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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2020 #40 **November 13, 2020**

INSIDE:

FDA Issues EUA for COVID-19 Monoclonal Antibody Therapy

The U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) designation for an investigational monoclonal antibody therapy to treat mild-to-moderate COVID-19 in adults and children. The therapy (bamlanivimab) from Eli Lilly "is authorized for patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (about 88 pounds), and who are at high risk for progressing to severe COVID-19 and/or hospitalization. This includes those who are 65 years of age or older, or who have certain chronic medical conditions," according to the FDA.

"As illustrated by today's action, the FDA remains committed to expediting the development and availability of potential COVID-19 treatments and providing sick patients timely access to new therapies where appropriate, while at the same time supporting research to further evaluate whether they are safe and effective," said FDA Commissioner Stephen Hahn, MD in an agency news release. "Through our Coronavirus Treatment Acceleration Program, the FDA continues to work around the clock and use every tool at our disposal toward these efforts." The Acting Director of the FDA's Center for Drug Evaluation and Research Patrizia Cavazzoni, MD added, "[t]he FDA's emergency authorization of bamlanivimab provides health care professionals on the frontline of this pandemic with another potential tool in treating COVID-19 patients. We will continue to evaluate new data on the safety and efficacy of bamlanivimab as they become available." The EUA was based on data from an interim analysis of randomized, double-blind, placebo-controlled phase II clinical trial in 465 hospitalized patients. "Of these patients, 101 received a 700-milligram dose of bamlanivimab, 107 received a 2,800-milligram dose, 101 received a 7,000-milligram dose and 156 received a placebo within three days of obtaining the clinical sample for the first positive SARS-CoV-2 viral test."

Eli Lilly Chairman and Chief Executive David A. Ricks stated in a company news release, "[t]his emergency authorization allows us to make bamlanivimab available as a COVID-19 treatment for recently diagnosed, high-risk patients — adding a valuable tool for doctors fighting the now-increasing burden of this global pandemic. The rapid development and availability of bamlanivimab could not have been achieved without the relentless work of our Lilly team, collaboration across the industry and the urgent work being done by the government to ensure appropriate allocation to patients who need it the most." HHS Secretary Alex Azar added in an agency news release, [a]uthorization and distribution of this new Eli Lilly anti

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Monoclonal Antibody EUA Issued by FDA (continued from page 1)

body treatment is a significant step forward in treating patients and bridging us to the rollout of safe and effective vaccines, with all of these efforts made possible by Operation Warp Speed. Federal allocation of therapeutics like Lilly's, in cooperation with our state and local government partners, will help ensure that they go to the patients who need them most just days after the product is authorized."

Additionally, the Centers for Medicare and Medicaid Services (CMS) announced that Medicare beneficiaries "can receive coverage of monoclonal antibodies to treat coronavirus disease 2019 (COVID-19) with no cost-sharing during the public health emergency (PHE)." CMS Administrator Seema Verma stated in an agency news release, "[t]oday, CMS is announcing a historic, first-of-its kind policy that drastically expands access to COVID-19 monoclonal antibodies to beneficiaries without cost sharing. Our timely approach means beneficiaries can receive these potentially life-saving therapies in a range of settings – such as in a doctor's office, nursing home, infusion centers, as long as safety precautions can be met. This aggressive action and innovative approach will undoubtedly save lives."

(Source: FDA News Release, 11/9/20; Eli Lilly News Release, 11/9/20; HHS News Release, 11/10/20; CMS News Release,11/10/20) ♦

