

2018 #28

August 24, 2018

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**OBRR Appoints Director**

The U.S. Food and Drug Administration (FDA) Office of Blood Research and Review (OBRR) has announced that Nicole Verdun, MD has been named director.

Dr. Verdun had been serving as acting director since April 2018 succeeding Jay Epstein, MD, who left the position earlier this year following a 22-year career at OBRR.

“I am highly confident that she will build upon Dr. Jay Epstein’s accomplishments over more than two decades that have led the office to be considered the premier regulatory authority globally for blood and blood components,” stated Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research (CBER) in an email announcement.

In her role as acting director, she has “facilitated the successful completion of several important draft and final guidance documents and has led the OBRR efforts to address requests from the Department of Defense for licensure of various blood products,” according to the announcement.

Dr. Verdun received her medical degree from the University of Chicago Pritzker School of Medicine and completed her residency in pediatrics at Children’s Memorial Hospital of Northwestern University and a pediatric hematology-oncology fellowship at the Children’s Hospital of Philadelphia (CHOP). She practiced pediatric hematology-oncology working as an attending physician at CHOP and Children’s National Medical Center prior to joining FDA’s Center for Drug Evaluation and Research in 2012.

Dr. Verdun became deputy director of OBRR in October 2016.

(Source: Email Announcement from CBER’s Peter Marks, 8/21/18) ♦

**Upcoming ABC Webinars – Don’t Miss Out!**

- **Quality Integration Part I** – September 18<sup>th</sup> at 3 p.m. EDT. Additional details forthcoming!
- **Quality Integration Part II** – November 29<sup>th</sup> at 3 pm. EST. Additional details forthcoming!



## Remembering Celso Bianco, MD



Celso Bianco MD, our friend, colleague, and teacher, passed away on August 16, 2018 in Bethesda, Md. after a long illness.

He is survived by his beloved wife Maria Rios PhD, children Marco, Christina, and Julia, his five grandchildren, and brothers Eduardo and Carlos in Sao Paulo, Brazil. His pride in his family was boundless.

Dr. Bianco came to the United States in 1969 from his native Brazil after graduating from *Escola Paulista de Medicina* (Medical School of Sao Paulo) with a MD degree in 1966 and completing an internal medicine residency at the Hospital Sao Paulo in 1968.

He began a research career in immunology at New York University, subsequently joining the faculty at the Rockefeller University and then SUNY Downstate in New York City. Dr. Bianco entered the blood community in 1982 at the Lindsay F. Kimball Research Institute of the New York Blood Center (NYBC). He was eventually the NYBC's Executive Vice President for Medical Affairs, and his positions at NYBC brought him to the Council of Community Blood Centers, America's Blood Centers' (ABC) original incarnation, at the beginning of the AIDS tragedy. Dr. Bianco's knowledge and insights from an urban epicenter of the epidemic were central to NYBC's reactions to the threat of HIV/AIDS to transfusion safety, shaping both the responses of the blood center and the greater blood community to AIDS. The credibility he earned ensured his influence in many subsequent blood safety and policy responses.

At ABC, he chaired the Scientific, Medical, and Technical Committee and participated on many others. He served on the Board of Directors, was ABC's President from 1999-2000, and its Executive Vice President from 2000 until 2012 when he retired.

His *curriculum vitae* includes more than 200 peer-reviewed publications, chapters, and abstracts. The subjects range from lymphocyte membrane receptors to hemovigilance to patient blood management.

Dr. Bianco served the U.S. Food and Drug Administration formally as a member of its Blood Products Advisory Committee from 2008-12. His informal service to the agency was measured in countless extended conversations with great and sustained impact, leveraging collegial relationships with the leadership in the Office of Blood Research and Review. He was a member of the Department of Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability from 2002-06 where he was an early champion of risk-based decision making—before that label became fashionable.

The number of U.S. and international organizations, committees, working parties, and consultations to which he volunteered his singular fund of knowledge and ability to foster consensus is too long to enumerate. They include his term as President of the International Society of Blood Transfusion 2014-16, his long tenure on the AABB Transfusion-Transmitted Diseases Committee, and so many more. Through his entire expatriate professional career, he never lost a deep love for his homeland, traveling often to Brazil to participate in their debates about the best ways to fulfill our fundamental mission—supporting delivery of the best possible care to the patients we serve.

