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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2018 #38 **November 9, 2018**

INSIDE:

FDA & DoD Sign MOU for 'Safe and Effective' Medical Product Use on Troops

The U.S. Food and Drug Administration (FDA) and U.S. Department of Defense's (DoD) Office of Health Affairs announced that the organizations have agreed to and signed a memorandum of understanding (MOU) for the development and assessment of medical products. "This MOU furthers the existing partnership between the Department of Defense and the FDA to equip our military with the best and most innovative military medical support possible," said Terry M. Rauch, PhD, MPH, MBA, acting deputy assistant secretary of Defense, Health Readiness Policy & Oversight at DoD in a news release issued by FDA. "Today's MOU reflects the commitment of the DoD and the FDA to ensure timely access to life-saving medical products for U.S. troops and to continue fostering the development of new innovative medical products that can help ensure the operational readiness of American troops. We look forward to continuing to work with the FDA as we analyze and implement measures to provide the best possible medical products and care to all military personnel - on the battlefield, stationed around the world and at home."

The MOU follows ongoing collaboration efforts to provide access to safe and viable medical products in a timely manner for service members to enhance treatment options and survival for battlefield injuries. The FDA and DoD reached agreement last year on a provision within the National Defense Authorization Act (NDAA) that allowed the FDA the ability to authorize medical treatments that haven't been approved by the agency for temporary use in emergencies and expedites product review.

The FDA and DoD then collaborated on a work plan in January 2018 to lay the framework for the emergency use authorization. In July 2018, the FDA granted an emergency use authorization to DoD for pathogen reduced (PR) freeze dried plasma produced by Centre de Transfusion Sanguine des Armées (referenced as French FDP in the emergency use authorization) that permitted the use of freeze dried plasma in the treatment of hemorrhage or coagulopathy for U.S. military members during emergency situations involving combat.

The new MOU will serve as the official framework under which both organizations operate moving forward with further collaborations to ensure that the agencies work together towards common goals of access to innovative and safe medical treatments for military personnel.

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FDA & DOD Sign MOU continued from page 1

"It's our honor and duty to support our military personnel by ensuring they have access to safe and effective medical products – especially products that meet the unique needs and settings in which soldiers may require medical treatment," said FDA Commissioner Scott Gottlieb, MD in the agency news release regarding the MOU. "The FDA has already been working closely with the DoD to identify opportunities to expedite availability of medical products, particularly those products used to treat injuries in battlefield settings. For example, … the Emergency Use Authorization for French freeze-dried plasma that was issued earlier this year. Our close collaboration with DoD has helped us target and more efficiently address DoD's immediate product priorities and foster development and review of these products in the most streamlined manner possible. We are looking forward to additional partnership opportunities under the MOU."

(Source: FDA News Release, 11/2/18)

Characterizing the Performance of Cerus' New Set for Pathogen Reduction Treatment of 'triple-dose' Platelet Collections

A small study examined the performance of Cerus' "triple storage (TS) set" when applied to three forms of triple-dose platelet collections: buffy coat platelet concentrates, Amicus apheresis platelet concentrates (APCs), and Trima APCs. Each of these three study arms underwent pathogen reduction treatment (PRT) using both the TS set (n = 6 units/arm) and Cerus' well characterized large volume (LV) set (n = 6 units/arm; used for control purposes). Numerous parameters were evaluated over seven days of product storage including changes (i.e., pre-versus post-PRT) in product volumes and platelet content, and changes in pH, pO2, pCO2, bicarbonate, glucose, lactate, ATP, lactate dehydrogenase (LDH), platelet-associated biological response modifiers, and degree of platelet activation.

While some statistically significant differences in performance were seen between the TS and LV sets (especially for pH, pO2, pCO2, and bicarbonate), and also across the three study arms (for most of the analytes), these did not appear likely to have clinical relevance – even at the seven-day limit of this study. The authors conclude, "[r]esults from the measured metabolic parameters and platelet variables obtained from PCs treated by LV and TS sets indicated good platelet function preservation up to 7 days of storage. The in vitro assessment results demonstrated acceptable platelet function for transfusion." TS is currently not available in the U.S.

