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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2019 #34 **October 4, 2019**

INSIDE:

FDA Releases Bacterial Risk Control Guidance

The U.S. Food and Drug Administration (FDA) finalized the "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion Guidance for Industry" this week. Several changes were included as requested by America's Blood Centers (ABC) and other industry stakeholder's including the guidance implementation timeframe being extended from 12 to 18 months. Instead of approaching from 5 or 7-day options, the final guidance approaches from a single-step versus two-step process:

- The single-step strategies for apheresis and pre-storage pools of whole blood derived platelets rely on large volume, delayed sampling (LVDS) no sooner than 36 or 48-hours depending on intended expiration, 5 or 7 days respectively. The 36-hour sampling option with a 5-day expiration is new to the final guidance. This method could be implemented with current available culture technology that can hold sufficient sample volume. Currently, there are no LVDS devices approved for use in the U.S. with an appropriate safety claim to extend the expiration date to 6 or 7 days. The other single-step option is pathogen reduction which is already available. If products are intended to be split, you must culture all splits units.
- The two-step strategies for all platelet products involve an initial culture no sooner than 24 hours as is currently performed, but with a sampling volume of 16 mL split evenly between aerobic and anaerobic culture media. Initial cultures may be either from the main/"mother" bag or the split units. Step two involves secondary testing no sooner than day 3. Secondary testing is either a second culture or rapid test. The culture must use at least 8 mL in an aerobic medium. If products have been split, each split must be cultured.

Also, the FDA explained that platelet counts to determine platelet yield are not required after secondary testing has been performed. The ABC Quality Blood Regulatory Review Committee is working with ABC staff in developing the next round of advocacy comments that will be submitted to the FDA. Please provide any feedback on the final guidance to ABC Director of Regulatory Services Ruth Sylvester.

ABC also issued a statement that acknowledged the importance of the FDA extending the implementation period and encouraged the agency to continue assessing the impact of the guidance and the significant operational complexities that remain, which could affect patient access to platelets, especially in rural and underserved communities. "Hospitals and the patients they serve rely on independent blood centers to collect and distribute a continual, robust supply of blood components,

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FDA Releases Bacterial Risk Control Guidance (continued from page 1)

including platelets," said Kate Fry, MBA, CAE, ABC's Chief Executive Officer in the statement. "ABC appreciates the continued opportunity to work with the FDA to ensure patient access to life-saving transfusions. We are fully committed to the safety of the U.S. blood supply and wholeheartedly share the FDA's goal of reducing the risk of bacterial contamination in platelets while ensuring a robust supply of this essential blood component."

In August 2019, ABC provided additional feedback to FDA regarding the December 2018 draft guidance that shared the "operational concerns" of independent community blood centers and urged the agency to consider more strategies to prevent the potential for unintended consequences from the guidance that potentially could put patients at risk.

(Sources: FDA Guidance, 9/30/19; MCN 19-067, 9/30/19; ABC Statement, 10/3/19) ♦

REGULATORY NEWS

The U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) will be holding their next public meeting on November 22nd. The meeting will take place at the FDA Campus in Silver Spring, Md from 8:30 a.m. to 4:45 p.m. eastern. It will include discussions and scientific considerations for the transfusion of cold stored platelets products including:

- product characterization;
- duration of storage; and
- clinical indications for use.

The official meeting notice and additional information are available here. Meeting materials will be posted at a later date including a link to the webcast for those unable to attend.

(Source: Blood Products Advisory Committee Meeting Notice, 10/2/19)

The FDA has published the "Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus (HCV) Guidance for Industry." It includes recommendations for donations that are repeatedly reactive for HCV antibodies using a licensed screening test and is consistent for current HCV testing practices. The guidance also features the recommendation asked for in joint comments from America's Blood Center, AABB, and the American Red Cross, for clarifying language that further testing should be performed on an individual donation or a follow-up sample.

