

Blood Centers Recruit Platelet Apheresis Donors Through Innovative and Varied Approaches

Recruiting whole blood donors is like bringing a horse to water, converting those horses into the unicorns that are apheresis donors is a whole other sport. Some estimates put whole blood donors at 10 percent of the general U.S. population (and even that can be considered generous by many), but only about 1 to 3 percent of those donors will convert to become platelet donors through apheresis, said David Leitch from Branch Consulting & Analytics—and that number is decreasing in some areas.

“Part of our platelet donor base shrunk,” said Marie Forrestal, director of donor recruitment at New York Blood Center (NYBC). “Some of that was they were aging out, now we’re trying to grow that base back up again.”

As many blood centers can attest, platelet apheresis donors are not easy to gain. Getting people to spend two hours of their spare time hooked up to an apheresis machine can take some finesse and a lot of marketing and recruitment know-how. A number of blood centers shared their approaches and experiences with us on how they are trying to generate new apheresis donors and keep up with the demand.

Apheresis donors generally have some different characteristics than their whole blood donor counterparts, said Stephanie Nunez-Leos, director of donor recruitment at LifeStream blood bank: they are generally older, more dedicated to donating, more likely to be home owners, have more time to devote to blood donations, and donate more frequently.

“Apheresis donors really crave that personal contact,” said Ms. Forrestal. “Some of the donors have such a great relationship with their donor specialists that they will follow that person to another blood center if they move.”

In an effort to identify new apheresis platelet donors, and especially those who can provide a double or triple donation, LifeServe Blood Center has implemented a Purple Top Program. The program was created to help the center grow its apheresis program by moving existing mobile-based red blood cell (RBC) donors to this specialized donation process. The program targets donors who meet their



current apheresis eligibility criteria (gender, blood type, etc.) and who live in a 25-mile radius of a LifeServe Blood Center location. People who donate at a mobile blood drive and match the criteria have an additional sample tube of blood collected from the diversion pouch (purple top tube). Once back in the laboratory, a platelet count is performed on the tube identifying those donors who have at least a platelet count of 250,000 cells per microliter (mcL). For those donors who have that count, the center sends these potential platelet donors a letter letting them know they would make an excellent platelet apheresis donor and encourages

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OUR SPACE

ABC Chief Medical Officer Louis Katz, MD

All Zika, All the Time II

Good News: The new Zika guidance is as clear as can be. Bad News: Universal ID-NAT is a titanic operational effort—unclear it can be finished on the FDA’s schedule. Good News: A universal mandate becomes a pass through that attenuates concerns about its cost—the end user (hospitals) will (appropriately) bear it. Bad News: Might the \$100 million* we will consume in the next year be put to better use, e.g., mosquito control? Many of us are asking if this is the best use of public health resources.

My list could be longer, but...

First message: “Just Do It.” The blood community, and ABC’s specifically, is committed to safety and pursuit of regulatory compliance.

Second message: The opaque process leading to the guidance, with its timelines, is not acceptable. The FDA is responsible for a lack of transparency and stakeholder engagement since the spring, and we are for not using validated crystal balls.

The agency is on committees with the blood community, but there was never a meaningful discussion of universal ID-NAT’s feasibility. I thought we were receiving clear signals the revised guidance would mandate testing across a wide swath of southern states, where the risk of mosquito transmission is concentrated. Assuming existing labs have the space and warm bodies required, and test vendors can deliver instruments, service, and reagents (huge assumptions), and had we been able to read our tea leaves with greater prescience, our preparation for (1) installation of investigational testing equipment and software, (2) training, (3) platform, assay, and operator qualification, (4) validation, and (5) implementation, our early, transparent engagement would have yielded longer timelines. The outcome would be a higher chance of success without delays and lower risk of cGMP mishaps—both for Zika testing and other safety activities.

Over the last six to eight weeks, many of my inquiries about details in the guidance were answered with, “we cannot talk about the details of guidance once we start writing.” I have tried to dig into FDA’s *Good Guidance Practices* and CFR to understand if this is true. 21 CFR 10.80(d)(1) states, “Details of a draft of a final notice or regulation may be discussed with an interested person outside the executive branch only with the specific permission of the Commissioner.” I cannot figure out if this language applies or not, but it should. I wonder if this kind of an approach isn’t the roadmap to more orderly promulgation of even urgent guidances. Inquiries are in progress.

Our interest is not an appeal about the content of the guidance. It is an appeal to regulators to appreciate our constraints around complex interventions in the face of the intricate processes involved—reasonable timelines being the “bottom line” in this instance.

* “Back of the envelope” cost recovery” at ≈\$7-8/reported result in the next 12 months.

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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BLOOD CENTERS RECRUIT PLATELET APHERESIS (continued from page 1)

them to schedule their next appointment as a platelet donor. For those that don't respond to the initial letter, a postcard is then sent, then a personalized tele-recruitment call caps off the process.

“After implementation of this program, the center has seen a double-digit increase in apheresis units for three years consecutively,” said Christine Hayes, vice president of operations at LifeServe Blood Center.

