



2026 #13

April 27, 2026

ABC Comments to FDA in Response to Form 483 Observations at the Conclusion of a CGMP Inspection

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America’s Blood Centers (ABC) has submitted [comments](#) to the U.S. Food and Drug Administration (FDA) regarding the agency’s [draft guidance](#) titled “Responding to FDA Form 483 Observations at the Conclusion of a Drug Current Good Manufacturing Practice (CGMP) Inspection.” In the comments, ABC recommends that FDA:

- “clarify that certain elements are not universally required for every Form 483 response and should be applied ‘only if applicable;’ [and]
- that FDA establish a voluntary option allowing manufacturing establishments to submit a ‘letter of intent to respond’ indicating their plan to provide a full response to an FDA 483.”

FDA [published](#) the draft guidance in March 2026, “to assist manufacturers who choose to respond to FDA when they receive an FDA Form 483 Inspectional Observations at the conclusion of a drug inspection to assess conformity with CGMP requirements.”

Comments are due by May 8th. ABC will continue to provide updates on our advocacy efforts as they become available. Please [contact us](#) with any questions.

(Source: ABC [Comments](#), 4/20/26) 💧

ABC Participating in NASEM Webinar on “Ensuring Continuity and Resilience of the U.S. Blood System

America’s Blood Centers (ABC) will take part in a May 4th [webinar](#) hosted by the National Academies of Sciences, Engineering, and Medicine (NASEM) from 2-5 p.m. EDT. The webinar is titled “Blood: Ensuring Continuity and Resilience of the U.S. Blood System” and will include ABC Vice President of Government Relations and Public Affairs Susan Leppke, MPH during session two which covers the blood supply chain system and key fragilities. She will join Meghan Delaney, DO, MPH (Children’s National Hospital), Bill Block (Blood Centers of America), and Courtney Hopkins, DO (Vitalant).

[Registration](#) is open. The webinar will also feature sessions exploring: Disruptions, Gaps, and Adaptive Strategies; and Pathways Toward Sustainable and Resilient Systems. The objectives of the webinar are to:

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NASEM Webinar on “Ensuring Continuity and Resilience of the U.S. Blood System (continued from page 1)

- “[e]xamine domestic and global supply chains for blood and identify key fragilities including manufacturing concentration, logistics, workforce, and infrastructure dependencies;
- [s]urface concrete use cases that illustrate key gaps and challenges, as well as adaptive strategies and promising solutions across sectors;
- [e]xplore policy, regulatory, and market/transportation dynamics that shape incentives, resilience, and investment in critical medical resource systems;
- [p]ropose models and strategies that support sustainable and resilient systems, including redundancy, diversification, public–private coordination, and regional or national approaches;
- [s]urface cross-cutting insights and questions to inform future research, convenings, and preparedness efforts.”

(Source: NASEM [Announcement](#), 4/23/26) ◆

AI-enable Forecasting of Prehospital Transfusion Needs Explored in *The Lancet*

Researchers in *The Lancet Digital Health* [sought](#) to create and “validate” machine learning algorithms to detect trauma patients that may “benefit” from early prehospital blood transfusions. The paper explained that the investigators used prehospital data to, “forecast the necessity of transfusions and distinguish between the types of blood products required, such as packed red blood cells (PRBCs), platelet concentrates, and fresh frozen plasma (FFP) [hypothesizing] that machine learning approaches integrating vital signs, injury patterns and patient anti-thrombotic medications might provide a more individuali[z]ed and prognostically relevant approach to assess early need for transfusion products.”

The authors noted that the retrospective study used multinational trauma registry data that met and adhered to, “established international guidelines for trauma management and blood product administration.” Inclusion criteria consisted of, “the presence of the same reporting variables with preclinical injury data, including injury patterns, vital signs, and anticoagulant premedication (i.e., medication taken before hospitali[z]ation), in combination with comprehensive documentation on transfusion products administered. [Patients were] excluded when transfusion data were not reported, the patients had trauma primarily from burn injuries, or patients had an overall Injury Severity Score (ISS) of 1. Transfusions within four hours after hospital arrival were considered. [Additionally, individuals] with prehospital cardiac arrest were excluded due to heterogeneous transfusion patterns.”

