

A B C N E W S L E T T E R

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2020 #17

May 8, 2020

Community Blood Centers Continue COVID-19 Response Efforts through Collection of Convalescent Plasma

Community Blood Centers Update. America's Blood Centers (ABC) members and blood centers around the country have continued to be at the forefront of responding to the COVID-19 pandemic by mobilizing to collect convalescent plasma from recovered COVID-19 patients to assist individuals battling COVID-19. Through a <u>partnership</u> between ABC and the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, both ABC members and Blood Centers of America, Inc. members shipped more than 6,000 units of COVID-19 convalescent plasma (CCP) including more than 5,000 to expanded access protocol (EAP) hospitals in March and April. These figures are expected to increase significantly this month as centers ramp up their efforts to ensure its availability for patients throughout the U.S.

FDA Answers Questions Regarding CCP. ABC reached out to officials at the U.S. Food and Drug Administration seeking answers for questions asked by member blood centers concerning under what conditions, excess CCP can be sent for further manufacturing into hyperimmune globulin (HIG) by centers not currently licensed to collect source plasma. When asked if CCP/apheresis FFP/PF24 could be collected and relabeled for further manufacturing prior to the one-year expiration date by centers who do not hold a source license, the agency answered, "[i]f blood centers wish to also collect COVID-19 convalescent plasma for further manufacture after the transfusion demand is met, they may do so provided the units are used for investigational use, such as for the development of hyperimmune globulin, under the applicable [investigational new drug applications] (INDs). We do not object if they release the apheresis plasma for further manufacture sooner than one year after collection for investigational use."

Additionally, centers sought clarification on whether they could collect CCP units for further manufacture from donors who test positive for HLA antibodies, RBC allo-antibodies, or at risk for malaria transmission and are not eligible for CCP for transfusion. FDA responded, "Blood centers that intend to release COVID-19 convalescent plasma for further manufacture after the transfusion demand is met must follow all donor eligibility requirements and qualifications under the applicable IND. We recommend that you touch base with the IND sponsor regarding the use of HLA-antibody positive units for their IND. That might not be desirable or accepted by the IND sponsor for further manufacture into investigational hyperimmune globulin." The full question and answer document and additional information can be found within MCN 20-056 on the ABC member website.

(Source: <u>MCN 20-056</u>, 5/7/20) ♦

INSIDE:

REGULATORY NEWS 2
RESEARCH IN BRIEF 2
BRIEFLY NOTED 3
WORD IN WASHINGTON
2020 ABC MD Workshop and Summer Summit is Going Virtual5
May 2020 Convalescent Plasma <i>Blood Bulletin</i> Updated5
MEMBER NEWS 5
COMPANY NEWS 6
GLOBAL NEWS7
CALENDAR 8
POSITIONS8

REGULATORY NEWS

ABC Newsletter

The U.S. Food and Drug Administration (FDA) released its final <u>guidance</u> this week on "Implementation of Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components." This guidance replaces the previous guidance from May 2016.

(Source: FDA <u>Guidance</u>, 5/5/20) ♦

RESEARCH IN BRIEF

COVID-19 and Its Effects on the Supply of Substances of Human Origin (SoHo). Recently, the European Centre for Disease Prevention and Control published a technical report "provid[ing] a risk assessment and management options for the safe and sustainable supply of SoHO" due to the COVID-19 pandemic. This includes blood and blood components which are considered to be 'critical SoHO', as there are typically "no alternative therapies" and it is "often life-saving and there are limited possibilities for storage." The report discusses treatment options such as convalescent plasma which remains under investigation as a potential therapy for improved outcomes in recipients including two small studies in China that support investigating convalescent plasma further in clinical trials. It also notes that there is no known risk of transmission of coronaviruses via blood transfusion. The report further states "the cell-entry molecules for SARS-CoV-2, the human angiotensin-converting enzyme 2 (hACE 2) receptors, are not detected in red blood cells, and are absent or present in very limited amounts in immunocytes and lymphatic cells. This implies that SARS-Cov-2 infection of blood cells is unlikely." It continues by describing how "data from Germany on a small sample of patients showed that no SARS-CoV-2 genome could be detected in the blood of asymptomatic patients or patients with less pronounced symptoms." The report notes "that the risk of SARS-CoV-2 transmission through blood components in asymptomatic donors seemed negligible." However, it also notes the potential risk to staff members in SoHo establishments including potential encounters with an infectious asymptomatic donor who could infect "attending staff or other donors in the waiting rooms." At this time, SoHO establishments have not reported any such cases. The pandemic heightens sustainability concerns about the blood supply being "particularly vulnerable as it requires daily frequent blood donations, and labile blood components have limited storage time and are generally irreplaceable." While there have been no reports of serious disruptions in the blood supply so far in the European Union, "these shortages have been largely mitigated by a decrease in demand due to the cancellation of elective surgeries and increased/adapted donor recruitment." The report further describes how the hospital response should include "implementation of patient blood management and a thorough evaluation of the appropriateness of blood component requests." It adds that blood centers should consider pre-selection measures that may include donations by appointment and triaging of donor's temperature at reception. This regulates the donor flow at the blood center and "enable[s] physical distancing and detect[s] those potentially infectious." Finally, it states the importance for the European Union and member states to "support" SoHO establishments in the development and implementation of business continuity plans due to the COVID-19 pandemic.

