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Blood Community Submits Joint Comments to HHS and CMS on CLIA Reporting Requirement

America's Blood Centers (ABC), AABB, and the American Red Cross have provided [joint comments](#) to the Centers for Medicare and Medicaid Services (CMS) regarding the [interim final rule](#) titled Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency.” The comments outline concerns about the agency’s interpretation “that the reporting requirements apply to blood centers’ antibody testing on donations from healthy individuals during the manufacture of convalescent plasma because:

- [t]he test reporting requirements in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, HHS’ June 4th guidance, and the interim final rule apply only to tests to detect the SARS-CoV-2 virus or diagnose a possible case of COVID-19 and therefore do not apply to antibody testing performed by blood centers;
- CMS’ interim final rule, if applied to blood center antibody testing, has the potential to negatively impact the availability of the blood supply during the COVID-19 pandemic; and
- [t]he requirements in the interim final rule will be unduly burdensome for blood centers without increasing donor or patient safety.”

The blood community also notes in the comments that, “[o]ur organizations appreciate the important public health activities being performed in response to the COVID-19 pandemic. While we support the need for data and surveillance, we do not believe that the results of antibody tests performed by blood centers will provide the government or public health officials with meaningful or useful information.”

ABC encourages all member blood centers to work towards compliance with the requirement as it is an interim final rule which imposes substantial civil monetary penalties for non-compliance. The association and the blood community will continue to advocate for a blood center exemption and will provide additional updates as they become available. Please contact ABC’s Senior Director of Federal Affairs [Diane Calmus](#) with any questions or for a copy of the MCN.

(Source: MCN 20-094, 10/23/20) ♦

Upcoming ABC Webinars – Don’t Miss Out!

- **ABC SMT Journal Club Webinar** – December 3rd from 12 – 1 p.m. (ET). Additional details coming soon.



CBER Updates 2020 Guidance Agenda

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has [published](#) an update to its guidance calendar for 2020. This agenda outlines the guidance and draft guidance documents that CBER plans to issue throughout the year. Blood-related topics that the agency still intends to address this year include:

- Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; Guidance for Industry;
- Blood Pressure and Pulse Donor Eligibility Requirements; Draft Guidance for Industry;
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion; Draft Guidance for Industry;
- Collection of Platelets by Automated Methods; Guidance for the Industry; and
- Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis, Guidance for Industry.

ABC has been advocating to the FDA on several of these issues and is pleased to see CBER addressing these topics of concern to our membership. A complete listing of the potential guidances is available on the FDA's [website](#).

The topics listed for Tissue and Advanced Therapies all involved gene therapy and chimeric antigen receptor T cell (CAR-T) therapies. The agency still intends to publish a draft guidance that addresses "Considerations for the Development of [CAR-T] Cell Therapies" and "Considerations for the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry."

(Source: FDA [Announcement](#), 10/27/20) 💧

ABC Issues Talking Points on Blood Shortages Being Experienced Amid COVID-19 Pandemic

America's Blood Centers distributed talking points to member blood centers this week to assist with inquiries from the media and other external stakeholders regarding the impact of COVID-19 on the nation's blood supply and shortages that are occurring across the country. The talking points contain aggregate statistics and data provided by ABC member blood centers. ABC will continue to provide additional resources to member blood centers and update you on the association's efforts to bring further awareness on the impact of the pandemic on blood donations and blood drives. Please contact [Member Services](#) with any questions or to receive a copy of MCN 20-095. ABC, AABB, and the American Red Cross previously issued a [joint statement](#) this month encouraging eligible individuals to donate blood amid increasing shortages across the country.

(Source: MCN 20-095, 10/26/20) 💧

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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

Are We Protecting Our Donors? “Recently, there has been increasing scientific focus on the safety and the well-being of donors” reported a study in *Vox Sanguinis*. “In 2010 the NOTIFY project developed a database which compiles scientific references of complications. TRANSPOSE (TRANSfusion and transplantation: Protection and SElection of donors) aimed to critically evaluate donation-related risks and to identify risks currently not (or insufficiently) included in donor vigilance as well as discrepancies between reported and anticipated donation related risks...It was initiated in September 2017 and involved 25 partners from 15 European countries.” The project included, “an investigation of current donation-related risks [launched] for all [Substances of Human Origin] SoHO [e.g. whole blood (WB), plasma for fractionation [PFF], hematopoietic stem cell (HSC), bone marrow, [and] medically assisted reproduction and tissues)...All TRANSPOSE participants were asked to provide donor vigilance data and to include data on adverse reactions, regardless of severity. Furthermore, participants were asked to send data from the previous three years...For WB, the long-term risk of iron deficiency was the highest rated anticipated risk to donors followed by adverse reactions directly associated with the donation procedure: vasovagal reactions, hematomas, and nerve damage.” The researchers noted, “[t]he highest rated risk to plasma donors was vasovagal reaction...[and] [t]he highest rated long-term risks for plasma donors was iron deficiency and low protein and/or immunoglobulin levels...For HSC donations, the highest rated risks were directly associated with the donation procedure.” The authors added that, “[d]ata showed that reported donor complications rates are low even when including non-serious reactions...However, as reporting is not mandatory a significant degree of underreporting is likely.” They conclude by stating that, “[t]here is already international consensus on the need for a standardized donor vigilance system and work has been done to harmonize current systems...However, [the] results for WB and PFF show that despite consensus there is still variation in the categories included in donor vigilance...The majority of the potential long-term effects of donation are risks that can be mitigated through clinical tests including routine monitoring of ferritin, immunoglobulin, protein levels, and a bone density scan.”

Citation: Mikkelsen, C., Mori, G., van Walraven, S.M., *et al.* Putting the spotlight on donation-related risks and donor safety – are we succeeding in protecting donors? *Vox Sanguinis*. 2020. Doi: [10.1111/vox.13014](https://doi.org/10.1111/vox.13014).

Contributed by Richard Gammon, MD, Medical Director at OneBlood 💧

BRIEFLY NOTED

A study in *Science* reports that most individuals with “mild-to-moderate” cases of COVID-19 mount a “robust antibody” that is “relatively stable” for five months at a minimum. “While some reports have come out saying antibodies to this virus go away quickly, we have found just the opposite — that more than 90 percent of people who were mildly or moderately ill produce an antibody response strong enough to neutralize the virus, and the response is maintained for many months,” said Florian Krammer, PhD, a professor of Vaccinology at the Icahn School of Medicine at Mount Sinai and a senior author of the paper, in a news release. “Uncovering the robustness of the antibody response to SARS-CoV-2, including its longevity and neutralizing effects, is critically important to enabling us to effectively monitor seroprevalence in communities and [in] determining the duration and levels of antibody that protect us from reinfection. This is essential for effective vaccine development.” The study included more than 30,000 individuals screened at Mount Sinai Health System between March and October 2020 using an enzyme-linked immunosorbent assay (ELISA) assay “developed” and “validated” by Mount Sinai. “When comparing overall titers, [the investigators] saw a slight drop from a geometric mean titer (GMT) of 764 to a GMT of 690 from the first to second testing time point and another drop to a GMT of 404 for the last testing time point, indicating that a moderate level of antibody is retained by most people five months after symptom-

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BRIEFLY NOTED (continued from page 3)

onset. In the higher titer range, they observed a slow decline in titer over time. Interestingly, they saw an initial increase in titer for individuals who had originally tested as having low to moderate titer levels. This is in agreement with earlier observations from their study group that indicate seroconversion in mild COVID-19 cases might take a longer time to mount,” according to the release.

(Source: Mount Sinai [News Release](#), 10/28/20)

The National Blood Foundation (NBF) has begun accepting applications for the Scientific Research Grants Program’s 2021 grant cycle according to a recent [announcement](#). NBF distributes funding to support “investigator-initiated original research” in blood banking, transfusion medicine, cellular therapies, and patient blood management. Applications are due December 1st. Grants will be awarded for research in the following categories:

- immunology;
- hematology;
- immunohematology;
- infectious diseases;
- cellular therapies; and
- patient blood management.

Close to \$11 million has been awarded by NBF to through this program to early-career investigators. Additional information can be found [here](#).

(Source: AABB [Announcement](#), 10/29/20) ♦

INFECTIOUS DISEASE UPDATES**MALARIA**

A [study](#) in *Nature Medicine* found that *Plasmodium falciparum* (*P. falciparum*), the most common of all malaria parasites, “decreases its endothelial binding capacity, allowing increased splenic clearance and enabling several months of subclinical parasite persistence.” According to a [report](#) on the study appearing in *The New York Times*, *P. falciparum* “enacts a genetic change that enables it to hide in an infected person’s bloodstream for months, undetected” during the dry season when less mosquito activity exists. The researchers discovered that the parasites were capable of “slow[ing] down their metabolism” which protected them from “trigger[ing] [the host’s] immune counterattack that might destroy them,” according to the *New York Times*. They performed regular interval blood draws on 600 children and young adults in Kalifabougou, Mali, a “town in rural Mali with distinct wet and dry seasons. Blood tests revealed that, even when samples had too few parasites to be seen under a microscope, about 20 percent of the study participants still had very low levels of parasites hiding inside some of their red blood cells.”

Citation: Andrade, C.M., Fleckenstein, H., Thomson-Luque, R. *et al.* Increased circulation time of *Plasmodium falciparum* underlies persistent asymptomatic infection in the dry season. *Nature Medicine*. 2020. Doi: [10.1038/s41591-020-1084-0](https://doi.org/10.1038/s41591-020-1084-0).

(Source: *The New York Times*, [A Malaria Mystery, Partly Solved: What Happens When the Rains End?](#), 10/26/20) ♦



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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.

Call for Nominations Opens for 24th Annual Awards of Excellence

ABC members are encouraged to nominate blood donation sponsors, corporations, and advocates for the 24th Annual *Awards of Excellence*. This program provides members with the opportunity to offer national recognition and showcase the best and brightest in the blood donation community. Additional details are available in MCN 20-093 for ABC member blood centers. The online submission form for each award is hyperlinked below. If your nomination is selected, you will be asked to upload a video of your award recipient being presented with the award (ABC will mail the award to the blood center). We will upload videos of all award winners to our website as part of national recognition of these individuals/organizations.

ABC members are permitted to submit up to three nominations per category. A full description of the awards is [available](#).

We encourage member blood centers to take advantage of this opportunity to recognize your supporters by submitting your nominations before Friday, November 20, 2020. Nominations are currently being accepted for the following awards:

- [ABC Outstanding Blood Drive of the Year](#)
- [Outstanding Public Relations Campaign](#)
- [Corporation of the Year Award](#)
- [Larry Frederick Award](#) (jointly presented by ABC and ADRP)
- [Thomas F. Zuck Lifetime Achievement Award](#)

Please contact [Leslie Maundy](#) with any questions about the *Awards of Excellence* or to receive a copy of the MCN.

(Source: MCN 20-093, 10/22/20)

ADRP Annual Conference Goes Virtual

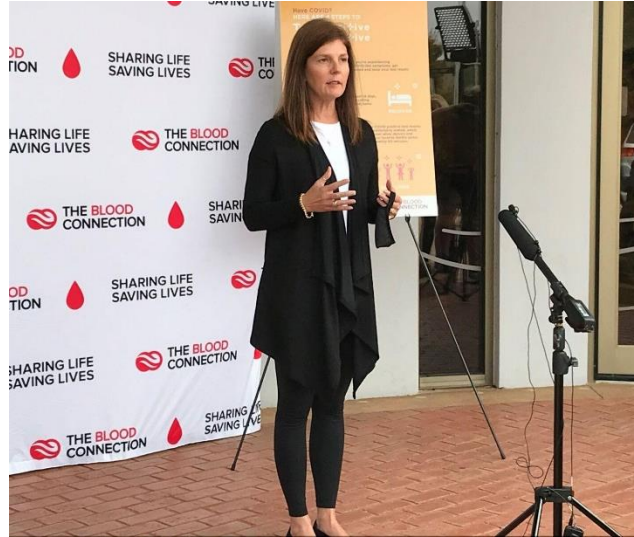
[Register](#) today for the [ADRP Annual Conference](#), now a virtual event, November 16th–18th, now a virtual event. Over the course of three days, individuals will have access to abstract presentations, roundtables, and an interactive virtual exhibit hall. As an attendee, you will be able to use the virtual conference platform for one year and have the opportunity to experience all of the sessions that you may not have been able to participate in at an in-person conference, an increase of more than 10 education hours! This event will benefit blood center staff in multiple disciplines including donor recruitment, collections, marketing, and communications. We encourage staff from all levels to attend, to enhance the collaboration within their individual donor center. Group discount rates are available for ADRP subscribers. More information is available [here](#). The full conference program can be viewed [here](#). 💧





MEMBER NEWS

South Carolina Lieutenant (Lt.) Governor Pamela Evette visited **The Blood Connection, Inc.** to donate convalescent plasma. She has recovered from COVID-19 after being diagnosed last month and took the opportunity to encourage other individuals, who have recovered, to donate. “Take a look at a family member you love who might find themselves in a bad position and let that be what inspires you to come and do something good,” said Lt. Governor Evette according to WHNS-TV FOX Carolina. “As South Carolinians we pride ourselves on the fact that we help each other, and this is one way we can all come together.”



(Source: WHNS-TV FOX Carolina, [Lt. Governor Pamela Evette donates convalescent plasma in Greenville after being diagnosed with Covid-19, 10/26/20](#))

GLOBAL NEWS

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom, is opening 14 new centers to collect convalescent plasma from individuals who have recovered from COVID-19. The expansion of its convalescent plasma operations raises the number of facilities collecting convalescent plasma from 28 to 42, a 50 percent increase, as part of efforts to support the ongoing NHS trials of convalescent plasma, which it states are the largest randomized controlled trials and “first to reach 1,500 randomizations.” NHSBT Associate Medical Director for Blood Donation Professor David Roberts said in a news release, “[w]e have so far seen a fantastic response from the public coming forward to donate plasma. We are rapidly building our capability to collect plasma so that we can move into supplying hospitals at scale, should the trial demonstrate patient benefit. With 14 new cent[ers] – an overall



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GLOBAL NEWS (continued from page 6)

total of 42 donation cent[ers] and pop-ups across the country – we need people in these areas who have had COVID-19 to come forward and donate plasma for patients. You could save lives.” NHSBT states the additional capacity “means that 80 percent of potential donors across England can reach one of the donor cent[ers] within 45 minutes.” Parliamentary Under Secretary of State (Minister for Innovation) Lord Bethell added, “[t]he use of convalescent plasma has shown promising results in treating coronavirus and the opening of more donation cent[ers] is an important step towards getting this innovative treatment to more patients, if clinical trials demonstrate it should be available on the NHS. More donations are needed, and everyone has a part to play in stopping this virus from harming our loved ones. I urge everyone who has had COVID-19 to come forward and donate – your contribution could save lives.”

(Source: NHSBT [News Release](#), 10/19/20) ♦

ABC Calendar of Events

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

CALENDAR

***Note to subscribers:** Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@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.)*

2020

Nov. 16-18. **2020 ADRP Conference (Virtual)**. More details available [here](#).

Nov. 17. **FDA Public Meeting – Communications About the Safety of Medical Devices (Virtual)**. More details available [here](#).

2021

Mar 8-10. **ABC Annual Meeting (Virtual)**. More details coming [soon](#).

June 25-26. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details available [here](#).

May 11-13. **2021 ADRP Conference, Kansas City, Mo.** More details coming [soon](#).

Aug. 4. **ABC Medical Directors Workshop, Cleveland, Ohio.** More details coming [soon](#).

Aug. 5-6. **ABC Summer Summit, Cleveland, Ohio.** More details coming [soon](#).

Sept. 15-17. **4th European Conference on Donor Health and Management, Hamburg, Germany.** More details available [here](#). ♦

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 and published after editorial review. Please send letters to the Editor at 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.

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, e-mail: newsletter@americasblood.org

POSITIONS

Quality Assurance Specialist. The Community Blood Center, Appleton, WI is seeking a Quality Assurance Specialist who will take a key role on our Quality Team. Under the supervision of the QA Manager, this individual will be involved in the development of quality metrics and key performance indicators for the blood center, analyzing and identifying trends in deviation/incident data to report to department management and assisting with supplier qualification activities and the maintenance of the qualified supplier list. The QA Specialist is also responsible for entering FDA reportable errors into the applicable computer application, compiling the appropriate paperwork, participating in corrective and preventive action teams, assisting with investigation and root cause analysis and verifying that corrective actions are implemented and effective. Approve equipment, blood product and computer system validations including installation qualification, operational qualification and performance qualification, participation in regulatory/accrediting agency inspections, preparation for and performance of internal audits with subsequent report to Center management. Bachelor's degree preferred with one to three years of experience in a blood center, biologics, pharmaceutical or medical industry with base familiarity of quality assurance practices, training, and federal regulatory practices. To view complete job description and apply, go to www.communityblood.org. The Community Blood Center is an Equal Opportunity Employer M/F/Disability/Veteran.

Manager, Donor Recruitment. LifeStream, a local non-profit organization providing blood services for more than 80 hospitals in Southern California, is searching for a Manager, Donor Recruitment to function as a member of the Donor Recruitment Team. The manager is responsible for overseeing, motivating, counseling and training of the Donor Recruitment team to ensure that daily, monthly, and annual collection goals are met. The Manager facilitates efficient use of company resources and is responsible for implementing effective strategies to maintain existing donor groups, gain new donor groups, and increase donation frequency. This position works closely with multiple departments to ensure successful drives. In addition, the Manager will assist the Department Director in the development of policies, goals, recruitment materials, and annual budget. Responsible for developing a team of highly effective Regional Account Managers who will achieve collection goals by providing quality customer service, education, and motivation to the public, donors, and blood drive coordinators. Apply online: www.LStream.org. Or send

cover letter, and resume to LifeStream: Human Resources, 384 W. Orange Show Rd. San Bernardino, CA 92408. E-mail: employment@LStream.org. EOE.

QA Specialist. Stanford Blood Center is seeking a QA Specialist to work in the Technical Services Laboratory. Under the general supervision of the Operations Support Supervisor, the QA Specialist will perform the quality assurance duties of the Technical Services department by writing/revising department equipment and process validation plans, managing equipment preventative maintenance program, manage training records, perform process and computer audits, write/revise procedures for regulatory compliance as necessary. Prepare training binders for new staff and monitor new and incumbent staff training is up to date. Ensure annual SOP and label review performed, review departmental records, help determine corrective actions for events by performing root cause analysis, and is involved in process improvement. Perform post-donation information follow-up that affects safety, purity, and quality of the product by quarantine/discard of units, notification of customers and tracking of recalls. Provide notification to hospitals, regulatory agencies and other customers of test results that affect patients/general population safety. For complete job description and to apply, please visit www.stanfordhealthcarecareers.com and reference req# 58277.

Laboratory Technician - Stanford Blood Center (Req# 57715). Stanford Blood Center is seeking a Laboratory Technician. Under the direction of the Laboratory Supervisor, prepares and labels blood components; monitors component inventory to assure proper levels are maintained; receives orders for blood products and issues, packs and ships blood components; processes deliveries of blood products into inventory and maintains accurate and detailed records of all work performed. Performs quality control on equipment and blood components, reviews quality control and maintains equipment as required. May be required to operate delivery vehicle for transport of blood products when necessary. Responds to blood storage alarms; cleans and disinfects areas and equipment according to laboratory policy and maintains a clean and organized work area. Answers telephones promptly; route calls or take messages as appropriate. Rotates beeper on-call for off hours emergency blood needs or equipment failure. This is not a research position. For complete job description and to

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POSITIONS (continued from page 8)

apply, please visit www.stanfordhealthcarecareers.com and reference req# 57715.

Components Manufacturing Manager (Bradenton, FL). SunCoast Blood Centers is accepting applications for a Components Manufacturing Manager to work at our Lakewood Ranch Head Quarters. This position manages and oversees component manufacturing activities and operations, and supervises Staff assigned to the department. Other Duties include: Assures that activities are conducted in compliance with SOPs and regulatory guidelines. Assists with the development and implementation of effective corrective action plans in response to non-compliance, deviations, or operational problems. Assists with the preparation and scheduling of periodic maintenance, calibration and validation of instruments and equipment and other duties as required to fulfill the organizations mission and vision. Qualified applications should possess an associate degree or equivalent experience. Prefer applicant to have MT or MLT licensure, but not required. Applicant must have four years component processing or other cGMP regulated environment, plus two years supervisory responsibility. To apply and view a complete Job Description of this position please visit <https://www.scbb.org/careers.html>. EOE. Applicant drug testing required.

Quality Assurance Specialist. Quality Assurance Specialist. The Quality Assurance Department at Hoxworth Blood Center provides regulatory, quality oversight for all processes at the Center. The position is responsible for conducting audits, quality assurance oversight and CLIA regulated laboratories processes. Assists with development of SOPs, data, report results, process and equipment validations, and compliance with applicable regulations. Ideal candidate will have experience with the following: 21 CFR Parts 210, 211, 600, 601, 606, 607, 610, 630, 640, 660, 42 CFR Part 493, ASHI standards, FACT standards, and AABB Standards. Have experience working in a clinical laboratory or FDA regulated environment; auditing experience; knowledge of histocompatibility testing; experience with quality management software and project management. Required Qualifications: Bachelor's degree with three (3) years of experience; - OR Associate's degree with five (5) years of experience; - OR seven (7) years of experience. Degree and experience must be in a related field. Experience may require at least one (1) year supervision. Apply [here](#) – Requisition # 49502. ♦