(Source: FDA Guidance, 10/2/19)

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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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REGULATORY NEWS (continued from page 2)

The FDA recently announced the publication of new Biological Product Deviation Reporting (BPDR) Codes. The codes can be accessed on the FDA website for both blood and human cell, tissue, and cellular and tissue-based product (HCT/P) products. Changes made on Oct. 1 are marked with a dagger (†). These codes are used in biological product deviation reports (BPDR), which report errors and accidents in the manufacturing of biological products. America's Blood Centers recommends that its member blood centers review the new BPDR codes for relevant changes as these may alter their reporting requirements.

(Source: FDA Blood and HCT/P BPDR Codes Announcements, 9/30/19)

BRIEFLY NOTED

President Trump is on the verge of announcing a chief medical executive at MD Anderson Cancer Center, Stephen Hahn, MD, as his nominee to be the next commissioner of the U.S. Food and Drug Administration (FDA). According to the report in *STAT News*, an official announcement could be forthcoming pending background checks by federal agencies. He would take over the role full-time for Ned Sharpless, MD, who has served as Acting Commissioner following the resignation of Scott Gottlieb, MD earlier this year. If nominated, Dr. Hahn would still need to be confirmed by the Senate. President Trump has until November 1st to make a formal nomination.

(Source: *STAT News*, Trump set to nominate Stephen Hahn as FDA commissioner, pending vetting process, 10/1/19)

The U.S. Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA) announced agreement with Platelet BioGenesis, Inc. to support the development of human induced pluripotent stem cell derived platelets, or PLT+, designed to assist in the treatment of thrombocytopenia and potentially improving platelet availability. "In a radiological or nuclear emergency, impacted communities will face a significant blood product shortage," said BARDA Director Rick Bright, PhD in an agency news release. "We are exploring donor-independent platelet technology to increase surge capacity within the blood industry. Our nation must find innovative ways to make essential blood products available to save lives in any type of mass casualty incident." The two-year agreement for $4.9 million will be a collaborative effort between BARDA and BioGenesis that could lead to the production of platelets outside the human body.

(Source: HHS Office of the Assistant Secretary for Preparedness and Response News Release, 9/30/19)

The International Medical Device Regulators Forum's (IMDRF) Medical Device Cybersecurity Working Group has published a draft guidance document for public comment entitled "Principles and Practices for Medical Device Cybersecurity." It is intended to provide fundamental concepts and considerations on best practices to facilitate international medical device cybersecurity convergence. More information including the consultation document is available on the IMDRF website. The IMDRF formed in February 2011 as a voluntarily convened group of medical device regulators from around the world that came together to build on the work of the Global Harmonization Task Force on Medical Devices, and to accelerate international medical device regulatory harmonization and convergence. The chairs of the Medical Device Cybersecurity Working Group are Suzanne Schwartz of the U.S. FDA and Marc Lamoureux of Health Canada.

(Source: IMDRF Announcement, 10/2/19)

Long-term Efficiency and Safety of Increasing Frequency of Whole Blood Donation (INTERVAL) Extension Study

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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

The original INTERVAL trial demonstrated over a two-year period, that the inter-donation intervals for whole blood donation could be safely reduced to meet blood shortages. This study was extended for two additional years to evaluate both the longer-term risks and benefits while comparing routine versus more intensive reminders to help donors keep appointments.

The results of this randomized trial with blood donors aged 18 and older from 25 fixed sites across England were published in *Lancet Haematology*. Participants agreed to continue trial participation on their originally allocated inter-donation intervals (men: 12 (standard), 10, and 8 weeks; women: 16 (standard), 14, and 12 weeks). They were randomized to routine vs. more intensive reminders. The intensive reminder system consisted of a three-step process that included email, text message, and phone call to encourage donation attendance, with a focus on donors missing appointments. The prespecified primary outcome was units of whole blood donations. Other secondary outcomes related to safety included:

- deferrals for low hemoglobin and other reasons;
- hemoglobin and ferritin concentrations; and
- quality of life and self-reported symptoms potentially related to blood donation.