Citation: <u>Coronavirus disease – 2019 (COVID-19) and supply of substances of human origin in EU/EEA-</u> <u>first update</u>. European Centre for Disease Prevention and Control. April 2020.

Contributed by Richard Gammon, MD, Medical Director at OneBlood





BRIEFLY NOTED

ABC Newsletter

The U.S. Food and Drug Administration has revised its policy on antibody tests in the "Policy for Coronavirus Disease-2019 Tests During Public Health Emergency" guidance. It supersedes the March 16th guidance and aims to "to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency… This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve more rapid and widespread testing capacity in the United States." It outlines new expectations for the development of SARS-CoV-2 antibody tests:

- [c]ommercial manufacturers will submit Emergency Use Authorization (EUA) requests, with their validation data, within 10 business days from the date they notified the FDA of their validation testing or from the date of this policy, whichever is later;
- [f]urthermore, the FDA has provided specific performance threshold recommendations for specificity and sensitivity for all serology test developers.

(Sources: FDA Voices, <u>FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy</u>, 5/4/20; FDA <u>Guidance</u>, 5/4/20)

Gary Disbrow has been named acting director of the Biomedical Advanced Research and Development Authority (BARDA), a part of the U.S. Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR). Dr. Disbrow joined BARDA in 2007 and most recently served as the Deputy Assistant Secretary (ASPR) and the Medical Countermeasures Program Director. Prior to his time at BARDA, he worked as an assistant professor of Oncology and Pathology at Georgetown Medical Center. He succeeds Rick Bright, PhD who had held the position of BARDA Director since 2016.

(Source: BARDA <u>Announcement</u>, 4/26/20) •

RESEARCH BRIEFS

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

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail. Contents and views expressed are not official statements of ABC or its Board of Directors. Copyright 2020 by America's Blood Centers. Reproduction of the *ABC Newsletter* is forbidden unless permission is granted by the publisher. (ABC members need not obtain prior permission if proper credit is given.)

ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

America's Blood Centers

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

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



WORD IN WASHINGTON

ABC Newsletter

The U.S. Department of Homeland Security (DHS) Cybersecurity and Infrastructure Security Agency (CISA) and the United Kingdom's National Cyber Security Centre (NCSC) disseminated a joint alert this week warning that advanced and persistent threat (APT) groups are targeting organizations involved in the COVID-19 pandemic response. The alert includes healthcare entities, medical research organizations, and pharmaceutical companies as, "APT actors frequently target organizations in order to collect bulk personal information, intellectual property, and intelligence that aligns with national priorities...CISA and NCSC are actively investigating large-scale password spraying campaigns conducted by APT groups. These actors are using this type of attack to target healthcare entities in a number of countries—including the United Kingdom and the United States—as well as international healthcare organizations. Password spraying is a commonly used style of brute force attack in which the attacker tries a single and commonly used password against many accounts before moving on to try a second password, and so on. This technique allows the attacker to remain undetected by avoiding rapid or frequent account lockouts. These attacks are successful because, for any given large set of users, there will likely be some with common passwords." More information is available on the DHS website.

(Source: DHS and NCSC Joint <u>Alert</u>, 5/5/20)

Sens. Tammy Baldwin (D-Wis.), Chris Murphy (D-Conn.), and Chuck Schumer (D-N.Y.) introduced legislation last week to federalize the medical supply chain in hopes of, "adding critical oversight and transparency to the supply chain for critical medical supplies and equipment," according to a news release. Requirements within the proposed legislation would include:

- publicly report national assessments on a weekly basis to determine national critical equipment supply and requirements;
- establish an Executive Officer to oversee acquisition and logistics for COVID-19 equipment production and delivery;
- increase transparency regarding the distribution of supplies and equipment;
- a comprehensive plan for COVID–19 testing, including viral and antibody testing;
- a GAO report to identify lessons learned and make recommendations on future pandemic response; and
- establish an Inspector General to oversee implementation of the Act.