In an effort to identify double or triple platelet donors—which can be a more cost-effective method in gaining platelet inventory—LifeServe Blood Center first draws whole blood donations on mobiles near their centers and caps them with purple caps. After testing the platelet levels on those samples, LifeServe finds those donors with counts above 250,000 per mL. The center then sends these high-count donors a letter letting them know they would make an excellent platelet apheresis donor. They explain the process and then in a few months, those who have not responded, get a postcard in the mail. After that, if the donor still has not come in to donate, they contact the donor via telephone, said Ms. Hayes. They find that continuous follow-ups work well in capturing the attention of the potential donor, which leads to more donations.



NYBC shared some of their methods in attempting to convert whole blood donors into apheresis donors, especially A+ donors, with a wide range of approaches. First they identify those donors that could be double or triple platelet donors, then they contact them via multiple channels: direct mail, email marketing campaigns, and text messaging. NYBC also offers donors a loyalty program called the Donor Advantage Program. Donors gain points, with apheresis donors gaining extra points, depending on how much they donate, where, and when. Donors can spend those points on the NYBC marketplace to buy anything from a Keurig cappuccino machine to board games. During critical supply times, NYBC also partners with a local baseball team, the Mets, to offer four free tickets for apheresis donors. They find casting a wide net helps in drawing in all kinds of apheresis donors.

Virginia Blood Services (VBS) also partners with a very recognizable name, the American Cancer Society (ACS), to help push out platelet education initiatives on how platelet apheresis donors help save cancer patients' lives. By having ACS spread information during ACS-held events like speaking engagements, survivor luncheons, relay planning events, breast cancer walks and more, the awareness of the need for platelet apheresis donors has grown, said Michelle Westbay, marketing and communications lead with VBS. VBS also co-brands certain blood drives with ACS, and maximizes their ACS partnership by tabling and placing ads at ACS-run events as well as sponsoring ACS events to help educate and sign up apheresis platelet donors.

LifeStream brought in outside help with [Branch Consulting & Analytics](#) to assist with their conversion rate for first-time platelet apheresis donors. Branch used a statistical formula, coupled with consumer data, to help develop a list of which donors have a higher probability of becoming platelet donors from their active donor base.



BLOOD CENTERS RECRUIT PLATELET APHERESIS (continued from page 3)

“Branch ran several statistical formulas on donor behavior and demographics to find the best 'lookalike' candidates in our whole blood donor base to target for recruitment. In the past, most of our work on donor conversion involved ABO targeted whole blood donors for conversion instead of a subset of them,” said Ms. Nunez-Leos. This method helped the blood center increase their tele-recruitment conversion rate of first-time platelet donors to 28 percent (industry standard is around 10 percent said Mr. Leitch). During the 10 week project over 350 new platelet donors were added to the system, increasing their active donor base by over 9 percent. Plans are in the works to make it an annual spring program to build the base in advance of summer.

For those in more rural areas, proximity can mean the difference between a frequent donor and one who only comes back twice a year.



“We just started our mobile apheresis program last summer,” said Joe Ferrara, program manager for donor engagement at Bloodworks Northwest in Seattle. “By giving donors in rural areas a chance to donate double red cells, platelets, or plasma at a local blood drive instead of driving to a donor center, we’ve seen increases in first time apheresis donations. When we started the program last summer, it was limited to the Seattle metro area, with only 30 or 40 mobile apheresis donors per month. Since expanding our program to include rural areas that are far from donor centers, we are aiming for 100 platelet donors per month now.”

Through increased accessibility, loyalty programs, partnerships that increase center visibility, and lists gained from statistical algorithms, blood centers are implementing innovative methods to increase their apheresis platelet donor rates and keep up with the demand.

We Welcome Your Articles

We at the *ABC Newsletter* welcome freelance articles on any subject relevant to the blood banking community. Writers are encouraged to submit short proposals or unsolicited manuscripts of no more than 1,100 words. While ABC cannot pay for freelance pieces, the writer’s name and title will be included at the end of the story, brief news item, or commentary. If proposing a story, please write a few paragraphs describing the idea and sources of information you will use, your present job and background, and your qualifications for writing on the topic. ABC staff cannot guarantee all stories will be published, and all outside writing will be subject to editing for style, clarity, brevity, and good taste. Please submit ideas and manuscripts to ABC Publications Editor Lisa Spinelli at newsletter@americasblood.org. You will be sent a writer’s guide that provides information on style conventions, story structure, deadlines, etc.



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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.



America's Blood Centers and ADRP Meet in New York City

ABC representatives traveled to New York City last week to attend an ADRP board meeting. During the meeting, the joint ABC/ADRP group took a tour of New York Blood Center and met with experts in all areas of marketing, donor recruitment, collections, and processing.



Photo courtesy of ADRP board member Asuka Burge, national manager of marketing and communications, New Zealand Blood Service.

