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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2023 #18 **May 19, 2023**

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FDA Finalizes Shift to Individual Donor Assessments

The U.S. Food and Drug Administration (FDA) published the final guidance titled "Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products." The guidance officially shifts the U.S. to individual donor assessments for blood donor screening rather than sexual orientation, eliminating time-based deferrals for sexually active gay and bisexual men and women who have sex with them. FDA did not state a specific timeframe for guidance implementation.

The final guidance is in part based on scientific findings and data from the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) study, which will be published in peer-reviewed medical journals. While the final guidance did not materially change from the draft guidance, it does include several clarifications such as:

- in line with America's Blood Centers' (ABC) joint comments to FDA, the agency included a recommendation that donor educational materials indicate that individuals should not discontinue their prescribed medications, including pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP), in order to donate blood.
- As requested in ABC's comments to FDA, the guidance provides clarification on the definition of a "new partner" by including examples of what would be considered having sex with a new partner, including having sex with someone for the first time, or having had sex with someone in a relationship that ended in the past and having sex again with that person in the last three months. Additionally, if a donor has questions about whether, for the purposes of blood donation, they are considered to have had sex with a new partner, the blood establishment's responsible physician must evaluate the donor's responses and determine the eligibility of the donor (21 CFR 630.5 and 630.10(a)).

Additionally, the final guidance continues the deferral for PrEP/PEP. Donor deferral for use of PrEP and PEP drugs, regardless of gender or sexual orientation, remains in place with an individual deferral of three months after the last oral dose or two years after the last injection of a medication to prevent HIV infection. The reason for this deferral is the available data demonstrate that the use of PrEP and PEP may delay detection of HIV by currently licensed screening tests for blood

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FDA Publishes Final Guidance (continued from page 1)

donations, potentially resulting in false negative results. The guidance also maintains the recommendations for deferral of individuals for HIV risk from April 2020 FDA guidance, including a three-month deferral for individuals who have exchanged sex for money or drugs, or have a history of non-prescription injection drug use, as well as individuals with other HIV risk factors, including contact with another person's blood, receipt of a blood transfusion, or a recent tattoo or piercing. Finally, the guidance continues the permanent deferral for any individual who has ever had a positive test for HIV or who has taken any medication to treat HIV infection. It also maintains the requirements that blood establishments test all blood donations for evidence of certain transfusion-transmitted infections, including HIV, hepatitis B and hepatitis C.

The FDA also published Guidance for Industry titled "Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components." This guidance recognizes, as acceptable, the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 4.0 dated May 2023, prepared by the Association for the Advancement of Blood & Biotherapies (AABB) Donor History Task Force.

ABC issued a news release supporting the FDA's policy change. "This shift toward individual donor assessments prioritizes the safety of America's blood supply while treating all donors with the fairness and respect they deserve," said ABC Chief Executive Officer Kate Fry, MBA, CAE. "The FDA's final guidance is based on data showing the best protection against diseases like HIV is through strong testing of all blood donations and a uniform screening process for all donors...It is important to note that these changes cannot be implemented overnight. We will continue working with our member blood centers to welcome impacted donors as quickly as possible."

The blood community also issued a statement in support of the final guidance. "ABC, AABB, and the American Red Cross "applaud the important, science-driven step forward in blood donation criteria that will base eligibility on an individual donor assessment using the same set of questions for all donors, regardless of sexual orientation…The blood community is united in its commitment to maintain the safety and availability of the nation's blood supply. Evidence from the Transfusion Transmitted Infections Monitoring System (TTIMS), other countries, and from the recent ADVANCE study support evaluating donor eligibility using individual donor assessment and other existing safeguards."

Talking points on this change are available in MCN 23-044. ABC will continue to provide additional resources as they become available, while also providing updates on its advocacy efforts regarding the guidance and implementation.

(Source: FDA Guidance, 5/11/23)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes 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 health care 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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ADRP Rebrands as ADRP: The Association for Blood Donor Professionals

Last week during ADRP Annual Conference in Charlotte, N.C., ADRP announced a new tagline and logo to the more than 400 attendees. As part of the organization's evolution, ADRP is now ADRP: The Association for Blood Donor Professionals.

"Our rebranding reflects ADRP's growth and the increased resources we are providing to blood donor professionals at blood centers around the world," said Amanda Farrell, president of ADRP. "From the COVID-19 pandemic to supply chain shortages to staff recruiting challenges, this is a time of immense change for the blood community. ADRP is changing with it to ensure blood donor professions have the support they need to thrive and make blood donation a priority in every community worldwide."