RESEARCH IN BRIEF

Variable Performance In Assays Affects Convalescent Plasma Seroprevalence. "Few published studies have evaluated and compared performance characteristics of high-throughput assays [for SARS-CoV-2 antibodies]," according to a recent study in the *American Journal of Clinical Pathology*. The authors "assessed [six assays] Beckman Coulter SARS-CoV-2 IgG, Euroimmun Anti–SARS-CoV-2 IgA, Euroimmun Anti–SARS-CoV-2 IgG, Roche Elecsys Anti–SARS-CoV-2 Total Antibody, Siemens Centaur SARS-CoV-2 Total Antibody, and Siemens Vista SARS-CoV-2 Total Antibody tests." They note that, "[a]ll except the Roche assay target antibodies against epitopes on the spike protein…Roche targets antibodies against nucleocapsid protein." The investigators used "[s]era from specimens [from one medical center] between January 1 and May 31, 2020…PCR detection of SARS-CoV-2 RNA was reported in patient charts." In order "[t]o assess specificity of the antibody assays, [the study] first tested specimens with prior coronavirus molecular positivity for possible antibody cross-reactivity…No cross-reactivity was exhibited except in two cases using the Euroimmun IgA assay." The authors then "assessed 33 samples from patients with respiratory symptoms that warranted [a] respiratory pathogen panel…One specimen exhibited cross-reactivity in the Beckman Coulter and both Euroimmun assays…This patient was critically ill with idiopathic pulmonary fibrosis and serial lung transplants…Assay specificity was 99 percent or greater for all assays

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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 (continued from page 2)

except the Euroimmun IgA (95 percent)…Examination of average day to seroconversion between assays [showed that in] all patients without immunosuppressants, seroconversion occurred in less than two weeks." The authors note that, "[a]ssays had a difference of seroconversion from one to more than five days between assays for each patient…A total of 154 specimens was tested including 58 from COVID-19 convalescent plasma (CCP) donors" for sensitivity. "For specimens with either molecular SARS-CoV-2 positivity or clinical diagnosis for CCP donation at more than 14 days after symptom onset, the sensitivity compared with clinical status" and ranged from 73-96 percent depending upon the assay." The study "did not find any correlations with disease course and continued antibody rise or plateau." The authors stated that the "result[s] raise concerns that seroprevalence studies may vary significantly based on the serologic assay utilized, even when the assays are from reliable manufacturers."

Citation: Zilla, M., Wheeler, B.J., Keetch, C., *et al*. Variable Performance in 6 Commercial SARS-CoV-2 Antibody Assays May Affect Convalescent Plasma and Seroprevalence Screening. *American Journal of Clinical Pathology*. 2020. Doi: 10.1093/AJCP/AQAA228.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Time for Individual Behavior-Based Risk Assessments for Men Who Have Sex With Other Men (MSM)? A commentary published in *Lancet Haematology* considers whether the U.S. should revise its MSM blood donor deferral. The authors cite changes in other countries and note the advances in testing that have ensured the safety of the blood supply, "Current screening practices target both donors and their blood products. Modern HIV testing platforms are highly accurate, with improvements in nucleic acid testing and development of fifth-generation antibody and antigen tests increasing sensitivity to almost 100% (95 percent CI 96·7–100) and specificity to 99·5 percent (99·1–99·9)…Currently, the window period is 10–23 days for antibody and antigen testing and 7–15 days for nucleic acid testing. Although missed diagnoses during the window period could be further complicated by use of pre-exposure prophylaxis, blood product testing remains very sensitive to the presence of HIV regardless of ability to diagnose acute infection. Currently, all blood products are subject to rigorous post-donation screening for HIV (among other pathogens), thereby protecting against transfusion of HIV-containing blood." Additionally, they state that blood shortages compounded by the pandemic are further evidence that a change is needed, The ongoing COVID-19 pandemic has decimated the US blood product supply, with more than 46 000 community-based blood drives cancelled as of September 2020, resulting in the loss of more than 1 million donations." The authors advocate for individual behavior-based risk assessments for all donors by stating, "[a]lthough HIV prevalence is higher in MSM than in other populations, recent [behavior] and individual risk (e.g., having multiple concurrent sexual partners) ultimately establish the likelihood of undiagnosed or recently acquired HIV infection. Thus, a [behavior]-based blood donation policy (i.e., banning all individuals who recently engaged in unprotected sex from blood donation regardless of sexual orientation) would be more equitable. Several countries have updated their blood donation regulations to a [behavior]-based approach. In Spain and Italy, MSM exclusions were replaced with a screening [program] that assesses risk via individual interviews with doctors." They conclude, "[n]o transfusion is entirely risk free, and regulations surrounding blood donation must be crafted with careful consideration of all available evidence, including sensitivity of virus detection assays, effectiveness of screening processes for similar pathogens, negative results of [stigmatizing] policies, and success of implementing [behavior]-based policies by many countries. In view of the unprecedented need for blood products and our health-care system's commitment to equitable and evidence-based practices, we argue it is time to discard overly restrictive policies and adopt individual [behavior]-based risk assessments."