"Our legislation will help respond to this public health crisis and prepare for the future by unlocking the full authority and power of the Defense Production Act to scale up nation-wide production of the testing supplies, personal protective equipment, and medical equipment our health care workers need to protect themselves, take care of patients, and save lives," said Sen. Baldwin in the release.

(Source: Sen. Tammy Baldwin News <u>Release</u>, 4/29/20) •

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The <u>calendar of events</u> 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!



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

2020 ABC MD Workshop and Summer Summit is Going Virtual

After careful consideration, America's Blood Centers (ABC) has decided to transition the 2020 ABC Medical Directors Workshop and Summer Summit to a virtual event. We believe this ensures the safety of our attendees and staff while continuing to offer opportunities to network and discuss the most pressing issues facing the industry. ABC is currently evaluating platforms and adjusting the program to reflect the new format and will have additional details in the coming weeks and months. Thank you for your patience during this process, and for your continued support of ABC.

(Source: <u>MCN 20-053</u>, 5/4/20)

ABC Newsletter

May 2020 Convalescent Plasma Blood Bulletin Updated

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

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

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

MEMBER NEWS

New York Blood Center has <u>partnered</u> with the Baylor College of Medicine's National School of Tropical Medicine, PATH, and the Center for Vaccine Development at Texas Children's Hospital in hopes of expediting the development process of a potential vaccine for COVID-19. Previously, the organizations worked as part of a consortium to "advance recombinant protein vaccines" for severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). The news release states that the new partnership aims to "generate proof-of-concept safety and immunological data in humans for a vaccine candidate originally developed by this consortium against SARS, but that also may have the ability to prevent COVID-19 because of genetic similarities, cross-protection, and neutralization between the SARS and COVID-19 coronaviruses." Deborah Higgins, senior director for PATH's Center for Vaccine Innovation and Access added in the news release that, "[a] vaccine is needed as soon as possible to provide protection against COVID-19, interrupt transmission and prevent future outbreaks globally, but it is especially critical in parts of the world where health systems are weaker and mitigation efforts like hand washing or social

(continued on page 6)

May 8, 2020

-5-

<u>MEMBER NEWS</u> (continued from page 5)

distancing are not feasible. As such, this collaboration is an important step toward understanding this vaccine candidate's potential as a COVID-19 prevention tool and ensuring that it can be within reach for everyone if successful, no matter where one lives."

(Source: Baylor College of Medicine News <u>Release</u>, 5/5/20)

Gulf Coast Regional Blood Center teamed up with the National Basketball Association's (NBA) Houston Rockets for a blood drive this week at the teams' basketball arena to support the local community and assist response efforts to the COVID-19 pandemic. "The blood drive today, we're going to do 150-plus people it looks like," said Rockets CEO Tad Brown to <u>USA TODAY</u>. "This is going to help the system really respond to the people in need. It's just such an honor to be able to do this."

(Source: USA TODAY, Rockets host blood drive at Toyota Center to aid COVID-19 response, 5/5/20)

COMPANY NEWS

Roche announced on May 3rd that it has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for a SARS-CoV-2 antibody test. The company states that the test "has a specificity greater than 99.8 percent and 100 percent sensitivity (14 Days post-PCR confirmation)" in a news <u>release</u>. "Thanks to the enormous efforts of our dedicated colleagues we are now able to deliver a high-quality antibody test in high quantities," said Roche Group CEO Severin Schwan, in the release. "I am in particular pleased about the high specificity and sensitivity of our test, which is crucial to support health care systems around the world with a reliable tool to better manage the COVID-19 health crisis." The test will be available for use in countries accepting CE mark and in the U.S. under EUA.

(Roche News Release, 5/3/20)

Hologic, Inc. has developed a second molecular assay to test for SARS-CoV-2. The company has begun distributing a "research use only" version of the test this week as it applies for EUA from the FDA while also registering a CE mark for diagnostic use in Europe later this month. Funding for the test is part of \$13 million in support from the Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response. "The ability to deliver test results when and where they are needed — so people can either get back to work or quarantine themselves — has emerged as a key to re-opening global economies," said Hologic, Inc. Chairman, President, and Chief Executive Officer Steve MacMillan in a news <u>release</u>. "We are responding to this need by developing a second test that can be produced in much larger quantities than our first and run on a much larger installed base of instruments."