ADRP's new logo embodies the association's expansion to include more members from more countries around the world. The organization continues to provide educational opportunities, networking, and resources to more than 1,000 members worldwide.

America's Blood Centers (ABC) Chief Executive Officer Kate Fry, MBA, CAE added in the news release, "ABC recognized the unique and important role of ADRP when we joined forces seven years ago this month. Since that time, ADRP has grown to support an increasing number of blood donor professionals around the globe at a time when education and collaboration are needed the most. This milestone moment reflects the value of ADRP to communities, blood centers, and individuals worldwide."

(Source: ADRP News Release, 5/10/23)

RESEARCH IN BRIEF

Quality of Cold and Delayed Cold-Stored Platelets with Storage to 21 Days. A study in *Vox Sanguinis*, "investigated the *in vitro* quality and platelet function from day 1 to day 21 in cold-stored interim platelet units (IPU) platelet concentrates (PCs) and compared this to delayed cold-stored IPU PCs when transferred from room temperature to cold storage on day five." The authors explained that "[t]he trial included 36 IPU PCs pooled and split into 18 identical pairs…Two ABO-identical IPU PCs were sterile connected and combined in one bag." The researchers noted that "[e]ach pair was stored for 21 days, where one IPU PC was stored agitated at room temperature (20–24ºC) for five days before transfer to cold storage without agitation, while the other IPU PC was stored continuously cold without agitation…Sampling was performed after pool-and-split on day one and on storage days five, seven, 14, and 21…All IPU PC units complied with the requirements in the Guide to the Preparation, Use and Quality Assurance of Blood Components (EDQM, 20th edition)." "[B]oth groups had PLT > 200 x 10^9/unit on day 21." The authors found that "there was a steeper decline in glucose concentration in the delayed cold-stored group, which continued after cold storage ($p < 0.001$)." They stated that "[t]here was measurable glucose in every unit in the cold-stored group on day 21, while there was one unit without detectable glucose on day 21 in the delayed cold-stored group…During storage, pH declined in both groups with the biggest decline in the continuously cold-stored group on day 21 ($p < 0.001$)." However, the lowest value of 6.9 was well above the recommended limit of 6.4 for PCs…Unstimulated platelets had higher CD62P (platelet activation response) mean fluorescence (MFI) in the continuously cold-stored group from day five ($p = 0.010$) and throughout storage…However, the stimulation response measured as difference in MFI between stimulated and unstimulated platelets was higher in the delayed cold-stored group from day five to day 21." The study concluded that the "results suggest that IPU PCs are suitable for cold storage from day one until day 21 and

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RESEARCH IN BRIEF (continued from page 3)

delayed cold from day five until day 14…The cut-offs expressed here are based on levels of glucose measured in the PCs and the results of platelet function analysis."

Citation: Braathen, H., Felli Lunde, T.H., Assmus, J., Hagen, K.G., Kristoffersen, E.K., Strandenes, G., *et al*. In vitro quality of cold and delayed cold-stored platelet concentrates from interim platelet units during storage for 21 days. *Vox Sang*. 2023

Contributed by Richard Gammon, MD, Medical Director at OneBlood

REGULATORY NEWS

The U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will meet July 6th-7th. According to the announcement in the *Federal Register* on May 17th, the ACBTSA will "discuss and vote on a recommendation related to surge capacity for blood and blood products." The meeting is open to the public via webcast and is tentatively scheduled to take place from 10 a.m. – 3 p.m. EST. Instructions for individuals who wish to provide written public comments are available here. Comments must be received by midnight on June 28th.

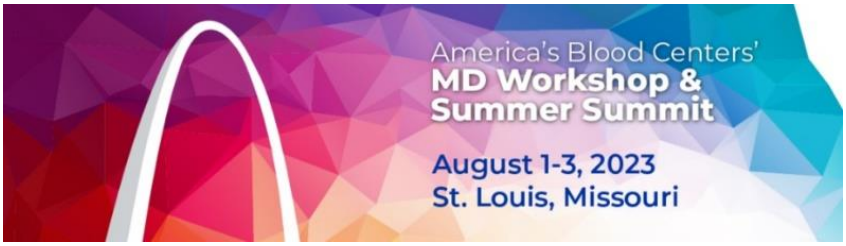
(Source: *Federal Register* Notice, 5/17/23)

The U.S. Food and Drug Administration (FDA) published approved variances on May 12th "Exceptions and Alternative Procedures Approved Under 21 CFR 640.120 (a) during January 2023 and March 2023." The document is available on the FDA website. "Under title 21 of the Code of Federal Regulations 640.120(a), the Director, Center for Biologics Evaluation and Research, may issue an exception or alternative to any requirement in subchapter F (Biologics, Parts 600-680) of Chapter I (Food and Drug Administration, Department of Health and Human Services) of title 21 of the Code of Federal Regulations regarding blood, blood components or blood products."

