresis Nurse/RN. Gulf Coast Regional Blood Center is accepting applications for a Medical Apheresis Nurse/RN. This position is responsible for the operation and performance of apheresis and therapeutic apheresis procedures on donors and patients. This role assists in the development of new procedures and review of procedures/policies pertaining to the apheresis program. Other essential duties include: Performing required apheresis equipment maintenance. Performing general nursing duties. Evaluating and maintaining technical procedures and policies as appropriate to the apheresis program. Communicating with physicians regarding patient status. Adhering to policies, procedures and standards within regulatory compliance, budgetary specifications, including time management, productivity, and accuracy of practice; ensures an adequate supply inventory. Maintaining all records required by AABB, FDA, and other accrediting agency or vendor standards, including procedure/patient care data forms. Participating in management of and coordination of clinical research studies using apheresis, when necessary. The successful candidate must be a Graduate of an accredited School of

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POSITIONS (continued from page 10)

Professional Nursing with a current RN license in good standing. Minimum of three years of recent direct patient nursing experience, preferably in an acute-care hospital environment. Prior RN experience in apheresis or acute/chronic dialysis is required. Current unrestricted Texas RN license or current unrestricted RN license from another state with the ability to acquire a Texas license within 90 days of hire. Certified in Basic Life Support. To apply, visit www.giveblood.org today! We are an EOE.

Technical Supervisor in our Consultation and Reference Lab. Gulf Coast Regional Blood Center is accepting applications for a Technical Supervisor in our Consultation and Reference Lab. This position reports to the Consultation & Reference Laboratory Manager and is responsible for all technical aspects of the Immunohematology Reference Lab program to include assisting in supervision of staff, development and maintenance of policies and procedures, and monitoring of quality assurance activities of the department. Other essential duties include: Organizes and supervises daily technical activities to ensure compliance with AABB IRL standards. Function as IRL Technical Supervisor/Consultant (CLIA >88), and maintain departmental documents as required. Performs testing and reviews of IRL cases. Performs other duties in the Consultation and Reference Laboratory as assigned. Evaluates/Monitors performance and quality of test results. Prepares lectures for and actively participates in local/regional industry committees/programs (AABB, ABC, other). Manages training and competency programs. Assists in interviewing, hiring, evaluating, counseling and dismissal of employees. Assists in preparation and maintenance of Standard Operating Procedures. Participates in QC and QA improvements within the department. The successful candidate must be an MLS (ASCP or equivalent) from an accredited program; SBB with a minimum of three years recent (within past two years) experience in blood banking and immunohematology plus supervisory experience. To apply, visit www.giveblood.org today! We are an EOE.

Chief Medical Officer (Associate Professor, Full Professor). The University of Washington, Department of Laboratory Medicine and Pathology and Bloodworks Northwest is accepting applications for Chief Medical Officer (Associate Professor, Full Professor). This position involves overall responsibilities for providing medical direction and support for all aspects of Bloodworks' activities. The position requires licensure as a physician (M.D. or D.O.) and board certification in Blood Banking/Transfusion Medicine. In lieu of board certification, candidates who meet the requirements for CLIA laboratory director with 3 years' experience in blood collections, immunohematology, apheresis, and cellular therapy will also be considered. University of Washington faculty engage in teaching, research, and service. Please apply at https://usr58.dayforcehcm.com/CandidatePortal/en-US/bloodworks/. EO employer – M/F/Vets/Disabled