Between October 19, 2014, and May 3, 2016, 20,757 donors (10,843 men, 9,914 women) participated in the study. Compared with routine reminders, more intensive reminders increased annual donations in men to 3.50 vs. 3.39 units ($p=0{\cdot}0003$) and mean 2.33 vs. 2.28 units ($p=0{\cdot}0094$) in women. Each week, the shorter inter-donation interval increased blood collection by a mean of 0.23 units per year in men and 0.14 units per year in women (both $p<0.0001$). More frequent donation also resulted in more deferrals for low hemoglobin (odds ratio per week 1.19 in men and 1.10 in women) and lower mean hemoglobin (difference per week –0.84 g/L in men and –0.45 g/L in women) and ferritin concentrations (percentage difference per week –6.5 percent in men and –5.3 percent in women; all $p<0{\cdot}0001$). No differences in quality of life were observed, nor serious adverse events, or self-reported symptoms other than a higher reported frequency of physician diagnosed low ferritin concentrations and prescription of iron supplements in men ($p<0.0001$).

During a period of up to four years, shorter inter-donation intervals and more intensive reminders resulted in potentially 75,000 more units of blood being collected without a detectable effect on donors' mental and physical wellbeing. The authors concluded that the findings suggested that blood collection services could safely use shorter donation intervals and more intensive reminders to meet shortages for donors who maintained adequate hemoglobin concentrations and iron stores.

An accompanying editorial emphasized that a dwindling (and aging) population of blood donors cannot be offset by reductions in use indefinitely. The editorial's author added that there is an inherent tension between the need for donations and the establishment of policies that protect donor health. Ongoing research is seeking to apply the principles of personalized medicine to blood donors such that donation programs could be created that consider the features of an individual donor's iron management, both with respect to supplements and their individual physiology. Such algorithms could move the industry away

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Whole Blood Donation INTERVAL Extension Study (continued from page 4)

from a one-size-fits-all policy and lead to high frequency donation by donors who can safely do so (e.g. super donors as they are called) and tailored inter-donation intervals for other donors who are at greater risk of anemia.

Citations: Kaptoge, S., Di Angelantonio, E., Moore, C. Longer-term efficiency and safety of increasing the frequency of whole blood donation (INTERVAL): extension study of a randomised trial of 20,757 blood donors. *Lancet Haematology*. 2019. Doi: 10.1016/S2352-3026(19)30106-1.

Devine, D. Ironing out frequent blood donation. *Lancet Haematology*. 2019. Doi: 10.1016/S2352-3026(19)30162-0.

WORD IN WASHINGTON

President Trump signed a temporary spending bill on September 27th to avert a shutdown of the federal government. The Senate passed a stopgap measure late last week to fund the federal government through November 21st of this year. The continuing resolution followed the House approving a short-term spending bill on September 19th that covered all federal agencies buying lawmakers more time to work towards a long-term spending bill.

(Source: *The Hill*, Trump signs stopgap measure, funding government through November, 9/27/19)

MEMBER NEWS

Versiti, Inc. recently announced that two members of its leadership team will each be honored with 2019 AABB President's Awards. Dan Waxman, MD, vice president of Transfusion Medicine Blood Services at Versiti, Inc. and senior medical director of Versiti Blood Center of Indiana, and Sue Johnson, director of Clinical Education and director of the Specialist in Blood Banking (SBB) Program at Versiti, Inc., are being recognized for extraordinary public service and contributions in healthcare that helps further the mission and goals of AABB. "I've been so fortunate to work with many dedicated members during my tenure with AABB and am grateful to receive this recognition," said Dr. Waxman in a Versiti, Inc. news release. Both he and Ms. Johnson will receive their awards in San Antonio during the 2019 AABB Annual Meeting later this this month. "It's an honor to be recognized for being a voice of the unsung Medical Laboratory Scientists/Specialists in Blood Banking in the lab who play a critical role in ensuring patients receive the blood they need," added Ms. Johnson in the release.

(Source: Versiti, Inc. News Release, 10/3/19)

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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.

Facebook Prepares for National Rollout of Blood Donation Tool

As previously announced, Facebook launched a pilot of their blood donation tool in June of this year. America's Blood Centers (ABC) has been informed that Facebook will now begin the process of expanding nationwide and expects all blood centers that are interested to be live on the tool over the course of the next six to eight weeks. Several ABC members have volunteered to participate in the testing phase of a self-service feature that will allow blood centers to manage the onboarding of their fixed facilities into the blood donation tool.