(continued on page 3)



## REMEMBERING CELSO BIANCO, MD (continued from page 2)

The respect of his peers is exemplified in the many honors they have accorded him including the Thomas F. Zuck Lifetime Achievement Award, Emeritus Membership from ABC, and Canadian Blood Services' Lifetime Achievement Award. The Celso Bianco Lecture, endowed by the Foundation for America's Blood Centers, is delivered each year by one of his many distinguished friends in the blood community at the ABC Annual Meeting.

At the end of the day, none of this captures Dr. Bianco's signal contributions to transfusion medicine. For over three decades he mentored more than a generation of community blood bankers (both medical directors and non-physicians) during challenging times with uncanny prescience, not to mention grace, kindness, and uncommon sense. To so many of us, from the donor rooms at the New York Blood Center to world renowned biomedical investigators, he was simply the brightest, most accessible, giving, authentically humble, and kindest colleague in our lives. His unflinching sense of humor (caustic only when necessary) in the face of the blood community's frustrations kept some of us on an even keel. This is how we will remember him.

He failed at only one ambition—to retire to Brazil as a cabana boy at his brother's beachfront home in Ubatuba.

We, ABC, and the broader U.S. and international blood communities, extend our deepest sympathy to his family, but especially our thanks for their having shared him with us.

His funeral was held in Rockville, Md. on August 21, 2018, and a memorial gathering will be announced in the near future by the family.

In lieu of flowers, donations may be made in his name to [Planned Parenthood](#), [Doctors Without Borders](#), or the [Icla de Silva Foundation](#) (a recruitment center for BE THE MATCH). Individuals wishing to send a note to the family may do so at:

Maria Rios  
6524 Elgin Lane  
Bethesda MD 20817

*Contributed by the ABC Community* 💧





America's Blood Centers®  
It's About *Life*.

## 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.*

### Summer Meeting Presentations Available

ABC members can access [presentations](#) from the 2018 Summer Meeting. The presentations have been posted to the [ABC Member Website](#). Members can download slides from the Medical Directors Workshop, Scientific, Medical, and Technical Forum, Business Forum, and ABC Members meeting. Please contact [Member Services](#) with any questions.

(Source: [MCN 18-033](#))

### ABC Issues Talking Points on Iron Depletion of Donors and Mitigation Strategies for Member Blood Centers

ABC has provided its members with tools to assist with any inquiries regarding iron depletion of donors and mitigation strategies. [MCN 18-032](#): Donor Iron Update was distributed last week and includes links to both [talking points](#) and a [position statement](#). Members of ABC can access these documents through the [ABC Member Website](#).

(Source: [MCN 18-032](#)) 💧

### 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 the Editor at [newsletter@americasblood.org](mailto:newsletter@americasblood.org) or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

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

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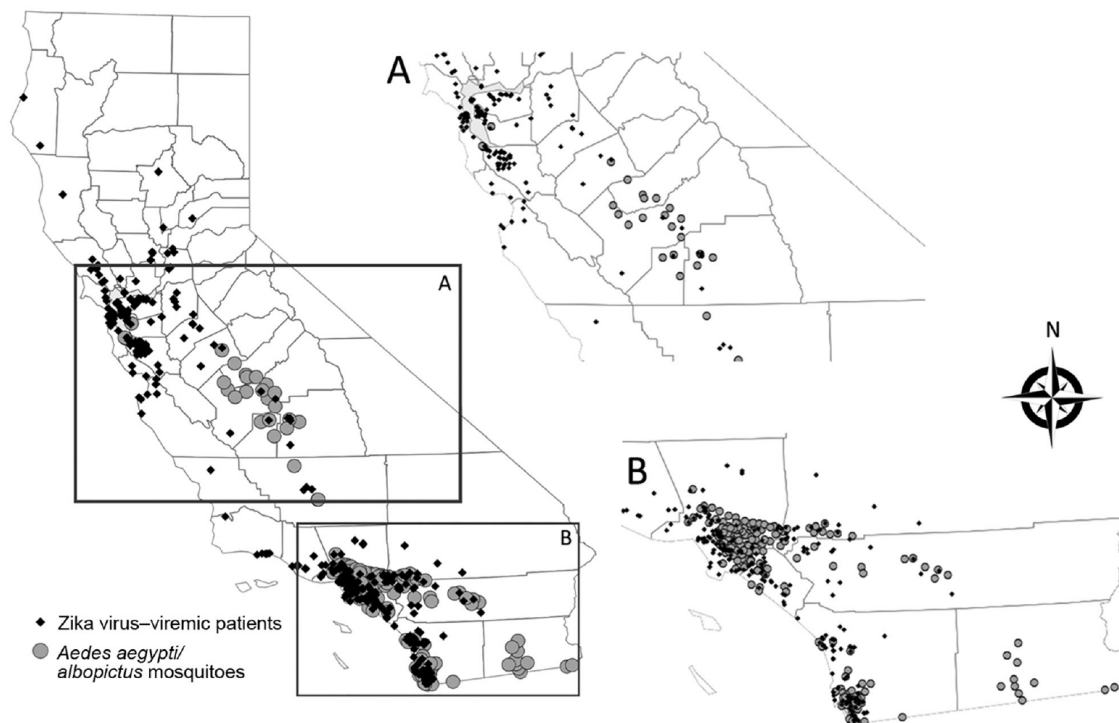