Citation: Lotens, A., de Valensart, N., Najdovski, T., Acquart, S., Cognasse, F., Rapaille, A. Influence of platelet preparation techniques on in vitro storage quality after psoralen-based photochemical treatment using new processing sets for triple-dose units. *Transfusion*. 2018. doi: 10.1111/trf.14909.

Contributed by Chris Gresens, MD, Senior Chief Medical Officer, North & West Divisions, Vitalant

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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.

ABC *Awards of Excellence* Call for Nominations

ABC members are encouraged to nominate blood donation sponsors, corporations, and advocates for the 22nd Annual *Awards of Excellence*. This year's ceremony on Monday, March 25th will be in Washington, D.C. during ABC's 57th Annual Meeting at the Ritz-Carlton (Pentagon City). Nominations are currently open until Friday, November 30th. Additional details are available in MCN 18-044. The online submission form is available here. ABC members are permitted to submit up to three nominations per category.

The following awards will be presented during the awards ceremony and are currently open for nominations:

- ABC Outstanding Blood Drive of the Year
- Outstanding Public Relations Campaign
- Corporation of the Year Award
- Larry Frederick Award (jointly presented by ABC and ADRP)
- William Coenen President's Award
- Blood Community Advocate of the Year Award
- Thomas F. Zuck Lifetime Achievement Award

A complete description of each award is available here. Please direct any questions about nominations or the awards ceremony to Leslie Maundy.

(Source: MCN 18-044)

ADRP Conference 2019 Call for Speaker Abstracts Open

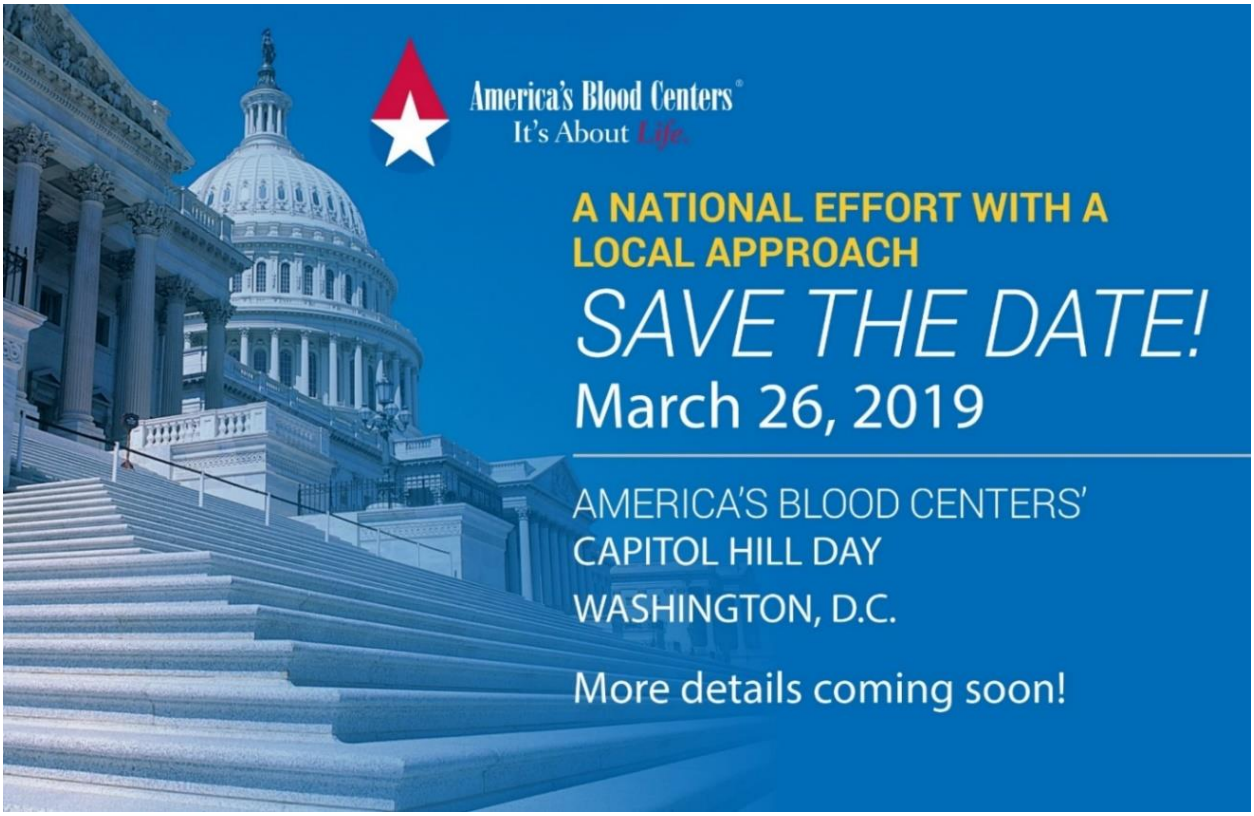
ADRP has opened the call for abstracts for its 2019 Annual Conference in Indianapolis, Ind. Marketing, communications, recruitment, and collections professionals and experts are invited to submit abstracts to share their expertise. The deadline to submit is Friday, November 30th. Speakers that are chosen will receive a 30 percent discount off conference registration. This year will feature speaker panels, breakout sessions, and roundtable discussions. Interested individuals can submit their abstracts here.