(Source: FDA Announcement, 5/12/23)

FDA's Center for Biologics Evaluation and Research (CBER) recently updated the information on its website related to a Fenwal bag shortage that began in January 2022. The agency still lists the shortage as "ongoing." The update states that "Fenwal has informed the FDA that due to manufacturing problems and quality procedures at Fenwal manufacturing facilities, including global supply chain issues related to the lack of some materials and components needed for the manufacturing process, the products listed in this notice may be in short supply and/or shortage until further notice. Shortages of ingredients, components and manufacturing supplies, and release timing issues are intermittent and unpredictable. Product may be placed on allocation as necessary to manage reduced or unavailable supply."

(Source: FDA Announcement, 5/12/23)



America's Blood Centers®
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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 staffs only, unless otherwise specified.

Registration Is Open for the ABC Summer Summit & MD Workshop

Mark your calendars for America's Blood Centers (ABC) Summer Summit and Medical Directors Workshop in St. Louis, Mo. The meeting will take place August 1st-3rd. Registration is open and hotel reservations can be made at Live! by Loews (St. Louis). Attendees will hear updates on blood center operational, scientific, and medical issues, case studies, engaging discussions, and have networking opportunities to connect with peers and colleagues. Additional details, including registration information and a preliminary agenda, are coming soon.

WORD IN WASHINGTON

Rochelle Walensky, MD, MPH is stepping down as director of the Centers for Disease Control and Prevention (CDC). According to a May 5th statement from the agency, she will officially leave the CDC at the end of June. "The end of the COVID-19 public health emergency marks a tremendous transition for our country, for public health, and in my tenure as CDC Director," stated Dr. Walensky in the announcement. "I took on this role, at your request, with the goal of leaving behind the dark days of the pandemic and moving CDC – and public health – forward into a much better and more trusted place. In the process, we saved and improved lives and protected the country and the world from the greatest infectious disease threat we have seen in over 100 years."

(Source: CDC Announcement, 5/5/23)

PEOPLE

Grifols has named **Thomas Glanzmann** as their new chief executive officer (CEO). He currently serves as the executive chairman of the Board of Directors and will remain in that role as well. According to a company news release, Mr. Glanzmann "will be responsible for the company's business decisions while creating and implementing its short- and long-term strategies with the management team. Additionally, Grifols announced that "**Victor Grifols Deu** will become chief operating officer (COO), focused on managing the day-to-day business, with all operating functions reporting to him. He will continue as a member of the company's Board of Directors. **Raimon Grifols**, currently Grifols Vice Chairman, will in addition to his Board duties assume the role of chief corporate officer, centered on optimizing the value of Grifols Corporate affiliates and partnerships, as well as leading key corporate initiatives."

(Source: Grifols News Release, 5/8/23)

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!

MEMBER NEWS

Blood Assurance has established a cellular therapy division in Nashville, according to a report in *The Tennessean*. The new 8,000 square facility will house a donor center and also "participate in research programs and provide a variety of other specialized treatments," stated the news outlet. "Blood banking has evolved. Cellular therapy is one more evolution of what we can do to help," said Blood Assurance Chief Executive Officer J.B. Gaskins in the news article. "Instead of just treating we can actually participate in helping to find cures."

(Source: *The Tennessean*, Blood Assurance opens unique cellular therapy center in Nashville, 5/9/23)

New York Blood Center (NYBC) recently made a $50 million investment in the "launch of an inaugural fund" for NYBC Ventures, "an early-stage life sciences investment fund dedicated to accelerating innovations in blood and cellular therapies, and related technologies." According to a news release, the mission of the Fund is "to improve patients' lives by advancing therapeutics, enabling platforms and technologies as well as drive strategic collaborations to further NYBC's impact… NYBC Ventures employs a model of patient capital and takes a flexible approach to financing vehicles and structures. The fund has developed streamlined scientific and due diligence teams to evaluate investment opportunities. NYBC Ventures is managed [by] Christopher D. Hillyer, MD, general partner, Jay Mohr, general partner, and Meg Wood, MPH, managing director, who collectively bring deep expertise in basic and clinical research, capital-raising, business and corporate development, and operations, from startups to complex organizations."