## RESEARCH IN BRIEF

**Tranexamic acid (TXA) to prevent postpartum bleeding.** A number of high-quality studies suggest that the inhibitor of fibrinolysis, TXA, can reduce bleeding after trauma, orthopedic surgery, and other indications. Now, a multicenter, double blind trial randomized 4,079 women to TXA or placebo after vaginal delivery to test whether TXA would be beneficial in preventing postpartum bleeding. The trial has failed to demonstrate a reduction in postpartum hemorrhage of at least 500 mL. The rates of this primary outcome were 8.1 percent with TXA and 9.8 percent with placebo (relative risk 0.83, 95 percent confidence interval 0.68-1.01). Secondary subgroup analyses did not demonstrate a protective effect in association with several risk factors for bleeding after vaginal delivery. Large trials will be required to identify subgroups that might benefit from receipt of TXA.

**Citation:** Sentilhes, L., Winer, M., Azria, E. *et al.* Tranexamic Acid for the Prevention of Blood Loss after Vaginal Delivery. *N. Engl. J. Med.* 2018. doi: [10.1056/NEJMoa1800942](https://doi.org/10.1056/NEJMoa1800942).

**Risk of local Zika transmission from travel-associated, imported cases in California?** Investigators from the California Department of Public Health have published an analysis of 588 travel-associated Zika cases during 2015–17 compared to the statewide distribution of *Aedes aegypti* and *albopictus* mosquitos, competent Zika vectors. The map below demonstrates the overlapping occurrence of the infections and the vectors, especially in Southern California. No vector-borne infections have been recognized or reported in California.



**Figure 3.** Locations where *Aedes* spp. mosquitoes were detected and residences of possibly viremic case-patients infected with Zika virus, central (A) and southern (B) California, USA, October 2015–September 2017. Insets show larger views of corresponding region.

**Citation:** Porse, C.C., Messenger, S., Vugia, D.J. *et al.* [Travel-Associated Zika Cases and Threat of Local Transmission during Global Outbreak, California, USA](https://doi.org/10.1093/emid/cdy001). *Emerg. Inf. Dis.* 2018.

(continued on page 6)

RESEARCH IN BRIEF (continued from page 5)

**Thrombopoietin (TPO)-independent acceleration of recovery from low platelet counts described.** Investigators from the Scripps Research Institute and Kyoto University describe a novel mechanism stimulating the production of platelets that does not involve the TPO signaling pathway. An activated form of the enzyme tyrosyl-tRNA synthetase designated YRS<sup>ACT</sup>, induced expansion of a megakaryocyte population capable of accelerating platelet production after their depletion. The enzyme was functional in cells from a patient deficient in TPO signaling. The authors speculate their observation “offers new approaches for treating thrombocytopenia, boosting yields from cell-culture production of platelet concentrates for transfusion, and bridging therapy for hematopoietic stem cell transplantation.”

**Citation:** Kanaji, T., Vo, M.-N., Kanaji, S. *et al.* [Tyrosyl-tRNA synthetase stimulates thrombopoietin independent hematopoiesis accelerating recovery from thrombocytopenia](#). *Proc. Nat. Acad. Sci.* 2018.