Upcoming ABC Webinars – Don't Miss Out!

- **Quality Integration Part II** – November 27th at 3 pm. EST. Additional details forthcoming!
- **SMT Journal Club** – December 12th at 12 pm. EST. Additional details forthcoming!

(continued on page 4)

INSIDE ABC (continued from page 3)



ADRP Award Nominations Are Open

Recognize a peer or outstanding donor group by nominating them for an ADRP Award. Submissions are being accepted until Friday, November 30th via the online nomination form. This year's categories include:

- Donor Recruiter of the Year
- Donor Collections Team Member of the Year
- Leader of the Year (Recruitment & Collections)
- Franzmeier Lifetime Achievement Award
- Gilcher MD/CEO Award
- Media Partner Award
- Blood Drive Award (Creative & Most Productive)
- School Blood Drive Award
- Humanitarian Service Award

REGULATORY NEWS

The U.S. Food and Drug Administration issued a safety communication warning against the use of genetic tests with unapproved claims to predict patient response to specific medications. The communication published on November 1st warned healthcare providers and patients that the agency has not reviewed the claims from many of these genetic tests and that such tests may lack the scientific and clinical evidence to support their use for most medications. The agency released a statement that says, "[i]n our safety communication, a collaboration between the FDA's Center for Devices and Radiological Health and

(continued on page 5)

REGULATORY NEWS (continued from page 4)

Center for Drug Evaluation and Research, we note our concern about health care providers and patients inappropriately selecting or changing drug treatment based on the results from insufficiently substantiated genetic tests, which could lead to potentially serious health consequences for patients. … It is important to note that there are some drugs whose use can be aided by the results of pharmacogenetic information. In those cases, there is scientific evidence to support relationships between the genetic variant and how a patient responds to a drug, which has been reviewed by the FDA. The FDA-approved labeling for such a drug and genetic test provide health care providers with adequate information on how to use genetic information reported by the genetic test to manage medication treatment using the drug."

(FDA Draft Safety Communication & Statement, 11/1/18)

The FDA's Oncology Center of Excellence will hold a public workshop entitled "Product Development in Hemophilia." The workshop will take place on December 6th from 8:30 a.m. to 4:30 p.m. EST at FDA's White Oak Campus. It will feature presentations and panel discussions that pertain to:

- Trial design;
- Patient experience and patient-reported outcomes in clinical drug trials;
- Issues with the assessments of factor VIII/IX activity levels for gene therapy;
- Use of factor activity levels as a surrogate endpoint that are likely to predict for bleeding outcomes;
- Long-term safety issues from pre-clinical studies; and
- Enrollment of pediatric patients in gene therapy trials.