Assuming no setbacks or major issues, all non-testing centers will be able to start using the tool at the end of October/early November. Additional information will be made available as it is obtained. Facebook will be able to share instructions on how to use the tool with a wider audience and anticipates having the training materials uploaded and made available publicly to empower centers with the ability to onboard themselves. Please feel free to reach out with any questions or concerns.

(Source: MCN 19-070, 10/3/19)

ABC Seeks Member Participation in 2019 Service Fee Survey

America's Blood Centers has launched the annual survey of member service fees. Members are encouraged to participate by completing the online survey available in MCN 19-065. The results from this survey are important in assisting ABC in its advocacy efforts on behalf of member blood centers for better reimbursement for blood products. Only aggregate data will be reported and no individual data or identifiable information from any center will be shared. A copy of the survey questions is also available in the MCN.

(Source: MCN 19-065, 9/19/19)♦

ABC 2020 Meetings & Workshops

Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9th-11th	Washington, D.C.	Ritz-Carlton (Pentagon City)	More details coming soon!
ADRP 2020 Conference	May 19th-21st	Phoenix, Ariz.	Hyatt Regency	More details coming soon!

Notes:

For the most up-to-date information on all events, members of ABC may check the calendar on ABC's Member Site.

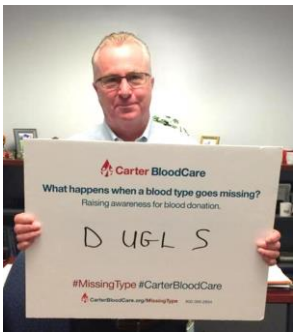
Non-members may attend all events; information will be updated on ABC's Public Site.

IN MEMORIAM

Dr. Shuping Wang, a medical doctor that exposed the role of paid plasma donations in the spread of HIV and hepatitis C in rural parts of China in the 1990s passed away on September 21st at the age of 59. She is considered an unsung hero for her role as a whistleblower in exposing the truth about the epidemics even challenging Chinese government officials for their lack of oversight into the practices of Chinese plasma centers during that time. Dr. Wang and her family faced criticism and persecution, resulting in her moving to the U.S. in 2001, where she continued her work as a medical researcher. "[Dr.] Shuping was the earliest medical worker to enter the fray in the war against AIDS," said Gao Yaojie, a doctor from Henan, China, according to a report in the *New York Times*. "For this, she suffered the most grievous attacks and pain of her life." A stage play based on her life story recently debuted in London. "She had the courage to keep collecting and sharing evidence even when officials didn't want information revealed," said Zhang Jicheng, a former Henan journalist, to the *New York Times*. "She had no official support; this was her personal choice, and she suffered for it."

Photo courtesy of the New York Times.

(Source: *New York Times*, Shuping Wang, who helped expose China's rural AIDS crisis, dies at 59, 9/30/19)



Doug Heath as he participated with Carter BloodCare's Missing Type Campaign, with ABC, in 2016.

Innovative, diligent, and patient-focused. These are just a few words that describe who **Doug Heath** was to his colleagues and the operations function of the blood banking industry, in which he worked for 40 years. The director of Laboratory Operations for Carter BloodCare died Saturday, September 28, 2019. Mr. Heath is survived by his wife, Virginia, and two adult children. He is already missed by many people. He began his blood banking career in the summer of 1980 as a hospital services representative for Gulf Coast Regional Blood Center. His consistent work-ethic and extreme determination earned him a supervisory position within a year. Mr. Heath eventually moved to BloodCare of Dallas prior to the merger with Carter Blood Center of Fort Worth. He had incredible knowledge of and a knack for blood product management; which gave way to his many bold and successful ideas. One of his greatest contributions was helping to develop a new resource-sharing inventory practice; it allowed blood centers to report, manage, and distribute blood products among themselves, based on each other's needs. This practice is now widely used in the larger blood banking community. Mr. Heath's extensive resource-sharing experience was pivotal in his career, as it not only improved operations, but helped create a seamless transition between BloodCare and Carter Blood Center's distribution/hospital services teams during the Carter BloodCare merger. He was also instrumental in shipment logistics, as demonstrated during the many natural disasters that struck throughout his career; including Hurricane Harvey and others outside of the Carter BloodCare region that required blood product support. One example of this, as recalled by a colleague, was during Hurricane Alicia (1983) in Houston, Texas. Mr. Heath and other hospital service representatives were the few Gulf Coast employees present at the blood center as the hurricane made landfall. They managed operations for nearly 72 hours straight, making sure STAT blood orders were filled for Houston-area hospitals. Mr. Heath's colleagues admired his commitment to hospital patients. Providing for their needs was his priority and everything else followed. They also say that he truly redefined what it meant to be a blood banker, outside of technical services. Mr. Heath was a gem in this industry and personally. He will be dearly missed by Carter BloodCare and his numerous blood banking friends and counterparts. His family is hosting a celebration of his life Saturday, October 5th in Bedford, Texas.