**American Society of Hematology (ASH) solicits comments on its [draft guideline](#) for transfusion support of patients with sickle cell disease (SCD).** This draft document is based on a systematic review of published evidence and begins by posing 10 questions, followed by recommendations, an assessment of the quality of supporting evidence, an extended description of that evidence, and enumeration of “additional considerations” from the guideline panel. Comments only be accepted [online](#) and must be submitted by October 1<sup>st</sup>, 2018. 💧

**BRIEFLY NOTED**

**Canadian Researchers recently reported on the development of a more efficient enzyme removal technique that could potentially create type O blood by removing type A and B antigens from red blood cells.** The results from their report demonstrate that the human gut microbiome enzymes used in their research are 30 times more effective than results seen from previous studies. The researchers discovered new enzymes that line the gut through glycosylated proteins (mucins) that provide sugars allowing gut bacteria to attach. Some of the mucins resemble antigens in blood types A and B. “We’ve fortunately been successful in finding one particular class of enzymes that is 30 times more efficient than any other that had been discovered,” said Stephen Withers, PhD, during the American Chemical Society Convention in Boston, Mass according to the online publication OurWindsor.ca. “We have now this purified enzyme which we can produce in quantity and can convert these A red blood cells to O red blood cells.” Previously, Canadian researchers had used directed evolution, which involved inserting mutations into the gene that codes for the enzyme, and selecting mutations that are more effective at inactivating the antigens. Those researchers were able to remove the vast majority of the antigens in type A and B blood though it was noted that further improvements were needed before using this method in clinical trials to ensure that all antigens were removed.

(Sources: Sci-News.com, [Newly found enzymes can help turn type A and B blood into universal type O](#), 8/21/18; OurWindsor.ca, [Canadian Blood Services thrilled by UBC’s new technique for making universal blood](#), 8/22/18)

**AABB and Fresenius Kabi will collaborate to launch the 13th annual Blood Collectors week from September 2<sup>nd</sup> to 8<sup>th</sup>.** This celebratory week recognizes blood collection professionals for their role in helping to secure a safe and adequate blood supply for patients. Local blood centers may [register](#) to participate, as a number of resources are available for participants including marketing and social media tools to assist in promotion. Blood centers are encouraged to share stories and photos about exemplary blood collection professionals. More information can be found at <http://www.bloodcollectors.org>.

(Source: Blood Collectors Week [Website](#)) 💧

## REGULATORY NEWS

The Centers for Medicare and Medicaid Services (CMS) has published the 2019 Inpatient Prospective Payment System (IPPS) final [rule](#). The agency believes the changes in the proposed rule will promote improved accessibility for patients to hospital price information and electronic health records. America’s Blood Centers is in the process of fully reviewing the final rule for its potential impact on member blood centers and will provide updates and report on any implications in a timely manner. ABC previously joined the National Marrow Donor Program (NMDP) along with a coalition of advocates in submitting a comment [letter](#) to CMS regarding the proposed rule. The letter raised awareness of the potential for a lack of access by patients that depend on therapies such as hematopoietic stem cell transplants due to a lack of funding for such patients in the inpatient setting that may require these therapies.

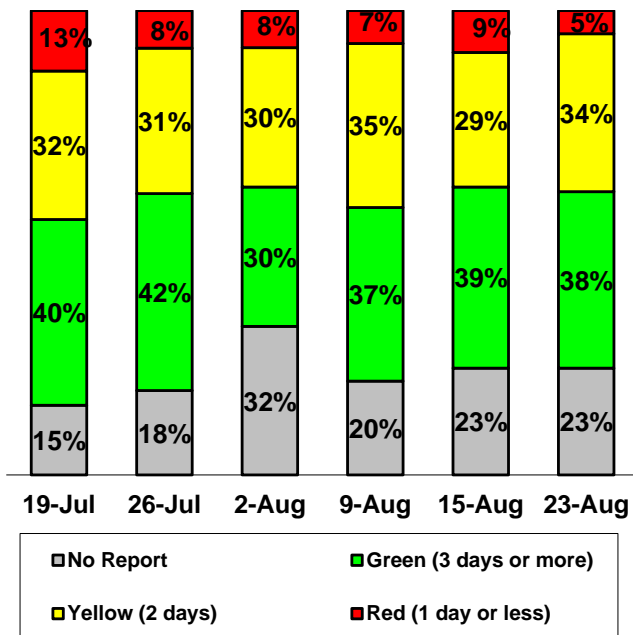
(Source: CMS Final [Rule](#), 8/17/18)

The Becton-Dickinson (BD) BACTEC™ Platelet Aerobic/F Culture vials and Platelet Anaerobic/F Culture vials have been cleared by U.S. Food and Drug Administration (FDA). These culture bottles are cleared for use with the BD BACTEC™ FX instrument “for quality control testing of leukocyte reduced apheresis platelet (LRAP) units, both leukocyte reduced single and a pool of up to 6 units of leukocyte reduced whole blood platelet concentrates (LRWBPC).” No safety claim has been approved. More information including the inserts for both the [aerobic](#) and [anaerobic](#) platelet culture vials are available on the FDA [website](#).