(Source: NYBC Ventures News Release, 5/11/23) ♦

GLOBAL NEWS

The World Health Organization (WHO) has ended the public health emergency of international concern (PHEIC) for mpox. In a statement, the WHO Director-General in consultation with members of the International Health Regulations (2005) (IHR) Emergency Committee regarding the multi-country outbreak of mpox concluded that based on a "significant decline in the number of reported cases compared to the previous reporting period and no changes in the severity and clinical manifestation of the disease," that mpox outbreak "no longer constitutes a PHEIC."

(Source: WHO Statement, 5/11/23)

The WHO also recently announced on May 5th that the SARS-CoV-2 pandemic is "now an established and ongoing health issue which no longer constitutes PHEIC." The WHO Director-General intends to "convene an International Health Regulations (IHR) Review Committee to advise on Standing Recommendations for the long-term management of the SARS-CoV-2 pandemic, taking into account the 2023-2025 COVID-19 Strategic Preparedness and Response Plan. During this transition, States Parties are advised to continue following the issued 'Temporary Recommendations.'"

(Source: WHO Statement, 5/5/23)

The Association for the Advancement of Blood & Biotherapies (AABB) and the Korea Testing and Research Institute (KTR) have partnered. According to announcement, the collaboration aims "to foster economic growth in the fields of testing and certification and to support advancements in the fields of in vitro diagnostics and laboratory support equipment." Additionally, AABB "will now serve as the primary third-party reviewer for KTR's submission of eligible medical devices as part of the FDA's 510(k) process." KTR is a part of the South Korean Ministry of Industry.

(Source: AABB Announcement, 5/3/23) ♦

COMPANY NEWS

Data from a clinical trial of an investigational chikungunya vaccine candidate developed by **Emergent BioSolutions, Inc.** has been published in *Science Translational Medicine*. According to the authors, the investigational vaccine "is well tolerated and induces a robust and durable (≥2 years) immune response. Our results show that two doses of [investigational] vaccine induce high levels of neutralizing antibody against all chikungunya virus genotypes, and its breadth of response extends to several other arthritogenic alphaviruses. We also profiled the B cell response to vaccination, which revealed the induction and persistence of antigen-specific B cells in blood, with type-specific and broadly neutralizing capacity."

Citation: Raju, S., Adams, L. Earnest, J., *et al*. "A chikungunya virus–like particle vaccine induces broadly neutralizing and protective antibodies against alphaviruses in humans." *Science Translational Medicine*. 2023.

Gamida Cell Ltd. recently announced that the U.S. Food and Drug Administration approved its cell therapy (Omisirge®). The therapy can be used "in adult and pediatric patients 12 years and older with hematologic malignancies planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection." According to the announcement, this is the "first allogeneic stem cell transplant therapy to be approved on the basis of a global, randomized Phase 3 clinical study."

(Source: Gamida Cell Ltd. News Release, 4/18/23)

Upcoming ABC Webinars & Virtual Events – Don't Miss Out!

- **ADRP: The Association for Blood Donation Professionals Master Class: Change Is Good – The Journey of Donor Eligibility** – Sept. 20-21. Registration is open. More information available here.

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2023

June 5-9. **U.S. Food and Drug Administration's (FDA) Regulatory Education for Industry (REdI) Annual Conference 2023 (Virtual).** Registration is open. More information available here.

June 13-14. **FDA Science Forum (Virtual).** Registration is open. More information available here.

June 17-21. **International Society of Blood Transfusion (ISBT) Regional Congress, Gothenburg, Sweden.** More information available here.

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CALENDAR (continued from page 7)

July 6-7. **U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) (Virtual).** More information available here.

July 31. **Blood Centers of America (BCA) Medical Directors Meeting, St. Lois, Mo.** The meeting will be held from 9-5 pm at the Loews. Please contact Stacy Conway for more information.

Aug. 1-3. **ABC Medical Directors Workshop and Summer Summit, St. Louis, Mo.** Registration is open. More information available here.

Sept. 17-20. **American Association of Tissue Banks Annual Meeting, National Harbor, Md.** More information available here.

Sept. 20-21. **ADRP: The Association for Blood Donation Professionals Master Class: Change Is Good – The Journey of Donor Eligibility (Virtual).** Registration is open. More information available here.