We continued with talks that were previously started between ADRP and ABC members about our merger and next steps on how the two organizations will work together in the near future. The joint group discussed key areas for Fiscal Year 2017 and 2018 (and beyond) with the goals of eliminating redundancies between the associations and building value for ABC members and ADRP subscribers. Some of the areas covered included: education, awards, sponsorships, communications and publications, subscriptions and memberships to the associations, as well as global initiatives. We all walked away having formed new bonds and having made some real headway into how the two associations will work together toward a mutually beneficial future. We will keep our members informed on all details with the merger as they occur.

ABC Seeks Zika Guidance Comments from Members

Last week, the Food and Drug Administration (FDA) issued a revised guidance recommending blood centers and collection establishments test every blood and blood product donation for Zika. For some centers, the agency has given four weeks to enact their guidelines, others have as long as mid-November. Please read the full guidance [here](#). ABC is responding to the FDA guidance and would like to remind chief medical officers at our member centers to send comments on this revised guidance to ABC CMO Dr. Louis Katz by September 14, 2016. Read ABC's official press release [here](#). ♦



RESEARCH IN BRIEF

The presence of sickle cell trait (SCT) in soldiers modestly increases the risk of rhabdomyolysis but not death compared to subjects without the trait. Previous studies of patients with SCT have suggested an association of SCT with exertional rhabdomyolysis and death. A new study assesses the risks of exertional rhabdomyolysis and death according to SCT status in 47,944 active-duty African American U.S. Army soldiers using the Stanford Military Data Repository. The investigators found a slightly higher adjusted risk for exertional rhabdomyolysis with SCT (hazard ratio, 1.54; 95 percent CI, 1.12 to 2.12). There was no significant difference in the risk of death for soldiers with SCT, compared to controls (hazard ratio, 0.99; 95 percent confidence interval [CI], 0.46 to 2.13).

Citation: Nelson D.A., Deuster P.A., Carter, III, R., *et al.* Sickle Cell Trait, Rhabdomyolysis, and Mortality among U.S. Army Soldiers. *New England Journal of Medicine*. August 4, 2016. DOI: 10.1056/NEJMoa1516257.

Physicians overestimate the benefits as well as the risks of medical tests and procedures. A voluntary 18-question- survey was completed by 117/132 eligible residents and attending internal medicine physicians at two academic medical centers from November 2015 until March 2016. Most overestimated the benefits (92 of 117 [78.6 percent] across seven “benefit” questions) and harms (77 of 117 [65.8 percent] average across three “harm” questions) of common medical tests and treatments. There was no difference in accuracy between residents and attendings. The authors recommended better descriptions of “high risk procedures and treatments with graphs to help patients and physicians visualize the probabilities of patient outcomes. A commentary to the review agreed that more training of all physicians is needed to better communicate and understand the obligations of risk communication. The authors of the commentary suggested improving an online resource named *Choosing Wisely*, and modeling it to resemble more closely the one [Mayo Clinic has established](#), to better serve physicians in helping their patients choose medical interventions in-line with their goals.

Citation: Krouss M., Croft L., Morgan D.J., *et al.* Less Is More. *JAMA Internal Medicine*. August 29, 2016. DOI:10.1001/jamainternmed.2016.5027. ♦

RECENT REVIEWS

A review of clinical data helps find timely assessments and interventions to achieve hemostasis for cardiovascular and transplant surgery patients. In a recent review of practical data regarding the use of viscoelastic testing, e.g., TEG and ROTEM, the authors review the available techniques, “provide practical examples of its use in complex cardiac surgical and transplant cases,” and discuss their technical limitations and the pressing need for high-quality clinical trials to demonstrate beneficial impacts on relevant clinical outcomes.

Citation: Williams B., McNeil J., Crabbe A., *et al.* Practical Use of Thromboelastometry in the Management of Perioperative Coagulopathy and Bleeding, *Transfusion Medicine Reviews*. August, 2016. DOI: <http://dx.doi.org/10.1016/j.tmr.2016.08.005>.

The majority of studies investigating trauma-induced coagulopathy (TIC) proceed without clear causal insights, leading to a serious risk of misalignment between laboratory studies and clinical interventions (including transfusion approaches) when treating these patients, concluded a recent review of TIC data. A major challenge in treating trauma patients is the wide range of biochemical and physiologic changes that can be measured during resuscitation and recovery. The authors of a recent review of data—from multiple studies of upward of 3,000 severely injured patients—found the laboratory

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RECENT REVIEWS (continued from page 6)

foundation on which current research efforts are based is often weakly linked to “true clinically evident coagulopathic bleeding.” More high-level data from randomized controlled trials, combined with mechanistic studies, are needed to overcome the diagnostic and therapeutic challenge posed by TIC.

Citation: Chang R., Jessica C. Cardenas J.C., Wade C.E., *et al.* Advances in the understanding of trauma-induced coagulopathy. *Blood*. August 25, 2016. DOI: 10.1182/blood-2016-01-636423. ♦

BRIEFLY NOTED

The Federal Trade Commission (FTC) announced it is taking the OMICS Group Inc., iMedPub, and Conference Series LLC., all publishers of hundreds of online academic journals owned by the same person, to court.* The FTC charged the three groups with masking hidden fees and deceiving academic researchers and professors. According to the FTC’s complaint, “OMICS does not tell researchers that they must pay significant publishing fees until after it has accepted an article for publication, and often will not allow researchers to withdraw their articles from submission, thereby making the research ineligible for publication in another journal.” (Source: [FTC](#), August 26, 2016.)