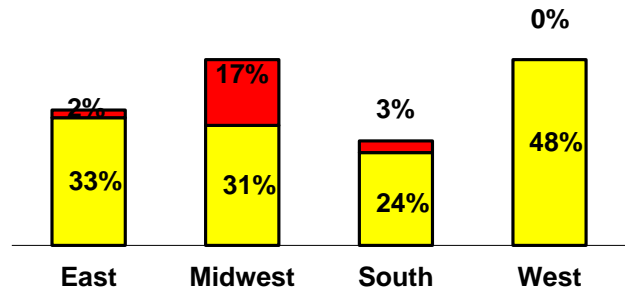
(Source: FDA Premarket 510(k) Notification [Letter](#), 8/8/18) 💧

### STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, August 24, 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](http://www.AmericasBlood.org)



## PEOPLE



*Photo courtesy of Houchin Community Blood Bank.*

Houchin Community Blood Bank CEO and President **Greg Gallion** has announced that he will retire at the end of the calendar year. Mr. Gallion has led the organization since 2001. Under his leadership, the Houchin workforce has more than doubled in size and the blood bank was recently named Nonprofit of the Year for 2018 by Sen. Jean Fuller (California 16<sup>th</sup> Senate District) for their outstanding work on behalf of individuals within the community. “I’m a product of the ‘50s, so I’ve always felt driven to hard work,” said Mr. Gallion in a news release provided to KBAK, their local CBS affiliate. “I want to know what it feels like to relax and not be in charge of something after 53 years.”

(Source: KBAK, [Houchin CEO Gallion announces his retirement](#), 8/20/18)

The Armed Services Blood Program has named Army Col. Audra L. Taylor as the new division chief. “I am honored to continue my work with the Armed Services Blood Program and further the efficacy of our efforts to save the lives of Soldiers, Sailors, Airmen, Marines, and their families around the world,” said Col. Taylor in an Armed Services Blood Program Announcement. “It is my mission to implement improvements to the support we provide to those in need.” Col. Taylor will replace current division chief Navy Capt. Roland L. Fahie, who has held the role since 2014. She is currently the director of the Army Blood Program where her accomplishments include “the implementation of Group O Low Titer Whole Blood, cold storage platelets in theater, the blood management system, and several ongoing research and development efforts,” according to the announcement.



*Photo courtesy of the Armed Services Blood Program.*

(Source: Armed Services Blood Program [Announcement](#), 8/15/18) ♦

## GLOBAL NEWS

Denmark plans to revise blood donation restrictions for men who sex with other men (MSM) according to published reports. The new regulations would begin in 2019 as Health Minister Ellen Trane Nørby looks to “modernize” the country’s blood system and embrace “equality” [reported](#) the *Copenhagen Post*. “The authority [patient safety] has found a model we feel is safe and we will therefore incorporate it into Denmark. All safety mechanisms in our blood donation system are built on trust and we have some very advanced tests that screen the blood,” said Health Minister Nørby. Under the revised policy, MSM in a monogamous relationship will be permitted to donate, while all other MSM will be able to donate if they have not had sex with another man in the past four months.

(Source: *Copenhagen Post*, [Gay men greenlighted for blood donation in Denmark](#), 8/20/18)





## 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](mailto: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

Sept. 5-7. **3rd European Conference on Donor Health and Management, Copenhagen, Denmark.** More details available [here](#).

Sept. 11. **37<sup>th</sup> Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD.** More details available [here](#).


Sept. 12. **8<sup>th</sup> Annual Symposium Red Cell Genotyping 2018: Patient Care, Bethesda, MD.** More details available [here](#).

Sept. 13. **Advisory Committee Meeting on Blood and Tissue Safety and Availability. Arlington, VA.** More details available [here](#).

Sept. 24-26. **The MedTech Conference, Philadelphia, PA.** More details available [here](#).

Oct 15-16. **510(k) Submissions Workshop, Washington, D.C.** More details available [here](#).

### 2019

May 22-13. **IPFA/PEI 26th International Workshop on "Surveillance and Screening of Blood-Borne Pathogens, Krakow, Poland.** More details available [here](#). 

### ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

### CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: [lmaundy@americasblood.org](mailto:lmaundy@americasblood.org).