Individuals interested in attending must register online by December 3rd at 5 p.m. EST. Those unable to attend may participate via webcast with a link and additional details and instructions for accessing the webcast available at a later date. The workshop agenda is available and additional information on the agency's website.

(FDA Meeting Announcement, 11/2/18) ♦

RESEARCH IN BRIEF

It's all in the title: 'Getting Rid of Stupid Stuff.' A short article by Melinda Ashton, MD from Hawaii Pacific Health appearing in the *New England Journal of Medicine* reports on a simple hospital program that may have substantial relevance in our current good manufacturing practice (cGMP), documentation-happy environment. Starting with the premise that "many health care organizations are searching for ways to engage employees and protect against burnout, and involvement in meaningful work has been reported to serve both functions," it examines some impacts of their 'Getting Rid of Stupid Stuff' program that has actively solicited suggestions for changes in the electronic health record from the work force that fall into three categories of documentation: those that were never intended, that which was appropriate but could be made more efficient, and requirements for which the need was not clearly articulated or understood.

Citation: Ashton, M. Getting rid of the stupid stuff. *N. Engl. J. Med. 2018*. doi: 10.1056/NEJMp1809698.

Status of "Getting Rid of Stupid Stuff" Requests from Nurses and Physicians.*

Status	Nurses	Physicians
	no. of requests (%)	
Completed	68 (46.6)	19 (45.2)
Not possible	18 (12.3)	8 (19.0)
In progress	27 (18.5)	2 (4.8)
Assigned to work groups or not yet started	33 (22.6)	13 (31.0)

**Does not include 31 suggestions from other disciplines or related to issues other than improvements to electronic health records.*

Status of 'Getting Rid of Stupid Stuff' request from nurses and physicians. Courtesy of the New England Journal of Medicine.

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RESEARCH IN BRIEF (continued from page 5)

Learning the transgender vocabulary. Transgender* issues are frequently in the news, and their possible impacts relevant to blood collection and processing and transfusion medicine are increasingly recognized. These include, for example, the assessment of transfusion-related acute lung injury (TRALI) risk or the risk from sexual behaviors associated with HIV transmission. As many as 1.4 million transgender adults are currently in the United States according to estimates and the numbers are growing. The U.S. Food and Drug Administration (FDA) permits blood collection facilities to accept the stated gender of a prospective donor to drive both the questions required during the donor interview, but this has required a binary response (i.e. male/female) from the donor-applicant. This may no longer be adequate, as increasing numbers in the population insist on non-binary responses, and the blood community will need to adjust moving forward. A review has been published in *JAMA Internal Medicine* that should enhance the abilities of individuals "to engage with transgender patients…and be prepared to manage specific issues, …account for the unique needs of these patients within the facility, and through education and policy create a welcoming environment for their care." It covers, among other topics, anatomic considerations, impacts from hormone therapies, the interpretation of laboratory values and legal considerations.

**Individuals whose gender identity and/or expression differs from that assigned at birth.*

Citation: Rossendale, N., Goldman, S., Ortiz, G.M., and Haber, L.A. Acute clinical care for transgender patients: a review. *JAMA Int. Med*. 2018. doi:10.1001/jamainternmed.2018.4179.