(Source: Carter BloodCare Announcement, 10/1/19)

Contributed by Keoni Holoman, Public Relations Specialist, Carter BloodCare ♦

Letter to the Editor – Securing the future of the U.S. blood supply: an open letter to the health care community

Please note: The views/comments expressed in submitted letters from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers.

Dear Editor,

Driven by the growing fragility of the U.S. blood supply, it was a year ago I addressed the industry on the need for action. A rally call, so to speak, for healthcare providers and blood collectors to work in tandem to protect our nation's blood system before patient care is meaningfully harmed by inadequate supplies and limited product advancements.

Progress has been made to restore a more stable blood supply, however, obstacles remain. Industry demand for red blood cells continues to decline. While the pace of deterioration has slowed, its disruption to blood center operations and financial stability has not. Blood providers still confront the very real challenges of rightsizing their operations while working to fill the distinct demand for products like O negative red cells, AB plasma, pediatric units, and whole blood to meet the changing needs of the hospitals they serve.

Conversely, platelet use has grown nearly four percent each of the past four years. The U.S. transfuses more than 7,000 platelets a day and frequent shortages may indicate the true need is even greater. Worse, hospitals outside medium and large-sized cities often have limited access to platelets leaving their patients vulnerable to suboptimal care. The short two to three-day shelf life post-processing and bacterial testing make for a near-constant struggle with the donor-dependent supply.

This demand imbalance between platelets and red cells only increases the challenge of attracting and directing the right donors to the right blood drives to collect the optimum products. Universal and rare type donors are essential when stocking fewer products but recruiting and retaining these donors proves difficult and costly. With less than 10 percent of the eligible population donating blood, blood centers must operate a carefully orchestrated supply chain that can easily be upset by unplanned events. Natural disasters such as this year's Polar Vortex wreak havoc on a well-balanced supply network and results in weeks-long recovery times.

Intensifying the risk of too few eligible donors is the rapid proliferation of paid plasma collections and the potential cannibalization of volunteer blood donations. Plasma collections in the U.S. have nearly quadrupled since 2005. Both volunteer and paid plasma collections are important contributors to healthcare, however, U.S. paid plasma collections far exceed the U.S. demand for the resulting therapies.

The remainder of the letter in its entirety is available here.

Chris Hrouda
President, Biomedical Services
American Red Cross

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 in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2019

Oct. 15-16. **Biomedical Advanced Research and Development Authority Industry Day 2019, Washington, D.C.** More details available here.

Oct. 19-22. **2019 AABB Annual Meeting, San Antonio Texas.** More information available here.

Nov. 12-14. **U.S. Food and Drug Administration Center for Drug Evaluation and Research Small Business and Industry Assistance Clinical Investigator Training Course, College Park, Md.** More details available here.

2020

Jan. 14-15. **IPFA/EBA Workshop on Plasma Collection, Location to be announced.** More details available here.

Mar. 9-11. **2020 ABC Annual Meeting, Washington, D.C.** More details coming soon.

Mar. 25-26. **IPFA 5th Asia Workshop on Plasma Quality and Supply, Thailand.** More details available here.