*Dr. Katz and Lisa Spinelli do not cite these sources in the *Newsletter*.



AABB and German-based medical equipment company Fresenius Kabi will launch their 11th Annual Blood Collectors Week on September 4 through the 10th. During this week, more than 200 blood centers across the U.S. will

host celebrations and tributes to their phlebotomists and other blood collector personnel, some of these centers will have local government officials present. Participating blood centers and donors are encouraged to submit a [success story online](#) highlighting how someone has gone above and beyond in supporting the nation’s blood supply or in creating a positive donor experience. Participants are also encouraged to show their support for the week on social media using the hashtags #BloodCollectorsWeek and #SavingLives. Blood Collectors Week is on Twitter @bloodcollectors. (Source: [AABB press release](#), September 1, 2016.) ♦

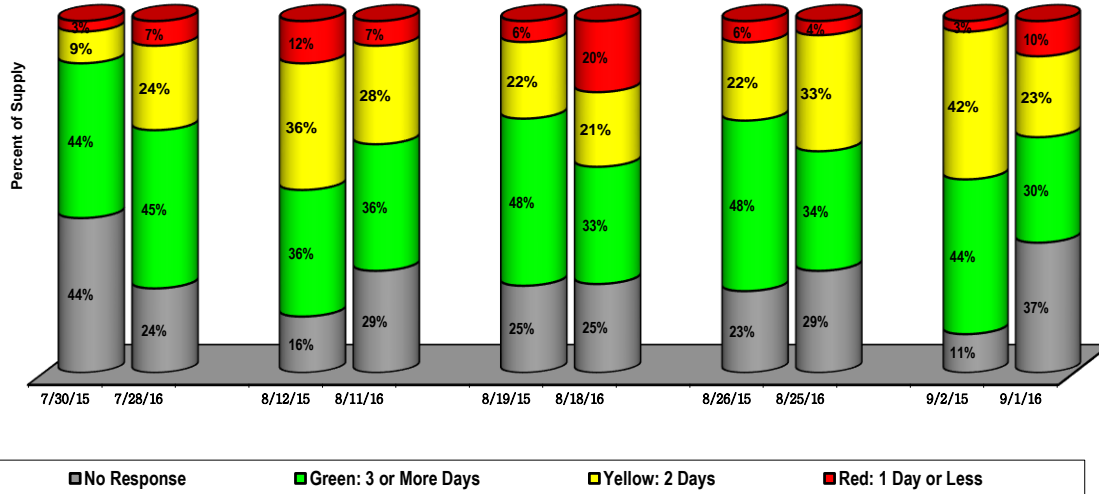


We Welcome Your Letters

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. Please send letters to ABC Publications Editor Lisa Spinelli at newsletter@americasblood.org or fax them to (202) 393-1282. 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.



STOPLIGHT®: Status of the ABC Blood Supply, 2015 vs. 2016



The order of the bars is (from top to bottom), red, yellow, green, and no response

AMERICA'S BLOOD CENTERS' Information Technology Workshop Minneapolis, MN – September 13-14, 2016



Innovative Blood Resources and our Minnesota Division, Memorial Blood Centers, are pleased to host the 2016 ABC Information Technology Workshop near our headquarters in St. Paul, Minnesota. Attendees will benefit from the shared knowledge of fellow IT professionals while exploring topics impacting our changing and interconnected healthcare environment. We look forward to seeing you in September!

– Donald C. Berglund, CEO, Innovative Blood Resources



Negotiated hotel room rate: \$199 + tax
http://bit.ly/renaissance_minneapolis

2016 Workshop Fees (early bird/regular)
2-day registration: \$410/\$465

Registration opens **July 13**. Non-members (non-vendor), contact Lori Beaston at lbeaston@americasblood.org for invitation, registration fees and information.

Scholarship opportunities available to ABC members to cover the cost of registration fees and help with travel expenses. Application form and details will be made available when registration opens.

Sponsorship opportunities available. Contact Jodi Zand at jzand@americasblood.org for details.

✈ Minneapolis–Saint Paul International Airport (MSP) is served by most major US airlines. Visit www.mspairport.com.



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INFECTIOUS DISEASE UPDATES

AABB has launched its [Zika Virus Biovigilance Network](#).

The site voluntarily collates the number of blood donations in the U.S. and Puerto Rico that are presumptively or confirmed reactive for Zika during IND testing. Interested parties can sign up for alerts at [AABB](#) to receive notifications when a positive Zika blood collection is reported. The site joins other AABB hemovigilance sites for infectious diseases West Nile Virus and Chagas. The reporting is voluntary.

The Centers for Disease Control and Prevention reported an asymptomatic man may have spread Zika via sex to his female partner. The Maryland man traveled to the Dominican Republic and had contact with mosquitoes, however, did not have symptoms. He had unprotected sex with his female partner who had not travelled. She developed symptoms 10 days later consistent with Zika infection.