Case report: Daratumumab for an ABO-incompatible allogeneic stem cell transplant. ABO blood group incompatibility after stem cell transplantation can lead to delayed red blood cell (RBC) engraftment and RBC aplasia with prolonged transfusion dependence. It is present to some degree in 25-50 percent of such transplants and results in rates of pure RBC aplasia of 6-30 percent related to persisting recipient isohemagglutinin producing plasma cells. Daratumumab is a monoclonal antibody that reacts with CD38 on antibody producing plasma cells. A blood group O recipient of blood group A stem cells had RBC aplasia, substantial levels of anti-A antibodies, and transfusion dependence till lasting almost 400 days after transplant, having failed standard immunosuppression, rituximab (anti-CD20) therapy, and steroids while maintaining a blood group O RBC phenotype. Since rituximab does not affect CD20 negative mature plasma cells, a course of six doses of daratumumab was given. The recipient's blood type rapidly converted to blood group A, anti-A disappeared, and the patient became transfusion independent.

Citation: Chapuy, C.I., Kaufman, R.M., Alyea, E.P. and Connors, J.M. Daratumumab for delayed red-cell engraftment after allogeneic transplantation. *N. Engl. J. Med.* 2018. doi: 10.1056/NEJMoa1807438. ♦

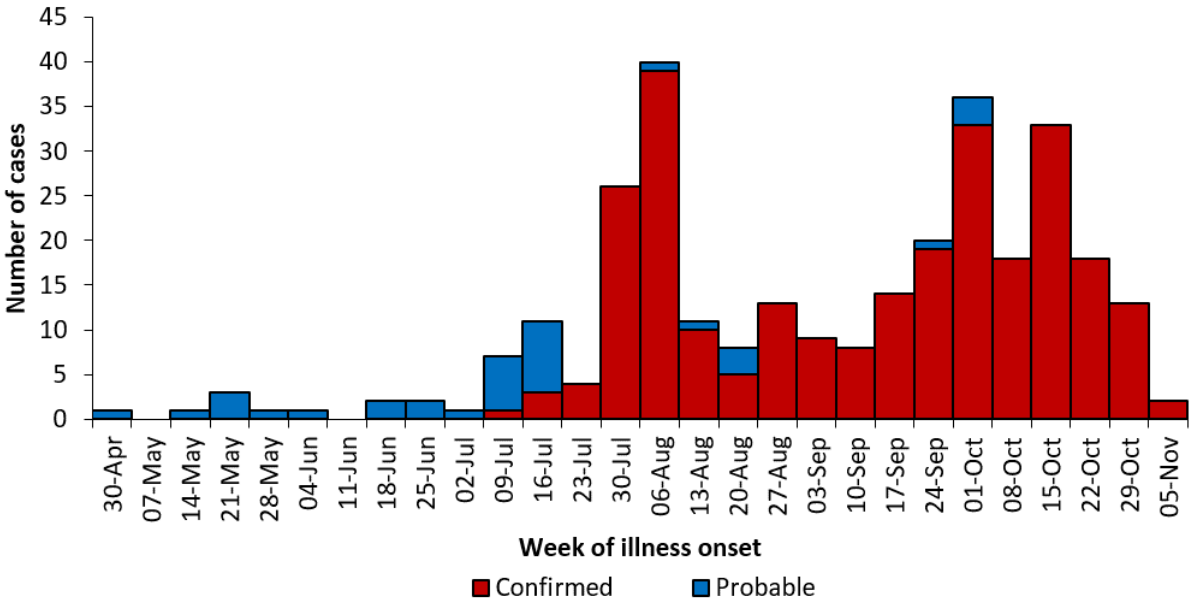
INFECTIOUS DISEASE UPDATES

EBOLA

The Ebola outbreak in the Democratic Republic of Congo continues. The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) have not classified the affected areas as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The U.S. Food and Drug Administration (FDA) guidance requires that "in the event that one or more countries is classified by CDC as having widespread transmission of Ebola virus, your donor history questionnaire (DHQ), including your full-length and abbreviated DHQ, and accompanying materials, must incorporate elements to assess prospective donors for symptoms of recent or current illness with Ebola virus infection or disease, and travel to, or residence in, an area endemic for Ebola virus in accordance with 21 CFR 630.10(e)(2)."