(Source: Hologic News Release, 4/29/20)

Cellphire, Inc. recently announced that BARDA will continue its support of a phase two clinical trial in bleeding thrombocytopenic patients to assess the efficacy a platelet-based freeze-dried hemostatic product, Thrombosomes®. "The continued funding commitment from BARDA is a testament to the government's foresight and recognition of the potential of Thrombosomes® to stop bleeding and be readily available at all treatment levels to secure the nation's blood supply," said Cellphire, Inc. President G. Michael Fitzpatrick, PhD in a news <u>release</u>. "In partnering with BARDA, we have developed a product that could be stockpiled to potentially alleviate shortage or critical supply situations occurring during natural disasters,

f **Y O** May 8, 2020

<u>COMPANY NEWS</u> (continued from page 6)

radiological accident or attack, or pandemics like COVID-19. We look forward to continuing our partnership with BARDA and bringing Thrombosomes® through to FDA approval." BARDA and Cellphire, Inc. have partnered since 2013 to advance the development of freeze-dried platelets for disaster response.

(Source: Cellphire, Inc. News <u>Release</u>, 4/21/20) •

GLOBAL NEWS

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom, announced that transfusions of COVID-19 convalescent plasma (CCP) have begun taking place at hospitals in England. "We're delighted the first patients are receiving convalescent plasma transfusions thanks to the generosity of our donors," said NHSBT Chief Medical Officer, Gail Miflin in a news release. "We're carrying out a clinical trial to see how effective transfusions are and we wish every patient well. Several hospitals are already taking part and this number will quickly grow as more people become eligible to donate plasma... Plasmapheresis donation is new to NHSBT but we're quickly increasing appointments and we've taken more than 400 donations so far. We're rapidly building collection capacity so that if our trial shows the transfusions are effective, we can supply hospitals at a large scale." NHSBT is working to expand CCP collections to all 23 of its donor centers. CCP transfusions will be taking place as a part of the international REMAP-CAP trial. According to Anthony Gordon, a professor at Imperial College London, in the NHSBT news release, "[t]he REMAP-CAP trial has been specifically designed to provide answers about the best treatment options for the most seriously ill with COVID-19. It is fully adaptive, meaning that new treatments can be added as we learn more, the sample size isn't fixed and it keeps recruiting until it finds that a treatment is better, worse, or the same as another. It also 'learns' from that data so that patients are more likely to receive those interventions that are performing best."

(Source: NHSBT News <u>Release</u>, 5/7/20)

Health Canada, the regulatory body for blood centers in Canada, announced that it has authorized the CONCOR-1 clinical trial to explore the use of convalescent plasma collected from recovered COVID-19 patients as a potential treatment for individuals with COVID-19. A news release stated that the study, "is designed to assess the safety and effectiveness of administering convalescent plasma collected from donors who have recovered from COVID-19, to patients admitted to hospital with COVID-19, to decrease the risk of serious disease and prevent death. Canadian Blood Services and Héma-Québec are responsible for the collection and processing of donor plasma for this clinical trial. More than 40 hospitals across the country will participate in this national study. Establishments that wish to collect convalescent plasma, must meet acceptable quality and safety requirements in accordance with the applicable Health Canada authorizations."

(Health Canada News <u>Release</u>, 5/1/20)

Canceled Meetings

May 12-13. AABB and Mayo Clinic Laboratories Transfuse 2020, Rochester, Minn. 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 <u>here</u>.

f Y 0

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 <u>newsletter@americasblood.org</u> or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2020

Aug. 28-29. 64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif. More details available here.

Sept. 9. 10th Annual Symposium Red Cell Genotyping 2020: Visionary Solutions, Bethesda, Md. More details available here.

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

Sept. 23-25. 4th European Conference on Donor Health and Management, Hamburg, Germany. More details available <u>here</u>.

Oct. 3-6. 2020 AABB Annual Meeting, Baltimore, Md. More information available here.