### POSITIONS

**Blood Services Technical Manager.** Unyts, Western New York's ONLY Organ, Eye, Tissue and Community Blood Donation Center has an immediate opening for a Blood Services Technical Manager. This position is responsible for the administrative and technical management of blood processing and distribution. Ensures compliance with the standards of the FDA, NYSDOH and for all other pertinent industry standards. Manages process for proficiency testing for the QC lab to meet CLIA requirements. Responsible for implementing and maintaining policies and procedures

relevant to transfusable blood and blood products. Manages current and potential future technology needs of blood lab. Performs testing and other component processing procedures as necessary. Qualified individuals will have a bachelor's degree, plus a NYS Clinical Laboratory Science license with a minimum of six years experience as a Med Tech, with a minimum of two years in blood banking experience including component

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## POSITIONS (continued from page 9)

preparation preferred. Please visit this job listing at [www.unyts.org/about/careers/](http://www.unyts.org/about/careers/) for full details and to submit your application.

**Director of Project Management.** Central California Blood Center is seeking a Director of Project Management. Reporting to the CFO, this position is responsible to ensure the processes and organization IT infrastructure are designed and operating at maximum efficiency/effectiveness. Continuously evaluate for potential of increasing efficiency/effectiveness in collaboration with the appropriate coworkers, develop and manage new projects as assigned as well as identify new projects for improvement. As appropriate coordinate and collaborate with Subject Matter Experts (SME's) to complete RFP's if outside vendors are part of the process improvement or change process. Organize/lead teams with guidance from project champion to accomplish strategic inter/intra departmental goals. Develop goals/timelines according to the priority of implementation of new or existing project/processes. Qualified candidate will have a BA or BS degree with minimum five years previous project management/coordination or management experience. Requires good working knowledge of IT Systems along with leadership/mentoring skills and excellent communication and collaboration skills. Blood Bank or medical experience preferred, Lean/Six Sigma training a plus. EOE/M/F/VET/Disability/Gender Expression. Apply at <https://www.donateblood.org/career-opportunities/>

**Laboratory Supervisor – Processing and QC.** Stanford Blood Center, a subsidiary of Stanford Health Care, is seeking a Laboratory Supervisor, to lead and administer laboratory processing functions. Core Duties: Direct and supervise the processing CLS and QC LST II staff. Lead the planning and operations for functions or programs. Schedule staff and workflow to ensure coverage for testing needs throughout the lab. Review quality control data and proficiency testing and take corrective action as needed. Serve as technical resource for instruments in the department. Oversee completion of equipment maintenance, instrumentation calibration, QC, documentation and ensure adequate supply of supplies and equipment. Perform manual and automated testing on donor and clinical samples. Evaluate programs, policies and procedures. Qualifications: Bachelor's degree in medical

technology or life science and five years of relevant experience in a clinical lab or blood center required. Current California Clinical Laboratory Scientist License required. Prior supervisory experience desired. Ideal candidates will also possess: demonstrated ability to establish priorities, manage shifting priorities, and handle numerous time-sensitive projects with multiple deadlines; ability to accomplish goals working through formal and informal channels, with diplomacy and tactfulness. For a complete job description, and to apply visit: [www.stanfordhealthcarecareers.com/](http://www.stanfordhealthcarecareers.com/) and reference #47128.

**Chief Executive Officer.** Coastal Bend Blood Center, Corpus Christi, Texas is in search of a strong individual to replace retiring Chief Executive Officer (CEO). The CEO is responsible for management and leadership to ensure that the mission and core values of the Blood Center are put into practice. Responsible for operations including compliance with all accreditation standards, federal regulations and applicable laws, and aspects of the Blood Center including fiscal, technical, administrative, recruiting and collection activities. The CEO is accountable for all functions of the Corporation and the execution of all programs and undertakings of the organization. The CEO shall have the authority to employ, dismiss, establish salaries and direct the activities of the agents and employees of the Corporation. The CEO oversees the quality management system, and enforces compliance of all quality standards, and is responsible for all matters of compliance set forth in the Code of Federal Regulations, Dept. of Health & Human Services with authority to represent the Blood Center in all pertinent matters with the Center for Biologics & Research (CBER). Strong leadership, organizational and communication skills. Minimum 10 years of experience in the blood banking field with at least five years in Management. Bachelor's degree or higher required. Submit resume to [hr@coastalbendblood-center.org](mailto:hr@coastalbendblood-center.org). ♦