As of November 6th, there were 308 reports (273 confirmed and 35 probable) in the DRC provinces of North Kivu and Ituri. Recently, CDC Director Robert Redfield, MD expressed concerns over the impact that social and political instability in the region could potentially have on containment efforts, "I do think this is one of the challenges we'll have to see, whether we're able to contain, control, and end the current outbreak with the current security situation, or do we move into the idea that this becomes more of an endemic Ebola outbreak in this region, which we've never really confronted," according to the *Washington Post*. ABC encourages member blood centers to review their SOPs and consider retraining if the original staff training was at a remote point in time.

Confirmed and probable Ebola virus disease cases by week of illness onset, data as of November 6th (n=303)



** Onset date unknown for five cases. Data in recent weeks are subject to delays in case confirmation and reporting, as well as ongoing data cleaning. Trends during this period should be interpreted cautiously.*

(Source: *Washington Post*, CDC director warns that Congo's Ebola outbreak may not be containable, 11/5/18; World Health Organization, Ebola virus disease – Democratic Republic of the Congo, 11/8/18)

PEOPLE

Galen Kline has been named the next chief executive officer of Houchin Community Blood Bank following a nationwide search. He is currently the chief operating officer and will succeed Greg Gallion on January 1, 2019 following Mr. Gallion's retirement at the end of December. "Galen is an outstanding leader with a proven track record of success. Employees, blood donors and recipients, and the community can expect Houchin Community Blood Bank to continue to grow and prosper with Galen at the helm," said Joseph Engel, chairman of the board at Houchin Community Blood Bank. Mr. Kline joined the blood bank in 2017 as the director of quality. His career in blood banking began in 2001 and includes positions at Versiti and Vitalant. He holds a bachelor's degree in business administration from Sonoma State University with a concentration in Psychology. Prior to his career in blood banking, Mr. Kline worked as a bioecologist.

(Source: Houchin Community Blood Bank Announcement, 11/8/18)

MEMBER NEWS

Oklahoma Blood Institute will honor military personnel on Veteran's Day (November 12th) by providing individuals with the opportunity to thank active servicemen and women through written letters to show support and thanks for their sacrifice. "Our dedicated volunteer donors, many of whom are veterans of war and active military members, know the importance of giving blood regularly," said John Armitage, MD Oklahoma Blood Institute President and CEO in a news release. "We deeply value the heroes who served, or are currently serving, our country. Providing blood to our military is not only our duty, but we are proud to make it a critical part of our life-saving mission."

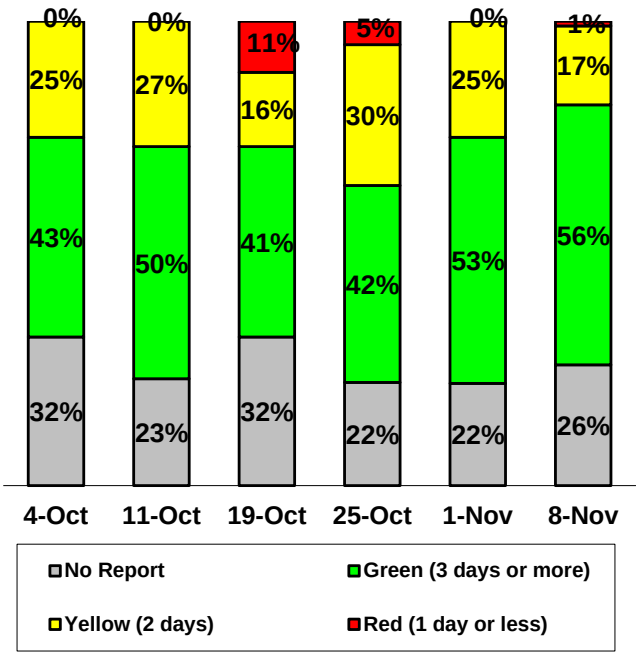
(Source: Oklahoma Blood Institute News Release, 11/8/18)