Citation: Brooks R.B., Carlos M.P., Myers R., *et al.* Likely Sexual Transmission of Zika Virus from a Man with No Symptoms of Infection — Maryland, 2016. *CDC Morbidity and Mortality Weekly Report*. August 26, 2016. DOI: <http://dx.doi.org/10.15585/mmwr.mm6534e2>. ♦

REGULATORY NEWS

WORD IN WASHINGTON

Governor Rick Scott of Florida announced he will be coming to the U.S. Capitol the first day Congress is back in session to seek funding for Zika.

Gov. Scott said he would meet with several lawmakers starting on September 6 during his second visit to Washington, D.C., this year to rally support for the spending bill that would help fund Zika prevention and intervention health efforts. Highly critical of the Centers for Disease Control and Prevention (CDC) for what the governor calls their lack of support, Gov. Scott said the CDC has ignored requests for supplies, including Zika-testing kits and additional lab support. The agency countered with the fact that they already spent \$35 million in Florida to help in Zika-related efforts and agreed to send additional testing kits. (Source: *The Hill*, [Florida Gov. to take Zika funding pitch to Congress](#). August 25, 2016.)

Table 3: Transfusion-Associated Fatalities by Complication, FY2011 – FY2015

Complication	FY11 No.	FY11 %	FY12 No.	FY12 %	FY13 No.	FY13 %	FY14 No.	FY14 %	FY15 No.	FY15 %	Total No.	Total %
Anaphylaxis	2	7%	2	5%	-	0%	2	7%	2	5%	8	5%
Contamination	4	13%	3	8%	5	13%	1	3%	5	14%	18	10%
HTR (ABO)	3	10%	3	8%	1	3%	4	13%	2	5%	13	7.5%
HTR (non-ABO)	6	20%	5	13%	5	13%	4	13%	4	11%	24	14%
Hypotensive Reaction	-	0%	-	0%	-	0%	1	3%	1	3%	2	1%
TACO	4	13%	8	21%	13	34%	5	17%	11	30%	41	24%
TRALI*	10	33%	17	45%	14	37%	13	43%	12	32%	66	38%
Other	1**	3%	-	0%	-	0%	-	3%	-	0%	1	.5%

Note: FY15 denotes an imputability of *Definite/Certain, Probable/Likely, or Possible*

*FY11-FY14 numbers include both *TRALI* and *Possible TRALI* cases^{22,23}

**Other: GVHD (Graft vs. Host Disease)

The Food and Drug Administration (FDA) released its “Fatalities Reported to FDA Following Blood Collection and Transfusion” report for Fiscal Year 2015 (FY2015). During FY2015, the FDA noted it received a total of 62 fatality reports from transfusion services; 42 mortality reports on transfusion recipients and 20 on donors. Of the 42 transfusion-associated fatality reports, the FDA found 88 percent were definitely, very likely, or possibly caused by the transfusion, 10 percent of the fatalities were unlikely to have been caused by the transfusion, and about 2 percent were inconclusive. Transfusion-related acute lung injury (TRALI) and transfusion associated circulatory overload (TACO) were the most common associa-



REGULATORY NEWS (continued from page 9)

tions for the recipients (n=11 definite for TACO; n=12 for TRALI). The FDA noted transfusions remain incredibly safe given there are many millions of blood units transfused every year. Among 20 reported donor fatalities, one was possible, and 19 (95 percent) were of doubtful, unlikely, improbably or not associated with donation. FDA's Center for Biologics Evaluation and Research has made the [data on these transfusion-related fatalities and those from FY2011 to 2015 publicly available](#).

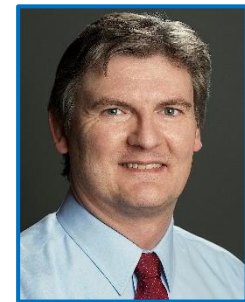
The Food and Drug Administration (FDA) issued Roche an Emergency Use Authorization for their LightMix® Zika rRT-PCR Test. The LightMix test is an assay for the qualitative detection of Zika viral RNA in combination with a full process RNA control meant for patients who meet the Centers for Disease Control and Prevention criteria for at-risk Zika infection, including those exhibiting symptoms. The optimal time to use the test in serum and EDTA plasma is within seven days of infection. The FDA notes that positive results should be followed up with clinical observations and epidemiologic data to determine a true positive. There are no FDA approved/cleared tests available that can detect Zika virus in clinical specimens in the U.S. (Source: [FDA](#), August 26, 2016.) ♦