April 14-15. **16th Annual U.S. Food and Drug Administration and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** More details available here.

May 13-14. **IPFA/PEI 27th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal.** More details available here.

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details coming soon.

Upcoming ABC Webinars – Don't Miss Out!

- **Staffing Success & Challengers at Blood Centers Webinar** – November 19th from 3 - 4:30 p.m. (ET). Additional details coming soon!
- **SMT Journal Club Webinar** – December 5th from 12 – 1 p.m.(ET). Additional details coming soon!
- **Irradiator Replacement at Blood Centers Webinar** – January 21st from 3 – 4:30 p.m. (ET). Additional details coming soon!

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!

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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

Laboratory Operations Supervisor. Cascade Regional Blood Services in Tacoma, Washington is looking for a Laboratory Operations Supervisor. The Laboratory Operations Supervisor will be responsible for all operational oversight of the laboratory, including Hospital Services, Components Laboratory, and QC Testing. Supervise staff, in coordination with Technical Director, to ensure compliance with all SOP, FDA, and AABB regulations. Monitors performance in the areas of productivity, proficiency, and customer service. Ensures blood bank maintains adequate inventory and imports or exports as necessary. Education/Certification: Baccalaureate degree in medical technology or biological science, with a minimum of five years' experience in blood center, transfusion medicine, cellular therapy, clinical laboratory or related field. MT/MLS/SBB (ASCP) strongly preferred. MLT may be considered with relevant experience. Experience Required: Demonstrated familiarity with quality assurance requirements, blood banking, cell processing and cryopreservation, sterile technique and safe handling of potentially infectious human blood/tissues. Demonstrated knowledge of cGMPs, cGTPs and principles of QA/QC. Working knowledge of AABB and related FDA regulations. Minimum of three years of relevant supervisory experience. Team or project leadership experience preferred. Apply at: www.crbs.net/job-opportunities.

Physician/Chief, Infectious Diseases Section. The Department of Transfusion Medicine in the Clinical Center, National Institutes of Health is recruiting a physician faculty member to oversee the Infectious Disease Section, provide medical support for Clinical Center patients and perform subspecialty consultation related to infection transmission through blood, blood components, and cellular therapies. The successful candidate will oversee a section of 14 staff including a CLIA-approved testing laboratory. Additional functions include research related to transfusion-transmitted infections, and teaching in an ACGME-accredited training fellowship in Transfusion Medicine. The Department of Transfusion Medicine is a full-service collector and provider of blood, blood components and cellular therapies. The position requires detailed knowledge of molecular, genetic testing for transfusion-transmitted agents. Candidates must be board certified or eligible in Blood Banking / Transfusion Medicine, Hematology, Infectious Disease, appropriate subspecialty certification(s) must have an M.D. or equivalent degree and must possess an active, current, full, and unrestricted license or registration as a physician from a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States. Salary commensurate with training and experience. Please submit your curriculum vitae and a letter describing your skills and experience by Nov. 4, 2019 to: Lacey Gholson, Administrative Officer, NIH/CC/DTM, 10 Center Drive, Building 10/Room 1C711 (MSC 1184), Bethesda, Maryland 20892-1184. DHHS AND NIH ARE EQUAL OPPORTUNITY EMPLOYERS.

Senior Regulatory Affairs Officer (Macopharma USA). Responsibilities include: Develops appropriate regulatory strategy for bringing Macopharma Transfusion and Biotherapy products (Medical Devices and Drugs to the US). Identifies the status of the product according to the country (Medical Device, medicine). Sets the elements necessary for the compilation of files according to the regulations and regulatory guidelines. Collects data to assess compliance with the expectations of the authorities. Edits and submits the registration file to the competent authorities or notified bodies. Develop good relationships with the authorities. Keeps abreast of regulatory changes and analyze whether these changes have an impact on our business. Exchange with the service Materio/Pharmaco/ Biovigilance as part of risk management plans, the submission of periodic reports vigilance and change requests for medical information. Skills and requirements: Education and experience with FDA submissions/registrations for medical devices and drugs. Four years degree required in scientific field. Ability to multi-task effectively under tight deadlines. Expertise with Microsoft Package. Excellent organization and follow-up skills. High level accuracy and attention to detail. High level of discretion and confidentiality. Ability to communicate in a clear and articulate manner. By interest please forward your application to stephanie.ehrenberg@macopharma.de.