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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 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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AI-enabled Forecasting of Prehospital Transfusion Needs Explored in *The Lancet* (continued from page 2)

The study included in the derivation cohort 455,437 eligible patients from the U.S. the National Trauma Data Bank in calendar year 2020. The paper explained that, “54,210 eligible patients from the TraumaRegister DGU (between January 2007 and September 2024 from Germany, Austria, and Switzerland), the National Office of Clinical Audit–Major Trauma Audit (between January 2014 and December 2021 from Ireland), and the Alberta Trauma Registry (between January 2015, and December 2023 from Canada) were used for external validation.” Patient characteristics described by the researchers included that, “[t]ransfused patients were younger across all four trauma registries compared with non-transfused patients. Most patients were male (272,059 [59.74 percent] for the derivation cohort, 35,601 [65.67 percent] for the external validation cohort), and male patients were also more frequently transfused than female patients (15,787 of 21,225 [74.38 percent] for the derivation cohort, 3,045 of 4,287 [71.03 percent] for the external validation cohort).”

The investigators explained that, “[m]ultiple models were trained to predict the transfusion of PRBCs, platelet concentrates, FFP, or any blood product (each binary), or predict a combination of blood products needed for transfusion (multiclass), with differentiation between PRBC, PRBC plus FFP, and PRBC plus FFP plus platelet concentrate, and no need for transfusion in a one-versus-rest manner.” The study noted that, “[t]ransfusion of PRBCs appears to be the most important blood product in the context of preclinical administration.” The authors explained that, “[t]o further assess the practicality of our approach in the pre-hospital setting, we performed an additional analysis using an alternative injury severity estimate available in the TraumaRegister DGU. Emergency physicians assessed injury severity across nine body regions using a four-point scale (none, minor, moderate, and severe) at the scene. [Although this] score was only available in the TraumaRegister DGU, we additionally mapped the National Trauma Data Bank injury coding system to approximate this classification to enable external validation across registries, with similar results. These findings suggest that even simplified prehospital severity assessments can support reliable prediction on transfusion need, independently of unavailable prehospital imaging.”

The PRBC prediction model also determined that, “patients at high risk for transfusion need had [the] greatest mortality, particularly within the first three days. Over the 10-week long-term follow-up, patients with initially the highest probability of transfusion need exhibited the highest cumulative incidence of overall mortality (low predicted transfusion probability vs. high predicted transfusion probability).” The study also found that, “[a]t the 72-hour timeframe, death from h[e]morrhage, as reported in the TraumaRegister DGU, revealed a strong association with transfusion probability. Mortality due to h[e]morrhage was 0.9 percent, 4.7 percent, and 16.2 percent for low, intermediate, and high transfusion probability groups, respectively (low predicted transfusion probability vs. high predicted transfusion probability).”

The researchers concluded that, “[m]achine learning outperformed conventional methods to estimate blood loss, enabled prognostic short-term and long-term predictions, and could differentiate between blood products needed independently of blood sampling. Importantly, model performance was robust across countries, years, and age groups, supporting generalizability and highlighting its potential to support clinical decision making in a time-critical setting. The implementation of machine learning models in trauma care could lead to several clinical benefits. Early and accurate identification of patients in need of blood transfusion can facilitate timely interventions, potentially reducing mortality and improving overall outcomes. Additionally, the models can assist in optimizing resource allocation in trauma centers, ensuring that blood transfusions are administered efficiently and effectively.” Limitations of study acknowledged by the authors included: “transfusion decisions reflect clinical judgement and institutional practice, not purely physiological need, introducing heterogeneity into the ground truth labels; the registries we used are from regions of the world with similar medical standards and overall similar trauma injuries. Consequently, the application of the derived machine learning models in countries with fewer resources and less stringent medical care standards must first be investigated to ensure its effectiveness and adaptability in such settings;

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AI-enabled Forecasting of Prehospital Transfusion Needs Explored in *The Lancet* (continued from page 3)

injury severity was assessed using the Abbreviated Injury Scale; whole blood transfusion was not modeled due to low prevalence, despite its growing role in trauma resuscitation; [and] our models were developed using registry data, which inherently lack certain qualitative clinical features, such as capillary refill time, pallor, thirst, diaphoresis, or clinician gestalt, which are often integral to prehospital judgement and hemorrhage recognition.”