PEOPLE



BloodCenter of Wisconsin's (BCW) Blood Research Institute, in collaboration with the Medical College of Wisconsin, welcomes two new editions to their team. Karin Hoffmeister, M.D., will be the new Senior Investigator at BCW and Hervé Falet, Ph.D, will serve as the new Associate Investigator. Both doctors come to the Blood Research Institute from Harvard Medical School. Dr. Hoffmeister received her medical degree from RWTH Aachen University, Germany, and then completed training in cardiology before coming to the U.S. She attended Harvard Medical School's Brigham and Women's Hospital for postdoctoral research training. She will direct a Glycobiology Center that will work to understand the role

of surface carbohydrates, or sugars, in hematopoietic cell function under healthy and pathologic conditions. Dr. Falet received his masters and doctorate degrees from Paris Descartes University, and completed his postdoctoral fellowship at Brigham and Women's Hospital. He joined the Department of Medicine faculty at Harvard Medical School in 2001 and the Division of Hematology at Brigham and Women's Hospital in 2014. At BCW, Falet will seek to better understand how platelets form in the human body and work toward the scientific breakthrough of developing synthetic platelets. ♦



MEMBER NEWS



The San Diego Blood Bank (SDBB), a California Blood Bank Society-appointed distributor of blood to Southern California during times of disaster or terrorism, announced it has furthered their disaster planning with the addition of a HAM radio operator. By using a HAM radio and SDBB donor volunteer Roy Gallagher as a HAM radio operator, SDBB will help keep the Coronado's First Responders, Amateur Radio Emergency Service (ARES), Radio Amateur Civil Emergency Service (RACES), and Club de Radio Experimentadores de Baja California (CREBC) emergency response groups connected when time is most critical. Mr. Gallagher, a 15-gallon donor, has been volunteering at SBDD for five years and belongs to a nationwide group of HAM radio operators who donate time and equipment toward the cause. The HAM radio technology and donated WinLink computer software

(continued on page 11)



MEMBER NEWS (continued from page 10)

allows SDBB to communicate directly with the Sheriff's department and every hospital in Southern California via radio airwaves when phone lines or the internet are unavailable. By aligning SDBB with HAM radio volunteers, the center has much greater access to emergency resources throughout San Diego and Southern California. Upgrades are in progress that will ensure that SDBB has one of the best communication systems in San Diego County. (Source: SDBB press release, August 29, 2016.) ♦

COMPANY NEWS



Inovio Pharmaceuticals, Inc. announced it has initiated a clinical study of a Zika vaccine in Puerto Rico. The study will consist of 160 subjects being given the experimental vaccine GLS-5700, being made in collaboration with GeneOne Life Science, Inc. In June, Inovio started a 40-person Zika trial with sites in the U.S. and Canada and expects to report results before the end of this year. (Source: *StreetInsider.com*, [Inovio Pharma \(INO\) Commences Zika Vaccine Study in Puerto Rico](#). August 29, 2016.)

Theranos, the blood testing company founded by Elizabeth Holmes, announced it plans to appeal sanctions placed on it by federal health regulators. The Centers for Medicare and Medicaid Services (CMS) sanctioned the company's lab in Newark, Calif., for allegedly jeopardizing patient health and safety. The startup denies they were conducting patient testing. The CEO was barred from running the company effective starting September 2016. (Source: *Fortune*, [How Theranos Plans to Fight For Its Lab](#). August 26, 2016.)

The Food and Drug Administration (FDA) approved Haemonetics Corporation's request to market their InstaMatch 1.0.0 blood establishment computer software (BECS) system. Instamatch is a web-based software application that matches patient, donors, and blood products to inventory with specific attributes like human leukocyte antigen and antibodies. Haemonetics filed for FDA approval of this BECS in June 2016. (Source: FDA, August 18, 2016.)



MEETINGS

Sept. 8

FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.

This free, first-come-first serve, public workshop titled the "[Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval](#)" was organized to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products subject to premarket approval, including stem cell-based products. The workshop will take place at White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room in Silver Spring, Md.

Sept. 12 - 13

FDA Public Hearing on HCT/Ps, Bethesda, Md.

This public hearing was created to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found [here](#).

(continued on page 12)

MEETINGS (continued from page 11)

Sept. 13 - 14

ABC IT Workshop, Minneapolis, Minn.

Experts in the field will gather in Minneapolis to discuss the implications of blood center corporate mergers on IT, service metrics, and cost saving initiatives. Come for the discussions on pressing IT topics and stay to network with your peers at this ABC workshop. To register or learn more, contact the ABC Meetings Department at (202) 654-2901 or e-mail: meetings@americasblood.org.

Sept. 21

Red Cell Genotyping 2016: Clinical Steps, Bethesda, Md.

The BloodCenter of Wisconsin (BCW) and the Department of Transfusion Medicine at the National Institutes of Health (NIH) Clinical Center, are co-hosting the 6th Annual Red Cell Genotyping Symposium at Lister Center Auditorium, National Library of Medicine, NIH Building 38A, 8600 Rockville Pike, Bethesda, Md., from 8:25 a.m. to 4:15 p.m. This symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. For information, program fee and advance registration visit BCW's [website](#) or contact Phyllis Kirchner phyllis.kirchner@bcw.edu.

Oct. 6 - 7

Pre-Clinical Evaluation of Red Blood Cells for Transfusion, Bethesda, Md.