Citation: Skelly, A., Kolla, L., Tamburro, M., Bar, K. Science over stigma: the need for evidence-based blood donation policies for men who have sex with men in the USA. *Lancet Haematology*. 2020.

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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.

ABC Develops New Membership Database and Resource Center

In a continued effort to provide value and services to ABC member blood centers, the association has launched a new membership platform that we encourage you to explore and use. This platform replaced the former Member website (please remove https://members.americasblood.org from your browser bookmarks) where members had grown accustomed to finding various member-only resources over the years.

Member blood centers can find the new system at https://login.americasblood.org which features a user-friendly interface and dashboard to help you quickly and efficiently navigate to relevant member resources and benefits. Start your visit on the Member Resources page and choose the area you would like to access. Additionally, to learn how to setup your profile, view this short how-to video. We encourage member feedback. If you are unable to access the platform with your current email address, please contact Member Services for assistance.

REMINDER: 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)

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ABC Annual Meeting is Moving Virtual

The 59th ABC Annual Meeting, scheduled for March 8th—10th, 2021, will be held virtually. Although we will not be in-person, this meeting will provide plenty of opportunities to connect and explore industry trends through educational sessions and our annual Advocacy Day. This year challenged our industry in many ways, highlighting the need for community blood centers to come together to reflect on lessons learned and strategize ways to prioritize the important role of community blood centers within healthcare as we continue to discover ways to thrive moving forward.

The Preliminary Program will be released in the coming weeks.

CTF COMMONWEALTH TRANSFUSION FOUNDATION

CALL FOR GRANT PROPOSALS

Commonwealth Transfusion Foundation (CTF) is a non-profit, private foundation whose mission is to inspire and champion research and education that optimizes clinical outcomes in transfusion medicine and assures a safe and sustainable blood supply for the U.S. Our current funding priorities include: Ensuring an adequate, post-pandemic blood supply; research on novel blood donor recruitment strategies; the role of blood centers in the battle against COVID-19; insight into the changing blood banking landscape; innovations in transfusion safety and patient blood management; better understanding of the supply chain and economics underpinning the blood industry; and promoting understanding and inclusion of cellular therapies in blood banking.

Interested parties should visit CTF's website (www.CTF.life) to learn more about our grants process and/or to begin the application process. Please pay special attention to what CTF does not fund. Applicants must apply through CTF's online portal beginning with a Letter of Inquiry (LOI) that briefly describes the proposal. If the LOI is approved, applicants may proceed to the full on-line application form. CTF has two grant cycles each year and the deadlines are December 20th and June 20th. For more information, feel free to contact us at info@CTF.life.

INFECTIOUS DISEASE UPDATES

MEASLES

The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) published a report in the CDC's *Morbidity and Mortality Weekly Report* (*MMWR*) highlighting that measles cases "surged" in 2019 to the highest reported levels since 1996. Close to 870,000 cases were recorded globally in the past year with more than 207,000 deaths. "We know how to prevent measles outbreaks and deaths," said Tedros Adhanom Ghebreyesus, PhD, Director-General of the WHO in a news release. "These data send a clear message that we are failing to protect children from measles in every region of the world. We must collectively work to support countries and engage communities to reach everyone, everywhere with measles vaccine and stop this deadly virus." Cases had steadily been trending downwards between 2010-2016, as experts "cite a failure to vaccinate children on time with two doses of measles-containing vaccines as the main driver of these increases in cases and deaths" in recent years. "Before there was a coronavirus crisis, the world was grappling with a measles crisis, and it has not gone away," said Henrietta Fore, UNICEF Executive Director, in the news release. "While health systems are strained by the COVID-19 pandemic, we must not allow our fight against one deadly disease to come at the expense of our fight against another. This means ensuring we have the resources to continue immunization campaigns for all vaccine-preventable diseases, even as we address the growing COVID-19 pandemic."