Citation: Sigle, M., Boos, M., Weiss, T. *et al.* “[AI-enabled forecasting of prehospital transfusion needs in patients with trauma: a multinational, registry-based, retrospective, machine learning development and validation study.](#)” *The Lancet Digital Health.* 2026.💧

BRIEFLY NOTED

Researchers at the University of California San Francisco (UCSF) have **announced** the publication of a paper in *Blood* titled “A Dried Platelet-Derived Biologic for Blood-Brain Barrier Repair and Hemorrhage Control Following TBI in Mice.” According to the authors, the research demonstrates that, “[a] freeze-dried blood product that could be stored for years on ambulances or in remote emergency departments is showing promise at treating traumatic brain injuries. [The product,] called ‘Thrombosomes,’ was originally developed to control bleeding in battlefield settings. It is derived from platelets that have been freeze-dried with a sugar called trehalose, which helps preserve some of their beneficial contents. It has a shelf life of up to five years—far longer than the seven-day shelf life of fresh platelets from human blood donors.” The news release describing the findings also noted that, “the team tested Thrombosomes on the blood vessel cells in petri dishes and in 3D organoid models of blood vessels. The product made both the cell layers and vessels resilient to damage. Mice that received the product either an hour or a day after a brain injury had less hemorrhage and their blood vessels were not as leaky. They also had less brain inflammation, which can lead to swelling. The scientists found that the product contained high amounts of a protein that activates a receptor on blood vessel cells, helping to stabilize them. This may explain how the product makes them less leaky. [The product] is in [p]hase II clinical trials for bleeding disorders, which means it has already been shown to be safe for people. This could hasten trials that test it for TBI.”

(Source: UCSF [News Release](#),” 4/23/26) 💧

WORD IN WASHINGTON

The Centers for Disease Control and Prevention (CDC) published a **statement** last week highlighting that, “Data Show Weekly Emergency Room (ER) Visits for Tick Bites Higher than Usual.” Specifically, the agency explained that, “[i]n all regions except the south central U.S., weekly rates of ER visits for tick bites are the **highest for this time** of year since 2017. Preventing tick bites is considered the best form of protection throughout tick season. If individuals do find an attached tick, they should remove it as soon as possible and not wait to get to the ER.” Ticks can cause **babesiosis** which can be transmitted from an infected donor through transfusion of blood products.

Data dashboard



Data dashboard



(Source: CDC [Statement](#), 4/24/26) 💧

ADVANCED THERAPIES NEWS

A [paper](#) published in *Nature* titled “Long-term HIV-1 remission achieved through allogeneic hematopoietic stem cell transplant from a CCR5Δ32/Δ32 sibling donor” describes, “in-depth clinical characterization along with extensive virological and immunological analyses of peripheral blood, gut, and bone marrow of a 63-year-old male individual with possible HIV eradication.” The authors noted that the, “patient was in good health with undetectable HIV RNA in plasma 60 months after CCR5Δ32/Δ32 allogeneic hematopoietic stem cell transplantation (HSCT) for myelodysplastic syndrome and 36 months into analytical treatment interruption (ATI).” The researchers explained that this paper, “contributes valuable evidence to the existing knowledge base regarding HIV cure cases. Moreover, this and other studies on HIV cure enhance our understanding of HIV pathology, molecular mechanisms and predictive biomarkers that may be of broader interest, extending beyond patients treated with allogeneic HSCT. [We reported] a case of sustained HIV remission after allogeneic HSCT from a sibling donor, extending observations from previous HIV cure cases. This is evidenced by the absence of detectable plasma HIV RNA, undetectable intact proviral HIV DNA in both peripheral blood and gut-associated lymphoid tissues, absence of replication-competent HIV DNA in peripheral blood and lack of HIV-specific T cell responses after the initiation of analytical treatment interruption. The Oslo patient is, together with the City of Hope patient (63 years old), one of the oldest patients to experience HIV remission after HSCT. Notably, the Oslo patient also exhibits full donor chimerism of GALTs after HSCT.”