The Food and Drug Administration is holding a free public workshop to discuss new methodologies for pre-clinical evaluation for the safety and efficacy of red blood cell transfusion products. The workshop is being held in partnership with the National Heart, Lung and Blood Institute; National Institutes of Health (NIH); the Department of Defense; and the Office of the Assistant Secretary for Health, Department of Health and Human Services and is located on the NIH campus with the Ruth Kirschstein Auditorium, Natcher Conference Center, Bldg. 45, 9000 Rockville Pike, Bethesda, MD. To register for the workshop, click [here](#).

Oct. 22 - 25

2016 AABB Annual Meeting, Orlando, Fla.

The AABB Annual Meeting is a health care professional event for those in the fields of transfusion medicine, cellular therapies, and patient blood management. AABB's 2016 Annual Meeting offers opportunities to learn the latest in the field, advance your career, explore state-of-the-art products and services, and network with your colleagues. The meeting will be held at the Orange County Convention Center in Orlando, Fla. More information is available at www.aabb.org/annual-meeting.

Oct. 31 - Nov. 1

FDA 510(k) Submissions Workshop, Washington, D.C.

AdvaMed hosts FDA and industry experts to teach the basics of 510(k) submissions. Learn about the FDA's updates to the 510(k) process, considerations for determining a product's regulatory route to market, factors to consider when planning and assembling a 510(k) submission. The workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register [here](#).

Nov. 2

FDA IDE Submissions Workshop, Washington, D.C.

Learn the regulatory and practical guidelines governing when an investigational device exemption is required during this interactive AdvaMed workshop. The

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MEETINGS (continued from page 12)

workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register [here](#).

2017

March 2 - 3

[IPFA 2nd Asia Workshop on Plasma Quality and Supply](#), Yogyakarta, Indonesia.

Registration for this workshop is open. The Internatioal Plasma Fractionation Association is holding this workshop to further the exchange of key issues, strategies and opportunities of plasma for fractionation and plasma-derived product professionals in Asia. Some of the topics it will cover are donor recruitment and selection, screening and diagnostic programs for blood born pathogens, quality management and regulatory issues. To register for the workshop, click [here](#).

May 16 - 17

[IPFA/PEI 24th International Workshop on “Surveillance and Screening of Blood-borne Pathogens”](#), Zagreb, Croatia.

Registration for this workshop is now open. The 24th IPFA/PEI International Workshop on blood-borne pathogens will address the detection, epidemiology, costs, and regulation of new and old agents that threaten the safety of blood components and plasma derivatives. To register, click [here](#).

Sept. 11 - 12

[IPFA/BCA 3rd Global Symposium on The Future for Blood and Plasma Donations](#), Atlanta, Ga.

The International Plasma Fractionation Association and Blood Centers of America are holding this meeting that will be hosted by Blood Assurance, a non-profit, full-service regional blood center. The meeting will cover a range of topics, including: clinical developments in plasma product use, plasma supply - optimizing plasma collection and economics, donor recruitment, industry developments in support of blood establishments, donor and product safety, regulatory issues, and quality management. [Registration will open in mid-September.](#) ♦

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) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Quality and Regulatory Services Manager. Small regional blood center in search for full time Tennessee licensed Medical Technologist with at least five years' experience. Strong communication and interpersonal skills required. Must have strong computer skills and be proficient in Microsoft Office including Word, Excel and PowerPoint. Candidate must be self-motivated and able to work independently. Position requires a strong work ethic and attention to detail. Responsibilities: Training,

auditing, donor management, project management, writing of Standard Operating Procedures, validation, equipment control and QC oversight. Ability to comprehend and apply regulations/standards from multiple agencies. Please submit resumes to: nikki.watling-ton@lifelinebloodserv.org.

Donor Testing Technician I. (Department: Donor Testing; Location: St. Paul, MN; Hours: Full Time, 1.0 FTE

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POSITIONS (continued from page 13)

(40hrs/wk), Non-Exempt; Shifts: 3rd Shift: Tuesday-Friday, 10:00 p.m. - 6:30 a.m. and Saturday, 8:00 p.m. - 4:30 a.m.; *Multiple positions available). Primary Purpose: Under general supervision, this position precisely and accurately performs sample handling/tracking/testing for one or more of the following: serologic testing for markers of hepatitis B, hepatitis C, human immunodeficiency virus (HIV), human T-lymphotropic virus (HTLV), syphilis, cytomegalovirus (CMV), red cell antibody screen, NAT(PCR), Chagas (T CRUZI) and additional viral screening assays on both blood donor and patient samples. Completes all required ancillary duties including reporting of test results, quality control/quality assurance activities and record maintenance. Operates a variety of computer systems and lab equipment, performs periodic equipment maintenance as necessary, performs primary review of test records, monitors and maintains adequate laboratory supplies, provides excellent customer service to both external and internal customers. To apply please go directly to our [website with an updated resume](#):

Clinical Laboratory Scientist (Full Time). Houchin Community Blood Bank, located in Bakersfield, California, is currently recruiting for a full time Clinical Lab Scientist. Houchin is centrally located in California, serving all of Kern County. Successful candidates must have a current state of California CLS License and have excellent communication skills, good laboratory practices and experience in quality control. Must have a bachelor's degree in a biological, physical, chemical or clinical laboratory science. Blood Donor Center or Transfusion Service experience is preferred. Duties include operation and maintenance of hematology instruments, performance of various testing, culturing of platelet products, and labeling of blood products. Knowledge of theory and test application in Immunohematology, microbiology and Hematology is required. Experience working with a computerized laboratory information system is necessary, as well as the ability to work independently. Applicants must be able to work daytime, weekend shifts, holidays and rotating on-call hours. We offer a competitive salary, great work environment, excellent benefits, including two retirement plans, and more. For more information about our company, visit www.hcbb.com. Resumes can be emailed to careers@hcbb.com.