(Source: WHO & CDC News Release, 11/12/20)

MEMBER NEWS

Fresenius Kabi recently announced the new inductees into the Blood Donation Hall of Fame for 2020. It recognizes individuals who have made extraordinary contributions to blood donation, either through their donations or enabling the donations of others. This year's inductees include the following donors from ABC member centers:

- Marsha Asplin, nominated by **Gulf Coast Regional Blood Center**;
- Steven Davidson, **LifeStream**;
- Sunnie Fenk, **Vitalant**;
- John Jenkins, **OneBlood**;
- Kris Kaveleris, **Versiti**;
- Joe McDonald, **San Diego Blood Bank**;
- Michael Otterman, **Blood Assurance**;
- Warren Pitcher, **LifeServe Blood Center**; and
- Rush Roberts, **OneBlood**.

Additional information including all the 2020 inductees and those from previous years are also located at the Fresenius Kabi Donation Hall of Fame.

(Source: Fresenius Kabi Announcement, 11/10/20)

Western Kentucky Regional Blood Center (WKRBC) received a $100,000 grant from Impact100 Owensboro. The grant will be used to purchase a new bloodmobile "The investment that the women of Impact100 have poured into our community is demonstrated every day," said Vicki Ellis, WKRBC's director of donor resources, to the *Messenger-Inquirer*. "When you see the red Girls Inc. buses out in the

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MEMBER NEWS (continued from page 6)

community or when a person receives resources from one of our shelters or when a child plays on an all-inclusive playground, that's Impact100. And when you see our new bloodmobile out in the community, we want you to think Impact100." The goal of Impact100 "is to provide high-impact grants that reach underserved populations, support nonprofits, and highlight unmet needs in our community."

(Source: *Messenger-Inquirer*, Impact100 announces winners of $226K in grants, 10/23/20)

GLOBAL NEWS

Results of seroprevalence study of blood donors in Kenya has been published in *Science.* The study includes more than 3,000 donations between the end of April and mid-June. Researchers discovered that, "[o]f the 3,098 samples, 174 were positive for anti–SARS-CoV-2 Spike IgG giving a crude seroprevalence of 5.6 percent (95 percent CI 4.8–6.5 percent). Crude seroprevalence varied by age (P = 0.046), ranging between 3.4-7.0 percent among adults 15-54 years; all 71 donors aged 55-64 years were seronegative…The Bayesian population-weighted and test-adjusted seroprevalence for Kenya was 4.3 percent (95 percent CI 2.9-5.8 percent) and the posterior sensitivity and specificity estimates were 92.4 percent (95 percent CI 88.0-95.6 percent) and 98.9 (95 percent CI 98.2-99.5 percent), respectively. Seroprevalence was higher (4.2-5.2 percent) in the younger age groups (15-44 years) and declined in the older age groups (45-64 years) but was similar for both sexes." They note that "[v]oluntary non-remunerated donors (VNRDs), who donate blood at community-based 'blood drives' comprised only 7.6% (236/3098) of our sample of donors; the remainder were family replacement donors (FRDs) who provide a unit of blood in compensation for a transfusion received by a sick relative." The investigators explained that, "SARS-CoV-2 seroprevalence in our study is comparable to estimates from large population-based serosurveys in China, Switzerland, Spain, and the USA after the initial epidemic peak and following many tens of thousands of deaths."

Citation: Uyoga, S., Adetife, I., Karanja, H., *et al*. Seroprevalence of anti–SARS-CoV-2 IgG antibodies in Kenyan blood donors. *Science*. 2020. Doi: 10.1126/science.abe1916.

Sanquin, the national blood provider for the Netherlands, recently updated the latest findings of its ongoing seroprevalence study. "The percentage of blood donors with antibodies against COVID-19 is increasing. Sanquin's latest measurement indicates that the average in the Netherlands has risen to 6.2 percent." The organization saw fluctuations "between 4 percent and 5 percent" over the summer. Sanquin described the study results on its website as, "[w]e see a peak among younger donors (18 to 40 years old) from Utrecht, Amsterdam, Rotterdam, and The Hague. In our largest cities, more than 1 in 10 (11 percent) of the donors have formed antibodies. This corresponds to the relatively high number of infections among young adults. In addition, the difference between the North and South of the Netherlands with regard to the presence of antibodies among donors is gradually decreasing."

(Source: Sanquin Announcement, 11/2/20)

COMPANY NEWS

Pfizer and **BioNTech SE** published an interim analysis of results from a phase III clinical trial of their COVID-19 vaccine candidate. The companies report that the "vaccine candidate was found to be more than 90% effective in preventing COVID-19 in participants without evidence of prior SARS-CoV-2 infection in the first interim efficacy analysis." Pfizer Chairman and Chief Executive Officer (CEO) Albert Bourla, PhD

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COMPANY NEWS (continued from page 7)

stated in a news release, "[t]oday is a great day for science and humanity. The first set of results from our phase III COVID-19 vaccine trial provides the initial evidence of our vaccine's ability to prevent COVID-19. We are reaching this critical milestone in our vaccine development program at a time when the world needs it most with infection rates setting new records, hospitals nearing over-capacity, and economies struggling to reopen. With today's news, we are a significant step closer to providing people around the world with a much-needed breakthrough to help bring an end to this global health crisis. We look forward to sharing additional efficacy and safety data generated from thousands of participants in the coming weeks." The interim analysis includes 94 cases, according to the companies, "split between vaccinated individuals and those who received the placebo indicates a vaccine efficacy rate above 90 percent, at seven days after the second dose. This means that protection is achieved 28 days after the initiation of the vaccination, which consists of a two-dose schedule. As the study continues, the final vaccine efficacy percentage may vary. The [Independent Data Monitoring Committee] has not reported any serious safety concerns and recommends that the study continue to collect additional safety and efficacy data as planned. The data will be discussed with regulatory authorities worldwide." BioNTech Co-founder and CEO Prof. Ugur Sahin, added in the news release, "[t]he first interim analysis of our global Phase 3 study provides evidence that a vaccine may effectively prevent COVID-19. This is a victory for innovation, science, and a global collaborative effort. When we embarked on this journey 10 months ago this is what we aspired to achieve. Especially today, while we are all in the midst of a second wave and many of us in lockdown, we appreciate even more how important this milestone is on our path towards ending this pandemic and for all of us to regain a sense of normality. We will continue to collect further data as the trial continues to enroll for a final analysis planned when a total of 164 confirmed COVID-19 cases have accrued. I would like to thank everyone who has contributed to make this important achievement possible." The companies anticipate having additional safety data available later this month, specifically, "a median of two months of safety data following the second (and final) dose of the vaccine candidate — the amount of safety data specified by the U.S. Food and Drug Administration (FDA) in its guidance for potential Emergency Use Authorization (EUA). According to the release, Pfizer and BioNTech will "produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021."

(Source: Pfizer & BioNTech Joint News Release, 11/9/20)

Beckman Coulter recently launched its Access SARS-CoV-2 Immunoglobulin M (IgM) assay in countries accepting the CE mark. "Our new SARS-CoV-2 IgM assay provides information about an individual's immune status with a positive predictive value of 96.9 percent in a population with disease incidence as low as 3 percent," said Julie Sawyer Montgomery, president of Beckman Coulter in a company news release. "As COVID-19 outbreaks continue to grow in intensity in many of our communities, highly accurate tests such as this are critical for providing reliable information for both individual health decisions as well as population-based immunity monitoring." Rob Young, United Kingdom general manager for Beckman Coulter, added, "[t]his latest addition to our already extensive offering, which spans serological, antigen, and other diagnostic solutions, brings greater visibility to help monitor the progression of COVID-19 in patients. We continue to innovate and provide a multitude of high-quality tests in high volumes to help clinicians identify patients with the virus and support efforts in fighting the disease." The CE mark designation allows the test to be sold in the European Economic Area (EEA) indicating it has been "assessed to meet high safety, health, and environmental protection requirements," according to the European Commission. The test received EUA status from FDA in October.

(Source: Beckman Coulter News Release, 11/10/20) ♦

Upcoming ABC Webinars – Don't Miss Out!

- **ABC SMT Journal Club Webinar** – December 3rd from 12 – 1 p.m. (ET). More details available in MCN 20-102. Contact Toni Mattoch for questions.

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

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POSITIONS (continued from page 9)

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