Citation: Myhre, A.E., Meyer-Myklestad, M.H., Gullaksen, H.H., *et al.* “[Long-term HIV-1 remission achieved through allogeneic haematopoietic stem cell transplant from a CCR5Δ32/Δ32 sibling donor.](#)” *Nature*. 2026.

InVita Healthcare Technologies has [announced](#) the rollout of HemaConnect 2.5 at Gulf Coast Blood. According to the announcement, the latest release includes, “specifically configured profiles and workflows for handling therapy-specific critical details; specialized scheduling designed to bridge the gaps from interview to sample to collection; and robust administrative capabilities that ensure traditional blood center collections and advanced biotherapy collections are harmonized where appropriate while remaining distinct where necessary. These capabilities are delivered alongside industry-leading donor engagement capabilities for tailored cell and gene therapy (CGT) donor recruitment.”

(Source: InVita Healthcare Technologies [News Release](#), 4/23/26) 💧

MEMBER NEWS

LifeServe Blood Center recently [announced](#) a partnership with UnityPoint Health, MercyOne Des Moines Medical Center, the Des Moines Fire Department, and the West Des Moines Emergency Medical Services (EMS) for a prehospital blood program. According to the announcement, “[e]mergency response vehicles in select units across the region are now equipped to carry and store blood products safely. EMS crews have undergone extensive training to ensure proper handling, storage, and transfusion procedures in the field. This new initiative brings hospital-level intervention directly to the scene of an emergency, bridging a critical gap in trauma care. For patients suffering massive blood loss, those extra minutes could mean the difference between life and death.”



(Source: LifeServe Blood Center [Announcement](#), 4/22/26) 💧



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 2026 ABC Advocacy Summit

[Register now](#) for the 2026 [America's Blood Centers \(ABC\) Advocacy Summit](#) taking place in Washington, D.C. at The Dupont Circle (part of The Doyle Collection Hotels) June 8th-9th. [Book your room now](#) to take advantage of the discounted rate and ensure availability. View the [preliminary schedule](#) and don't miss the chance to let your voice be heard as this event connects the blood community with national leaders in public policy and advocacy including meetings with members of Congress and their staff. The 2026 ABC Advocacy Summit includes advocacy training and group preparations for meetings with congressional offices on June 8th before heading to Capitol Hill on June 9th for group meetings with members of Congress and their staff, advancing ABC's advocacy priorities. We will coordinate the scheduling of meetings on behalf of all attendees and conclude the day with a reception. Please [contact us](#) with questions.

Congressional Champion Nominations Are Open

ABC is excited to launch [nominations](#) for Congressional Champions as part of the *Act for Blood* program! Awarded in Washington, D.C. as part of the [2026 ABC Advocacy Summit](#), a Congressional Champion is a member of Congress that has shown support for the U.S. blood supply and community blood centers through actions such as helping with an earmark request, assisting blood center outreach efforts to an administrative agency, introducing legislation, or even touring and donating at ABC member blood centers. While ABC is actively meeting with members of Congress to support the [ABC Advocacy Agenda](#), the work blood centers do as an ABC member (and a constituent of a congressional district) to build relationships with lawmakers is essential. This is a unique opportunity to [recognize](#) the work that a member of Congress has done, while continuing to build stronger relationships. Please submit your nominations by the May 7th deadline. [Contact us](#) with any questions and thank you for your ongoing support and participation in our advocacy efforts!

Time is Running Out to Register for the ADRP Annual Conference

View the [schedule](#) and [register](#) now for the [2026 ADRP Annual Conference](#) in Minneapolis, Minn., May 12th-14th, at the Hyatt Regency Minneapolis. [Hear](#) conference Keynote Speaker [Courtney Clark](#) deliver "The Short Cut: How Strategic Adaptability Outperforms Grit" as she shares insights from her National Goal Resilience Study. Ms. Clark will explore strategies to help individuals and teams avoid burnout, adapt to change, and focus on what truly drives progress. Attendees will learn how to:

- recognize when persistence helps — and when it holds you back;
- increase flexibility during change and uncertainty;
- distinguish between goals and plans, and focus on what matters most; and
- use a simple framework to prioritize competing demands.

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INSIDE ABC (continued from page 6)

Additionally, this conference offers a chance to learn about industry trends, share ideas, and connect with other donor recruitment, donor services, collections, marketing, and communications professionals. Join more than 300 of your peers by participating in pre-conference workshops, attending compelling educational sessions, engaging in roundtable discussions, and exploring an expansive exhibit hall filled with innovative solutions. Seize this extraordinary opportunity to learn, share, and grow within the blood community. Please [contact us](#) with any questions as we look forward to seeing you! 💧

GLOBAL NEWS

The Ministry of Health and Family Welfare in India has [published](#) a “roadmap to ensure universal access to safe blood in every district by December 2026,” according to a report from *Health and Me*. Through the roadmap, the government aims to, “ensur[e] timely access to safe blood.” Highlights of the plan include:

- “strengthening district-level ownership and administrative convergence; ensuring 100 percent licensing compliance of all operational blood centers;
- enforcing standard operating procedures for blood collection and donation camps;
- scaling up voluntary blood donation through structured outreach and awareness campaigns;
- adopting advanced testing protocols such as ELISA and CLIA-based screening;
- strengthening referral and linkage systems;
- 100 percent digital integration of blood services through [blood bank management systems]; [and]
- [t]he use of biometric donor identification under the Ayushman Bharat Digital Mission aims to improve traceability and efficiency.”

(Source: *Health and Me* “[India Sets Roadmap For Universal Access To Safe Blood By December 2026](#),” 4/22/26) 💧

COMPANY NEWS

Unlock Health has provided an updated [registration link](#) for this week’s webinar in partnership with LifeSouth Community Blood Centers. This virtual event will describe the blood center’s efforts to target their lapsed donor base. Using the Unlock Collect donor engagement system not only brought donors back to LifeSouth but kept them active and donating at a frequency close to their current base. The webinar will take place on Tuesday, April 28th at 3 p.m. EDT and is titled: “Don’t Call It a Comeback” featuring:

- Dave Leitch;
- Christine Medina; and
- Joe Ferrara.

(Source: Unlock Health [Announcement](#), 4/15/26)

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COMPANY NEWS (continued from page 7)

Cerus Corporation has announced a new four-year [partnership](#) for the Intercept Blood System with Établissement Français du Sang (the French Blood Establishment). According to the news release, “[the supply] agreement covers Intercept Blood System for platelets and plasma as well as the next generation, LED-based INT200 illumination device. [The platform] has been used in France since 2006, with broader nationwide adoption following a nationwide rollout in 2017. Intercept is also used throughout French overseas territories, including La Réunion, Guadeloupe, and Martinique. Implementation in those island territories was driven by the need to maintain a safe platelet supply during outbreaks of chikungunya, dengue, and Zika in these tropical regions.”

(Source: Cerus Corp. [News Release](#), 4/27/26) 

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.)*

2026

May 12. **FDA Center for Biologics Evaluation and Research (CBER) Public Webinar: “FDA Review of Biologics License Applications for Blood and Source Plasma.”** [Registration](#) is open. More information is available [here](#).

May 12-14. **ADRP: The Association for Blood Donor Professionals Annual Conference. Minneapolis, Minn.** [Registration](#) is open. More information is available [here](#).