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the Massachusetts General Hospital seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor

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POSITIONS (continued from page 10)

cell collection and processing. Service and teaching responsibilities will be shared with three other full and part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ233, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Director of Collections (Full Time). We are looking for inspirational leader, customer-focused individuals who value integrity, accountability, collaboration and communication, to join our team as the Director of Collections. We are the sole blood bank for the State of Hawaii. We need people who are dependable, detail-oriented and comfortable following established procedures. For more information about us, visit our website at https://www.bbh.org/. This position reports directly to the Chief Operating Officer and the ideal Director of Collections candidate is a highly motivated individual with exceptional customer service skills who is able to work independently while managing multiple priorities and provides effective leadership, supervision and direction to ensure excellent services and an adequate, safe, pure and potent blood supply for the operations of Collections. Must possess excellent written and verbal communication skills, be organized and creative, and have the ability to effectively evaluate and solve critical problems. Minimum of eight years' progressively responsible experience in a blood center, healthcare or other relevant environment with a minimum of five years' proven experience in positive management of multiple direct reports and budget experience. For complete job description and to apply, send resumes to hr@bbh.org.

Reference Laboratory Supervisor (Full Time). Blood Bank of Hawaii (BBH) is seeking a successful leader to oversee and coordinate all reference lab work and product quality control testing services. We are a nonprofit, community-based organization that provides blood components and clinical/technical services to hospitals, and patients throughout Hawaii. The ideal candidate will encompass a high standard for accuracy, follow-up and follow-through, and thrive in an environment where problem solving is a necessity. Will work with team members ensuring compliance at all times, and will also be responsible for the supervisory functions offering support and guidance to personnel. The incumbent will also serve as a technical resource to hospitals and other departments outside their primary responsibility. Minimum qualifications include baccalaureate degree in Medical Technology or in a related science from an accredited college or university; certified Medical Technologist by the ASCP. Previous work experience as an MT in hematology and immunohematology preferred. To apply, please submit a resume and cover letter to HR@bbh.org. BBH is an equal opportunity employer. We do not discriminate on the basis of age, race, sex, religion, color, national origin, ancestry, marital status, disability, sexual orientation, arrest and court record or any other protected category recognized by state and federal laws.

Assistant Manager of Component Laboratory. Innovative Blood Resources is seeking an Assistant Manager of Component Laboratory. Responsibilities: Supervise personnel and coordinate operations with the component evening lab. Ensure the lab's compliance and help with process improvement. Provide manufacturing support to staff when needed. Qualifications: Bachelor's degree: in Chemical, Physical, Biological Science, or Medical Technology. Two years component laboratory experience and one year supervisory. Experience with data management systems and Microsoft Suite. Apply today! View full job descriptions on www.innovativebloodresources.org/careers/. Applicants must apply and submit a resume online to be considered.

Clinical Lab Manager (San Francisco, CA; Req: 191475). Since 1941, Vitalant (formerly known as Blood Centers of the Pacific) has proudly served as a leader in the blood banking industry. We are a globally-recognized leader in blood transfusion medicine. Requirements: Bachelor's degree required. Master's degree preferred. Must satisfy CLIA requirements for High Complexity Testing required. Immunohematology Reference Laboratory (IRL). Specialist in Blood Banking (SBB) certification required. CA CLS/MT required. Seven years clinical laboratory experience required. To include: three years supervisory experience. Previous supervisory experience and experience in molecular techniques, immunohematology/ IRL techniques, automated testing preferred. Please click here to apply. EOE

Medical Director. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a Medical Director. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. This position includes the option of

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free medical coverage with a competitive benefits package, 403(b) retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, and much more. This position will be based out of the Ft. Lauderdale, Florida area, with some of the most gorgeous beaches in the nation! If you want to join our life saving mission and team of dedicated employees, visit our ***Careers*** page at www.oneblood.org to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability.