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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #25 **July 17, 2020**

INSIDE:

FDA Plans to Restart Domestic Inspections This Month

The U.S. Food and Drug Administration (FDA) announced that it is working to resume domestic on-site inspections during the week of July 20th. "Despite pausing on-site surveillance inspections in the U.S. in March, our investigators have conducted mission critical inspections and other activities to ensure FDA-regulated industries are meeting applicable FDA requirements," said the agency in a published statement from Commissioner Stephen Hahn, MD. "At the same time, we have been closely monitoring reopening criteria established at the federal, state, or county levels and planning to identify when and where to resume domestic inspections, prioritizing the inspections based on risk and other factors."

He noted that the agency has developed a new rating system to help determine when and where it is safest to perform domestic inspections. "The COVID-19 Advisory Rating System (COVID-19 Advisory Level) uses real-time data to qualitatively assess the number of COVID-19 cases in a local area based on state and national data. We are also making the Advisory Level data available to our state partners who carry out inspections of FDA-regulated entities on the agency's behalf under contract."

Commissioner Hahn also stated that the timeline is subject to change based on local and state COVID-19 trend data. "At this time, we are working toward the goal of restarting on-site inspections during the week of July 20. However, resuming prioritized domestic inspections will depend on the data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. In order to move to the next phase, we must see downward trends in new cases of COVID-19 and hospitalizations in a given area. Our ability to resume is also affected by other services that have been curtailed by the pandemic, such as public transportation. The availability of these services will be an important factor in how we determine resuming domestic inspections. The FDA has also determined that, for the foreseeable future, prioritized domestic inspections will be pre-announced to FDA-regulated businesses. This will help assure the safety of the investigator and the firm's employees, providing the safest possible environment to accomplish our regulatory activities, while also ensuring the appropriate staff are on-site to assist FDA staff with inspection activities…The health, safety, and well-being of our investigators, as well as the public, are of the utmost importance to us. We will ensure our investigators are outfitted with personal protective equipment and are equipped with other necessary equipment to carry out their work while adhering to state and local guidance as well as applicable [Centers for Disease Control and Prevention] guidance."

(Source: FDA Statement 7/10/20)

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) recently withdrew 48 blood memoranda and 20 biologics guidances, 16 of which are applicable to blood. These guidance documents appear to be older draft and final guidance documents whose contents have either been incorporated into the CFR or are no longer germane. America's Blood Centers has inquired with the agency about the withdrawal of the original July 1995 Guideline for Quality Assurance for Blood Establishments – Final Guidance, to see if the FDA feels this guidance was no longer needed because the requirements are included in the CFR and have been fully adopted by the industry. We will update members with the FDA's response.

(Source: MCN 20-070, 7/16/20)

The FDA published a guidance document titled "Providing Regulatory Submissions for Medical Devices in Electronic Format — Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act Guidance for Industry and Food and Drug Administration Staff." It replaces the draft guidance released in September 2019. The guidance "describes how FDA interprets and plans to implement the requirements of section 745A(b)(3), while individual guidances will be developed to specify the formats for specific submissions and corresponding timetables for implementation. Specifically, this guidance discusses:

1. the submission types that must be submitted electronically;
2. the timetable and process for implementing the requirements; and
3. criteria for waivers of and exemptions from the submissions in electronic format requirements."

The complete guidance document is available on the agency's website.

(Source: FDA Guidance, 7/15/20)

The FDA also released another guidance document on July 1st titled "Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking — Immediately in Effect Guidance for Industry and Food and Drug Administration Staff." The guidance "describes FDA's direct mark compliance policy for class III, LS/LS, and class II devices that are non-sterile, that are manufactured and labeled prior to their applicable direct mark compliance date, and that remain in inventory, as well as for class I and unclassified devices that are not LS/LS devices, that are non-sterile, that are manufactured and labeled prior to September 24, 2022, and that remain in inventory." It is being implemented with prior public comment. The guidance states that "[t]he compliance policy described in this guidance for certain devices in inventory that do not

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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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comply with the direct mark requirements is intended to facilitate use of those devices while still realizing some UDI-related benefits to patient safety. The lower burden of the approach outlined in this guidance also helps reduce the risk that industry will choose to avoid the cost of remediation by discarding inventory, potentially creating device shortages and negatively impacting patients and providers. Weighing the considerations at this time, we conclude that this direct mark compliance policy for certain inventory devices appropriately serves the public health." The full guidance document is available on the agency's website.

(FDA Guidance, 7/1/20)

RESEARCH IN BRIEF

International Survey – Convalescent Plasma to Treat COVID-19. "[T]he results of an international survey of centers undertaking early studies of CCP (COVID-19 convalescent plasma)" have been published in *Transfusion Medicine Reviews*. "The centers were identified on May 1st from a search of Clinicaltrials.gov, the Chinese Clinical Trial Registry (ChiCTR) and personal contacts of the authors." The researchers note that "responses [were received] from 20/64 (31 percent) studies from 12/22 (55 percent) countries...[Eleven] were randomized controlled trials (RCTs) and nine were case series…with blinding of the investigators to the intervention in 3/11 RCTs." The authors saw "huge variation" among RCTs "in the number of study sites (range 1-250)…There was also considerable variation in the number of patients receiving CCP in both the RCTs (range 40-5,000) and in the case series (6-10,000)…Most RCTs (9/11) included symptomatic, infected but not critically ill patients…[n]one of the studies focused on non-infected at risk individuals." The researchers report that "[t]he primary outcomes for the three largest RCTs were a composite of intubation or death at day 30 (USA-6), ventilation-free days (Canada-1) and mortality at 28 days (UK-2)…[D]onor eligibility criteria for the collection of CCP were very similar amongst the studies...[Six] studies including only two of the RCTs indicated that the CCP would be pathogen-inactivated...[Eleven of] 15 of all studies and 8/11 of the RCTs indicated that antibody testing would be carried out before the administration of CCP." The authors note that "[o]nly eight studies provided information about cut-off levels or titers of antibodies used to qualify donors...The responses raise concerns about [the studies] ability to determine the effectiveness of CCP…includ[ing] the lack of randomization in 11/20 studies and small sample size in 10/20…Only four of the RCTs plan to recruit 400 patients or more so that the majority of studies are unlikely to have sufficient power to detect significant changes in key outcomes...[Eight] RCTs are unblinded which may introduce bias in the assessment of outcomes other than mortality. The authors state that there is no consistency regarding the cut-off for antibody titer for acceptance as CCP." They concluded that the "COVID-19 pandemic provides the first opportunity in history to rigorously define the role of [CCP] in a critically important viral respiratory disease."

Citation: Murphy, M.F., Estcourt, L., Grant-Casey, J., *et al*. International Survey of Trials of Convalescent Plasma to Treat COVID-19 Infection. *Transfusion Medicine Reviews*. 2020. Doi: 10.1016/j.tmrv.2020.06.003

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Upcoming ABC Webinars – Don't Miss Out!

- **ADRP Webinar: What's Working? Hits and Misses** – July29th from 1 – 2 p.m. (EDT). Register here.
- **ABC SMT Journal Club Webinar** – August 10th from 2 – 3 p.m. (EDT). Additional details coming soon.
- **ABC QA Education Webinar** – August 18th from 3 – 4:30 p.m. (EDT). Additional details coming soon.

BRIEFLY NOTED

South Central Association of Blood Banks (SCABB) has announced that its Annual Meeting and Exhibit Show will be virtual this year. The online meeting is set to take place August 28th-29th. "We will be covering a magnitude of topics, including COVID-19 Town Halls from experts around the U.S., cutting edge advances in technology and novel blood products, as well as ExpressTalks," said Dr. Barbara Bryant, president of SCABB in an announcement. "The subjects cover basic to advanced level educational needs (donor recruiters, medical technologists, SBBs, researchers, physicians, CEOs, etc.), and there are several round table groups and meeting rooms for attendees to meet and share ideas and network. It's going to be an amazing (yet unusual) meeting. We are very excited about the platform." More information including registration information and the meeting schedule can be found at www.scabbregistration.org.

(Source: SCABB Announcement, 7/14/20)

The Centers for Disease Control and Prevention (CDC) issued a news release this week encouraging individuals within the U.S. to wear cloth face coverings citing new case studies as evidence to support its position. "We are not defenseless against COVID-19," said CDC Director Robert Redfield, MD in the news release. "Cloth face coverings are one of the most powerful weapons we have to slow and stop the spread of the virus – particularly when used universally within a community setting. All Americans have a responsibility to protect themselves, their families, and their communities." The agency used case studies published in the *Journal of the American Medical Association (JAMA)* and the CDC's *Morbidity and Mortality Weekly Report (MMWR)*. At this time, slightly more than half of the 50 U.S. states have made face coverings mandatory.

(Source: CDC News Release 7/14/20)

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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.

Still Time to Register for 2020 Virtual ABC MD Workshop

Registration remains open for the 2020 Virtual America's Blood Centers (ABC) Medical Directors (MD) Workshop. Reimagined as a virtual experience taking place over two days, ABC envisions this format providing flexibility for attendees' schedules without sacrificing the knowledge sharing and benefits of peer to peer discussions that are a hallmark of in-person meetings.

The MD Workshop (July 21st-22nd) will provide attendees with two days of timely, content-rich presentations that explore updates on COVID-19 testing, utilization of whole blood in hospitals, blood center experiences in lowering the platelet component dosage, along with interactive case study rounds. CMEs/PACE credits will be offered. ABC invites you to register to attend this event as we have reduced the registration fees from our traditional "face to face" meetings. Please contact member services with any questions.

(Source: MCN 20-067, 6/24/20)

ADRP Webinar: What's Working? Hits and Misses

Register today for the Wednesday, July 29th ADRP webinar titled "What's Working? Hits and Misses." This webinar will take place at 1 p.m. EDT and will feature presentations and a panel discussion on how to engage donors segmented into the following groups:

- schools and universities;
- businesses and corporate partners;
- churches and communities; and
- hospital partners.

ADRP subscribers may register for free and non-subscribers can participate for $25.

(ADRP Announcement, 7/16/20) ♦

WORD IN WASHINGTON

The U.S. Department of Health and Human Services (HHS) will now receive hospital data on COVID-19 directly rather than through the Centers for Disease Control and Prevention (CDC). At a news conference announcing the change, CDC Director Robert Redfield, MD stated, "As many of you know, CDC operates a system called the National Health Safety Network (NHSN). This is an important surveillance system in our nation's hospitals, which focuses on fighting antibiotic resistance. In April, HHS leaders, with input from CDC, created a new system, called HHS Protect, that allows us to combine data through systems like NHSN, as well as other public and private sources. The data reported from hospitals that went into HHS Protect either came through the NHSN, directly to HHS Protect from the states, or

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WORD IN WASHINGTON (continued from page 5)

through a system called TeleTracking. What we have now asked is that, going forward, states provide data from hospitals directly through the TeleTracking system or directly to the HHS Protect system. First, this reduces the reporting burden—it reduces confusion and duplication of reporting. Streamlining reporting enables us to distribute scarce resources using the best possible data." HHS Chief Information Officer Jose Arrieta added, "Before HHS Protect, CDC NHSN received data regularly from 3,000 hospitals related to COVID-19. However, there are approximately 6,200 hospitals in the United States. Through TeleTracking, HHS was able to start collecting additional data from 1,100 hospitals. HHS Protect collects data directly from 20 states and approximately 2,000 hospitals for COVID data. The additional capabilities provided by HHS Protect and TeleTracking provided increased visibility rapidly. The goal of HHS Protect was to provide confidentiality, integrity, and availability of data while ensuring security, transparency, data sharing, and privacy to as many first responders as possible. Visibility into what's happening at a zip code level across the United States helps us allocate resources and respond in real time."

(HHS & CDC Joint Statement, 7/15/20)

Sen. Robert Portman (R-Ohio) recently visited and donated blood at Hoxworth Blood Center. This marks the second time during the pandemic that he has donated as he wants others to follow his lead by remembering the importance of blood donation. "It's the second time I've given blood during this COVID-19 period and the reason I'm giving blood is to encourage those to give blood and give to those who need it," said Sen. Portman to WLWT News 5. "Some people are a little squeamish about giving blood and I get that. But it's not bad giving and the best part is when you're done, they give you free food and drink."

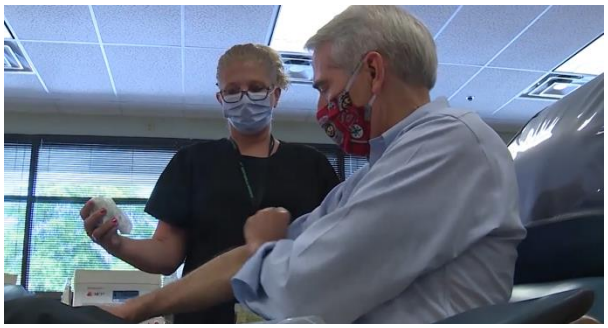

Photo courtesy of WLWT News 5

(Source: WLWT News 5, Sen. Portman donates blood at Hoxworth Blue Ash, encouraging others to do so, 6/26/20) 🩸

MEMBER NEWS

Bloomberg Law reported this week that the seroprevalence study being conducted as a collaboration of blood centers, testing laboratories, and research institutes that aims to measure the percentage of individuals with antibodies for SARS-CoV-2, the coronavirus that causes the disease COVID-19, has been expanded nationwide to cover all 50 states and Puerto Rico. The report notes that "[t]he [A]dministration is expanding a COVID-19 antibody study in an effort to create the first large-scale estimate of how many Americans have already had the disease." In May, a news release announced that the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) were providing funding for the study, which included Vitalant Research Institute, Creative Testing Solutions along with the American Red Cross, **Bloodworks Northwest**, **New York Blood Center**, **OneBlood**, **Vitalant**, and other regional blood collection organizations that are partnering on the "National SARS-CoV-2 Seroincidence Studies in Blood Donors" survey. The study previously was set to include 25 metropolitan areas throughout the U.S. as part an 18-month survey with participating blood centers and testing laboratories "providing residual blood donation specimens from around the country that will be tested for the presence of SARS-CoV-2 antibodies using validated assays and confirmation algorithms." In a news release announcing the launch of the study earlier this spring, Dr. Michael Busch stated, "[p]ublic health officials need access to ongoing infection rate

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MEMBER NEWS (continued from page 6)

data in order to make the best decisions for their communities." By collaborating with government institutions and leveraging the diverse donor populations and testing systems in place to support our national blood supply, the blood banking community can provide these data relatively quickly. This allows us to monitor and respond to ongoing outbreaks and help evaluate the effectiveness of evolving policies to prevent future widespread transmissions."

(Source: *Bloomberg Law*, Federal study on coronavirus spread expands to all 50 states, 7/14/20)

Hoxworth Blood Center recently teamed up with Major League Baseball's Cincinnati Reds on the 14th Annual Reds Week Blood Drive. The weeklong event resulted in the collection of more than 3,200 blood products from close to 3,000 registered donors. "As the only steward of the local blood supply, partnering with local organizations like the Cincinnati Reds is critical to recruiting volunteer blood donors," said Alecia Lipton, director of public relations at Hoxworth Blood Center in a news release. "At this time of the year, when blood donations fall but usage increases, we are enormously grateful to have the support of one of Cincinnati's most popular institutions to replenish our supply and save thousands of lives right here in our community." Cincinnati Reds President and Chief Operating Officer Phil Castellini added "[t]he Reds consider it a privilege to join Hoxworth Blood Center in their life-giving work. We appreciate the generosity of the thousands of donors who participated in this year's Reds Week blood drive, whose concern for others has made it a success."

(Source: Hoxworth News Release, 7/13/20) ♦

GLOBAL NEWS

Lawmakers in the Canadian province of Alberta will hold a committee meeting regarding a proposal by a member of the legislative assembly (MLA) that would "overturn" Bill 204, the Voluntary Blood Donations Repeal Act, according to a report from Canadian Broadcasting Corporation (CBC). The committee will listen to stakeholder input at an upcoming July meeting as it considers the bill proposed by MLA Tany Yao who stated at an earlier committee meeting, according to CBC, that "repeal will protect our domestic supply of plasma. With an ultimate goal of ensuring our patients have a secure and safe domestic supply of these life-saving products." Mr. Yao cited the percentage of the Canadian plasma supply that is produced domestically is about 13.5 percent, highlighting that Canada must import from other nation's such as the U.S. that allow paid plasma donation in order to ensure the availability of plasma which can be a key component of lifesaving therapies. CBC also reports that Mr. Yao stated that his proposal has the support of patient advocacy groups and described Canadian Blood Services' position on his proposal as "neutral." However, the committee would still like to hear directly from patient advocacy groups and Canadian Blood Services as it considers the legislation. "While we hear about a shortage, we don't hear anything about how the changes proposed in this bill are actually going to ensure that there is a greater plasma supply or even businesses operating in Alberta, and I think that has to be our focus," said MLA Rakhi Pancholi according to CBC. "It strikes me that this is a really national conversation that has to be had." Canadian Blood Services will open three voluntary plasma donation sites as part of a pilot. In 2018, Health Canada, the nation's regulatory authority, announced the publication of a report examining the country's self-sustainability of the immune globulin (Ig) supply in which an expert panel commissioned by the agency applied an "evidence-based assessment" exploring the impact of commercial expansion of the plasma industry on the Canadian blood supply...The findings of that report determined that a crisis did not exist in the "medium term" as supply can meet demand though efficiencies could be improved to collect more plasma and increase utilization. Currently, commercial plasma collection does not adversely impact

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GLOBAL NEWS (continued from page 7)

Canada's whole blood supply (though continued monitoring was recommended), and Ig and other plasma products remain "very safe" demonstrating "effective regulation and oversight."

(Sources: CBC, MLAs to hear from stakeholders on repeal of paid blood donation ban, 7/14/20; Health Canada Statement, 5/23/18)

The Robert Koch Institute, the German public health and disease control and prevention agency, has published findings from a study on COVID-19 antibodies among German blood donors. The analysis of an estimated 12,000 tested samples revealed that "antibodies were found in only 1.3 percent," according to *Reuters*. The results caused the institute "to [warn individuals that] almost everyone in the country may still be at risk of getting infected" reported the *Daily Mail*. Of the individuals with COVID-19 antibodies, 1.8 percent were male, and 0.8 percent were female.

(Source: *Daily Mail*, Germany 'is still vulnerable to second wave of Covid-19' as antibody study reveals only 1.3% of the country has developed any immunity, 7/15/20; *Reuters*, German blood donor study shows low immunity against COVID-19, 7/13/20)

Public Health England and researchers from the University of Oxford, and Oxford University Hospitals NHS Foundation and Trust reported results of an evaluation of four SARS-CoV-2 immunoassays for antibody detection. The study commissioned by the Department of Health and Social Care measured the sensitivity and specificity of four tests from Abbott, DiaSorin, Roche, and Siemens against "the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) Target Product Profile (TPP) for 'enzyme immunoassays' for SARS-CoV-2" during a 3-week period from May to June. The results are below:

Assay	Sensitivity [95% CI]	Specificity [95% CI]	Appraisal against MHRA Target Product Profile (TPP)
Abbott	92.7 (90.2, 94.8)	99.9 (99.4, 100)	Meets specificity criterion
DiaSorin	95.0 (92.8, 96.7)	98.6 (97.6, 99.2)	Meets specificity criterion
Roche	97.2 (95.4, 98.4)	99.8 (99.3, 100)	Meets specificity criterion
Siemens	98.1 (96.6, 99.1)	99.9 (99.4, 100)	Meets sensitivity and specificity criteria

Courtesy of Public Health England and researchers from the University of Oxford, and Oxford University Hospitals NHS Foundation and Trust

The Siemens test met both the sensitivity and specificity criteria from the UK Medicines and Healthcare products Regulatory Agency. The researchers also state that "[w]e also undertook secondary analyses, highlighting that the Roche assay could meet the current MHRA TPP sensitivity criteria with an assay threshold adjustment (e.g. at a revised assay threshold of ≥0.128 the sensitivity would be 99.4 [95 percent CI: 98.4, 99.9] with a specificity of 98.1 [95 percent CI: 97.0, 98.8]). Further, by optimi[z]ing assay thresholds to achieve a specificity of ≥98 percent and extending the sample timeframe specification to ≥30 days post-symptom onset (in lieu of the current MHRA TPP specification of ≥20 days), all four assays would meet the sensitivity criteria."

(Source: Public Health England and researchers from the University of Oxford, and Oxford University Hospitals NHS Foundation and Trust, Evaluation of sensitivity and specificity of four commercially available SARS-CoV-2 antibody immunoassays Report, 7/9/20) ♦

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

July 21-22. **ABC Medical Directors Workshop (Virtual).** More details and registration available here.

Aug. 14. **HHS Tick-borne Disease Working Group Meeting (Virtual).** More details and registration available here.

Aug. 28-29. **South Central Association of Blood Banks (SCABB) 2020 Annual Meeting & Exhibit Show (Virtual).** More details and registration available here.

Sept. 9. **10th Annual Symposium Red Cell Genotyping 2020: Visionary Solutions, Bethesda, Md.** More details available here.

Sept. 10. **39th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** More details available here.

Sept. 16, 23, 30. **ADRP Digital Marketing Solutions Virtual Master Class.** More details available here.

Oct. 3-5. **2020 AABB Annual Meeting (Virtual).** More information available here.

Oct. 27. **Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2020 (Virtual).** More information available here.

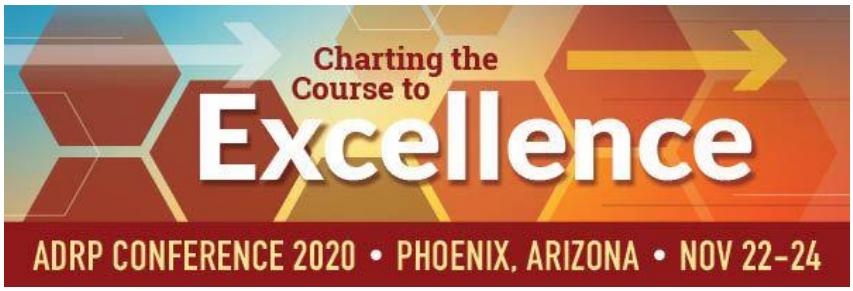
Nov. 22-24. **2020 ADRP Conference, Phoenix, Ariz.** More details available here.

2021

Mar 8-10. **ABC Annual Meeting, Washington, D.C.** More details coming soon.

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

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

Outside Sales Representative/Event Planner (Fort Smith, Ark.). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational & religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How to apply: http://arkbi.org/careers/.

Associate Medical Director. Blood Assurance is seeking an Associate Medical Director to work in our Nashville, TN facility. This position will assist the Medical Director with providing medical and professional guidance to employees of the company and to area medical professionals. Qualified applicants should possess: MD degree required; board certification or eligibility in pathology required (board certification must be secured within 1 year of hire); Transfusion Medicine board certification or eligibility preferred. Must be licensed to practice medicine in the states of our fixed facilities if required by that state (state licensure can be secured after hire). Minimum 5 years prior related experience; blood bank management and cellular therapy experience preferred. Advanced communications skills required, including ability to speak to groups; computer skills and ability to effectively interact with coworkers. Qualified candidates are encouraged to submit an online application at www.bloodassurance.org. Blood Assurance is an EOE and Tobacco Free Workplace.

Chief Medical Officer (Associate Professor, Full Professor). The University of Washington, Department of Laboratory Medicine and Pathology and Bloodworks Northwest is accepting applications for Chief Medical Officer (Associate Professor, Full Professor). This position involves overall responsibilities for providing medical direction and support for all aspects of Bloodworks' activities. The position requires licensure as a physician (M.D. or D.O.) and board certification in Blood Banking/Transfusion Medicine. In lieu of board certification, candidates who meet the requirements for CLIA laboratory director with 3 years' experience in blood collections, immunohematology, apheresis, and cellular therapy will also be considered. University of Washington faculty engage in teaching, research, and service. Please apply at https://usr57.dayforcehcm.com/CandidatePortal/en-US/bloodworks/. EO employer – M/F/Vets/Disabled