May 19-20. **FDA Regulatory Education for Industry (REDI) Annual Conference 2026: “Innovative Regulatory Strategies to Advance Medical Products”** Silver Spring, Md. (Hybrid). [Registration](#) is open. More information is available [here](#).

May 20-21. **IPFA/Paul-Ehrlich Institut[e] (PEI) 32nd International Workshop on Surveillance and Screening of Blood-borne Pathogens. Bilbao, Spain.** [Registration](#) is open. More information available [here](#).

June 8-9. **2026 ABC Advocacy Workshop. Washington, D.C.** [Registration](#) is open. More information is available [here](#).

June 19. **Alliance for Regenerative Medicine (ARM) Workshop: “From Platform to Patient: Defining Market readiness for Genetic Medicines. Paris, France.** [Registration](#) is open. More information is available [here](#).

June 20-24. **International Society of Blood Transfusion (ISBT) 39th International Congress. Kuala Lumpur, Malaysia.** [Registration](#) is open. More information available [here](#).

June 25-26. **National Heart, Lung, and Blood Institute (NHLBI) and the Sickle Cell Disease Association of America, Inc. (SCDAA) “Research That Heals: Partnering with Patients to Transform SCD Care.”** Rockville, Md. (Hybrid). More information is coming soon.

Sept. 16-17. **ADRP: The Association for Blood Donor Professionals Master Class (Virtual).** More information is coming soon.

Oct. 4-7. **Association for Advancing Tissue and Biologics (AATB) Annual Meeting. San Francisco, Calif.** More information available [here](#).

Oct. 5-7. **ARM Cell & Gene Meeting on the Mesa. Phoenix, Ariz.** More information is available [here](#).

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CALENDAR (continued from page 8)

Oct. 17-19. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Atlanta, Ga.** More information is coming soon.

Nov. 17-20. **American Society for Clinical Pathology (ASCP) and Canadian Association of Pathologists- Association Canadienne des Pathologistes (CAP-ACP) Joint Annual Meeting. Montreal, QC.** [Registration](#) is open. More information available [here](#).

2027

March 8-11. **2027 ABC Annual Meeting. Atlanta, Ga.** More information is coming soon. 💧

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

Transfusion Lab Manager Needed! Join Florida's leading blood center, **OneBlood**, as a Blood Bank Lab Manager in Bay Pines, FL. Bring your leadership, technical expertise, and management experience to support the transfusion testing procedures on patient and/or donor samples. Qualified candidates should possess five (5) or more years' experience in a related field. A valid and current Florida Clinical Laboratory Supervisor license in Immunohematology required; SBB certification preferred. To apply and view a complete Job Description of this Lab Manager position, visit www.oneblood.org/careers. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Financial Services Manager. LifeSouth Community Blood Centers is seeking an experienced and detail-oriented **Financial Services Manager** to join our team, in **Gainesville, FL**. This position oversees core financial operations, manages staff, and ensures compliance with organizational policies and deadlines. It provides leadership across accounts payable/receivable, fixed assets, payroll, and revenue cycle functions, driving accuracy and efficiency while supporting the organization's mission to provide a safe blood supply and exceptional service to the community. The Financial Services Manager will work closely with leadership to analyze financial data, identify trends, and support strategic decision-making while maintaining compliance with company policies and regulatory standards. 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 [apply here!](#)

Medical Technologist Careers Available! Join OneBlood's healthcare team as a Medical Technologist in the beautiful sunny state of Florida. In this dynamic role, you will perform basic through advanced testing procedures on patient and/or donor samples and interpret results in accordance with regulatory guidelines and organizational policies and procedures. A valid and current Florida Clinical Laboratory Technologist license, as well as a bachelor's degree in a biological science or related scientific field from an accredited college or university, is needed. We offer a comprehensive compensation and benefits package including healthcare, shift differentials, student loan repayment, 403b, and more! To apply and view a complete Job Description of these positions, go to www.oneblood.org and click on the **Careers** tab. OneBlood, Inc. is Employer/Vet/Disability. 💧