Chief of Donor Operations. SunCoast Blood Bank, serving four counties on Florida's Gulf Coast is seeking a blood bank professional to direct and oversee our recruitment, collections, therapeutic services, supply chain and facilities operations. The successful candidate will have the ability to think strategically and have the organizational skills necessary to plan and execute varying directives which will further the organization's mission. Requirements for this position include a bachelor's degree in healthcare management or other equivalent field; MBA preferred. Eight years blood bank operational experience, five of which includes senior management experience. Competitive salary and benefits package. To

apply please submit cover letter, salary requirement and resumes to jobs@scbb.org. Applicant drug testing required. EOE.

Advanced Clinical Lab Specialist (Part-time IRL). Blood Systems is one of the nation's oldest and largest comprehensive transfusion medicine organizations. We serve blood centers, hospitals and health systems, offering shared management and support services, quality excellence and effective contracting. Under minimal supervision, this position is responsible for routine testing of biological specimens. This position also provides skilled technical support in the laboratory. Works with other team members to ensure timely, quality, test results. Knowledge/ Education: Bachelor's degree required. Must satisfy CLIA requirements for High Complexity Testing required. California testing requirements must be met within one year required. Licenses/ Certifications: Immunohematology Reference Laboratory (IRL); Certification as a Medical Technologist or Blood Banking Technologist (BB) by a recognized certifying agency required. Experience: Immunohematology Reference Laboratory (IRL); three years clinical laboratory testing required. One year of transfusion service experience required. One year IRL experience preferred. Blood Systems, Inc. is an Equal Opportunity Employer. Apply at: <http://www.bloodsystems.org/careers.html> Req 16000310. EOE/Minority/Female/Disability/Vets

Lab Quality Specialists. Currently, Cleveland Clinic is seeking Lab Quality Specialists for our East, West and South Regions. These positions are responsible for driving operational standardization throughout our laboratories and ensuring daily activities comply with regulatory and accrediting agencies. This will involve the collection and review of quality metrics, the evaluation of compliance gaps, and the continuous implementation of process improvements. Qualifications: Bachelor's degree in Clinical Laboratory Science or a chemical, physical or biological science; Three or more years of experience in quality systems development, implementation and assessment, or in regulatory affairs focused on the manufacturing of biologics or pharmaceuticals; At least three years of experience as a Medical Technologist; A minimum of three years' experience within a blood bank/transfusion service/blood center; and data management experience. To apply, please visit www.ecentralmetrics.com/url/?u=22906184778-215.

Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE

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POSITIONS (continued from page 14)

Lead Laboratory Technologist – Blood Bank. The Lead Laboratory Technologist performs various duties that drive the continued success of our Blood Bank and other areas of our lab. From basic to advanced patient and donor testing, to the interpretation and validation of results, your work will determine donor-recipient compatibility as well as solutions for identified irregularities. You'll also be responsible for conducting instrument and equipment qualifications, managing reagent inventory, tracking quality metrics, recommending improvements, and serving as an educational resource for employees, residents and students. Qualifications: Associate's degree in Medical Laboratory Technology or another laboratory science, or a bachelor's degree in Medical Technology or a relevant chemical, physical, biological or clinical laboratory science; two years of blood bank experience; and one year of supervisory or quality assurance experience. To apply, please visit www.ecentralmetrics.com/url/?u=64006184865-215. Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE

Supervisor – Blood Bank. Currently, Cleveland Clinic is seeking Blood Bank Supervisors. In this highly visible role, you'll be responsible for supervising blood bank staff at multiple hospitals for our East, West and South Regions. This will involve overseeing the performance of basic and advanced patient and donor tests, helping train new employees, tracking and reporting on quality metrics, and leading performance improvement initiatives. Through these and many other contributions, you'll build on the continued success of our blood banks while moving forward in your career. Qualifications: Bachelor's degree in Medical Technology or a chemical, physical, biological or clinical laboratory science; Three years of blood bank experience; At least one year of management experience; and Working knowledge of Quality System Essentials. To apply, please visit www.ecentralmetrics.com/url/?u=32946184866-215. Cleveland Clinic strives to reward dedication with an integrated and comprehensive benefits program that meets the needs of a diverse workforce and provides meaningful choices. Along with pension/savings plans, wellness programs and medical/dental/vision coverage, we offer flexible spending plans, life insurance and disability plans, paid time off, a tuition assistance program, and reimbursement for professional certification. EOE. 📌