Oct. 9-11. **Advanced Medical Technology Association (AdvaMed) The MedTech Conference, Anaheim, Calif.** More information available here.

Oct. 14-17. **AABB Annual Meeting, Nashville, Tenn.** More information available here.

Oct. 18-20. **American Society for Clinical Pathology (ASCP), Long Beach, Calif.** More information available here.

Nov. 18-21. **ISBT Regional Congress, Cape Town, South Africa.** More information available here.

2024

Mar. 4-6. **ABC Annual Meeting, Arlington, Va.** More information available here.

May 15-17. **2024 ADRP Annual Conference, St. Louis, Mo.** More information 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 members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Manager of Donor Resources. The Blood Connection is seeking a Manager of Donor Resources in Raleigh, NC to provide oversight to our recruitment team within the division. This position directs Account Managers to strategically manage our existing portfolio of blood donor groups and new business to reach collection targets. The Manager of Donor Resources monitors progress to goal proactively and effectively coaches and manages the team to success. The ideal candidate will have a strong background in territory management and team building. Candidates must possess excellent interpersonal, analytical, and strategic planning abilities. We offer an exceptional benefits package including a generous 401k match, 30 days PTO, company bonuses, tuition reimbursement, cell phone stipend, and yearly increases. Join one of the fasting growing blood centers in the country and help make an impact in your community today! How to apply: Manager of Donor Resources Application

Regional Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Regional Manager for McDonough, GA is responsible for overseeing daily operations of the region, is organized and decisive, and can motivate the team to reach daily and long-range collection goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position and to apply. https://www.lifesouth.org/work-at-lifesouth/

Purchasing Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Purchasing Manager at our headquarters location in Gainesville, FL is responsible for vendor selection, negotiation, establishment and maintenance of all

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POSITIONS (continued from page 8)

purchased materials, supplies, equipment, and services used by the company. The Purchasing Manager oversees daily operations of the Purchasing team, is organized and decisive, and can motivate the team to reach daily and long-range goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position and to apply. https://www.lifesouth.org/work-at-lifesouth/

Enterprise Medical Director. This position is part of an enterprise-wide Chief Medical Office. This role is responsible for providing medical directorship, administrative, technical, and clinical operations of the assigned hospitals, systems, program, and services as well as support medical directorship of New York Blood Center (NYBC) or the greater NYBC enterprise. This position supports management in making information medical decisions, develops and reviews medical oversight and responsibility for the technical and medical policies, processes, and procedures of specific operations. New York Blood Center Enterprises (NYBCe) is one of the largest community-based, non-profit blood collection and distribution organizations in the United States. We proudly serve as a vital community lifeline dedicated to serving patients and advancing global public health. Our four-part mission is to provide high quality blood products, therapeutic apheresis, cord, and stem cell services, conduct innovative research, develop new products and technologies, and train the next generation of industry leaders. We serve more than 600 hospitals through our six east coast and mid-west divisions and work with dozens of research organizations, academic institutions, and biopharmaceutical companies through our five research enterprises. Click here to view the full job description and apply: Enterprise Medical Director in New York, New York.

Supervisor, Immunohematology Reference Laboratory. Outstanding opportunity for qualified individual! This position reports to the Laboratory Services Manager and Director of Laboratory Services. This position also works closely with the New York Blood Center Enterprise IRL laboratories. Responsible for the supervision of Immunohematology Reference Laboratory (IRL) staff, daily workload, and compliance with applicable standards of the AABB, RI State, NY State and CLIA regulations. This position requires advanced technical knowledge of immunohematology techniques and knowledge of proper handling of biological materials and hazardous chemicals. Requires: BS in Medical Technology. Certified Specialist in Blood Banking (SBB.) At least six years' experience at the bench level or higher post baccalaureate degree and national certification. Exceptional compensation and benefit package. For more information and online application, please go to: www.ribc.org/careers.

Lead Technologist-Reference Lab. This position reports to the Manager of Laboratory Operations. Responsible for the review of daily workload, staff training and competency and compliance with applicable standards of the AABB, CLIA and NYSDOH. This position requires advanced technical knowledge of immunohematology techniques and knowledge of proper handling of biological materials and hazardous chemicals. Candidates must have a BS in Medical Tech or Clinical Lab Science, plus six years' experience at the bench level. Exceptional compensation and benefit package. For more information and online application, please go to: www.ribc.org/careers.