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

CLASSIFIED ADVERTISING

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

POSITIONS

Recruitment Director. Kentucky Blood Center (KBC) is seeking a dynamic professional to lead a team of Donor Recruitment Specialists who are responsible for growing the donor base by promoting blood donation and recruiting organizations and community groups to sponsor blood drives. The individual will motivate and mentor the team, managing performance to established goals, and will provide continuing education and development opportunities. The position is responsible for the utilization of data analysis in developing and implementing effective recruitment strategies and in setting donation projections. The ideal candidate will possess exceptional interpersonal and marketing skills, and will be goal-oriented, a creative thinker and problem solver, and a team player driven by a desire to help others. They must proactively identify, build, and maintain strong strategic alliances for the advancement of KBC's mission. Some regular in-state travel is required. Qualifications: Bachelor's degree in business, marketing/communications, or a related major. Minimum of 5 years of demonstrated success in sales/account management; 2 years of management experience. Excellent writing, public speaking/presentation, and interpersonal skills. MS Office proficiency; web-based applications, and internal software/systems. Valid Kentucky Driver's License. Click here to apply.

Director of Quality Assurance. Blood Assurance is seeking a Director of Quality Assurance to work in our downtown Chattanooga facility. The Director monitors the facility's compliance with all applicable standards and regulations and is responsible for the oversight of all activities relating to product quality. Determines appropriate Standard Operating Procedures (SOP's) exist for all manufacturing procedures and staff is appropriately qualified, trained, and competent. Evaluates reports of manufacturing errors and accidents, customer complaints, and variations from SOP's. Ensures records provide a complete and accurate history of all work performed. Audits all manufacturing systems to ensure compliance with applicable regulations and to identify opportunities for improvement. Determines new or revised processes are validated and equipment is appropriately qualified and validated. Qualified applicants should possess: Bachelor's degree with major in biological science or related field. Five years of experience in blood banking, biologics manufacturing or regulations and compliance. Extensive knowledge of AABB, FDA, CLIA, OSHA, and state Departments of Health requirements. Knowledge of quality control, SOP development, and auditing skills. Certification by American Society of Quality as a Certified Manager of Quality

POSITIONS (continued from page 8)

and Certified Quality Auditor desirable. Qualified candidates are encouraged to submit an online application at <u>www.bloodassurance.org</u>. Blood Assurance is an EOE and Tobacco Free Workplace.

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, 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.

Blood Collections Director of Quality/Projects. Kentucky Blood Center seeks a detail-oriented professional to lead a team focused on Blood Collections quality initiatives, and to facilitate the management and implementation of special projects. Supervises the Donor/Patient Services Nurse and related processes, and reports to the Vice President, Donor Services. Responsibilities include department planning, budgeting, employee supervision and development, quality oversight. Provides technical assistance for automated Blood



Collections procedures (apheresis platelets/plasma/red cells, double red cells), and special programs. Primary contact and lead for the Dendreon collection program. Guides inter-departmental collaboration fulfilling responsibilities, process improvement plans, and finding solutions. Oversees regulatory compliance, error management reporting, and procedural review and revision. Qualifications: BSN, and an active RN license required. Experience with good manufacturing practices, FDA, EU, and other regulated experience preferred. Experience with quality assurance, data analysis, and equipment/process validation highly desired. MSOffice proficiency; ability to effectively navigate other systems and webbased applications. Minimum two years of management experience required. Must be highly organized, reliable, and have outstanding interpersonal skills. Strong written and oral communication skills, solid work ethic, and a team player attitude are required. Qualified candidates must live in, or be willing to locate to, the Lexington, KY area. Click here to apply.

Clinical Laboratory Scientist. Located in the heart of the magnificent coastal redwoods of Northern California, The Northern California Community Blood Bank is a nonprofit blood bank serving Humboldt and Del Norte Counties. The Northern California Community Blood Bank has an immediate opening for a Clinical Laboratory Scientist. Both part-time and full-time, fully benefitted positions are available. The Northern California Community Blood Bank offers a low-stress environment, excellent work-life balance, and the opportunity to advance your professional development while working for an employer with a vibrant community relationship. The Clinical Laboratory Scientist is responsible for activities related to processing, testing, storage, transportation, and other handling of blood and blood products. The Clinical Laboratory Scientist performs reference immunohematological testing and participates in training, validation, implementation of new procedures, and compliance with regulatory and standard-setting agencies. Experience, Education and Licensure: Four-year degree from an accredited college or university in science, medical technology or a related field. Valid current CA license as a Clinical Laboratory Scientist. Experience preferred but will train a motivated new CLS. To apply, contact: Kristina Kelone, Technical Director, Northern California Community Blood Bank, 2524 Harrison Avenue, Eureka, CA 95501, (707) 443-8004.