San Diego Blood Bank will hold the second annual "San Diego Cares: It's in Our Blood" drive from mid-December through mid-January. Last year's blood drive was the first following the relocation of the National Football League's (NFL) Chargers franchise to Los Angeles from San Diego and was a single day event that resulted in approximately 700 units. This year's drive will span the holiday season but remain a celebration to bring the community together in assisting San Diego Blood Bank with its lifesaving work. "We're evolving, so we'll give this a try as we pursue our mission of having a robust, safe supply of blood available for the people who need it," said David Wellis, PhD CEO of San Diego Blood Bank to *The San Diego Union Tribune*. "We're really trying to convert that one day into a month of giving."

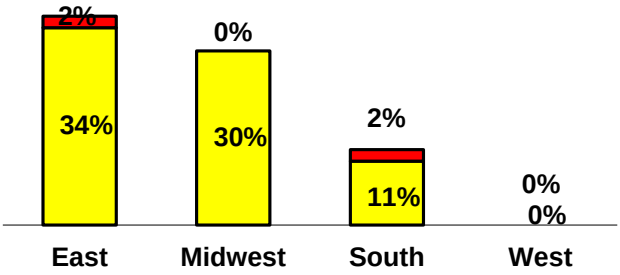
(Source: *The San Diego Union Tribune*, Thrown for a loss by Chargers, Blood Bank opts for 'season of giving' instead of one-day holiday donation event, 11/7/18)

STOPLIGHT®: Status of America's Blood Centers' Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, November 8, 2018



Percent of Total ABC Blood Supply Contributed by Each Region
East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at:
www.AmericasBlood.org

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!

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) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2018

Nov. 14. **2018 Cybersecurity Summit, Washington, D.C.** More details available here.

Nov. 29-30. **FDA Pathogen Reduction Technologies for Blood Safety Public Workshop, Silver Spring, Md.** More details available here.

Dec. 6. **FDA's Oncology Center of Excellence Product Development in Hemophilia Public Workshop, Silver Spring, Md.** More details available here.

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Calendar (continued from page 9)

2019

Feb. 4-5. **15th Annual FDA and the Changing Paradigm for HCT/P Regulation, Washington, D.C.** More details available here.

March 6-7. **IPFA 4th Asia Workshop on Plasma Quality and Supply, Hanoi, Vietnam.** More details available here.

March 22. **2019 International Blood Safety Forum, Washington, D.C.** More details coming soon.

March 23-26. **2019 ABC Annual Meeting, Washington, D.C.** More details coming soon.

May 14-16. **ADRP Annual Conference, Indianapolis, Ind.** More details available here.

May 22-23. **IPFA/PEI 26th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens", Krakow, Poland.** 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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: lmaundy@americasblood.org.

POSITIONS

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 (CLS). This is a full-time, fully benefitted position. 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: Jo Anna Ow, Administrative Services, Northern California Community Blood Bank, 2524 Harrison Avenue, Eureka, CA 95501; (707) 443-8004.

Medical Director. The European Blood Alliance (EBA) is looking for an expert with medical and blood service background to serve as a part-time Medical Director of EBA. The Medical Director will bring her/his expertise to support the secretariat and will report to the Executive Director (ED). She/he will work preferably in Belgium or virtual if the person is not based in Belgium. **Key goals** are to support the EBA membership by sharing technical/medical information in relation to blood services, contribute to EBA strategy and policies, represent EBA when medical expertise is sought and act as a facilitator of knowledge exchange on technical/medical matters among EBA members and in working groups/projects. The successful candidate must be able to demonstrate achievements in the field of blood services, have a thorough knowledge in transfusion medicine in Europe, donor management and health, as well as be able to work with a diversity of profiles, nationalities and cultures. A track record of networking and interacting with blood services from various countries would be a bonus. This post would ideally suit a person who has a well-established career, willing to work part time, and involves frequent travels mainly in Europe. More information on: https://wp.me/p4l3nF-2cC.