FDA Approves Donor Screening Assays for *B. microti* Nucleic Acid Test and Antibodies

This week, the U.S. Food and Drug Administration (FDA) approved Oxford Immunotec, Inc.’s Imugen *Babesia microti* (*B. microti*) Arrayed Fluorescent Immunoassay (AFIA) and their *B. microti* Nucleic Acid Test (NAT). Babesiosis is an infection caused by tick-borne parasites and is considered among the transfusion-transmitted infections most frequently reported for which no approved screening test was available prior to the FDA announcement.

The approval of the *B. microti* AFIA and NAT is for “in-house tests” that are to be performed at Oxford Immunotec, Inc.’s Norwood, Mass. facility. “While babesiosis is both preventable and treatable, until today, there was no way to screen for infections amongst blood donors,” said Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research in an agency news release. “Today’s actions represent the first approvals of Babesia detection tests for use in screening donors of whole blood and blood components, and other living donors.”

The *ABC Newsletter* contacted Oxford Immunotec, Inc. regarding the licensure of both their AFIA serologic and nucleic acid donor screening assays. Both assays were used extensively under investigational new drug applications (IND) for donor screening in high-risk regions of the Northeast U.S., including by ABC member Rhode Island Blood Center (Providence, R.I.). The company plans to commercialize the platforms as a service provided from their central facility and will consider alternative models moving forward.

While no requirement for testing donor samples for Babesia currently exists, the FDA includes a draft guidance on this issue in the 2018 CBER Guidance Agenda (the list of guidance topics CBER is considering for development in the calendar year).

The FDA’s Blood Products Advisory Committee (BPAC), a panel of experts that advises FDA, discussed mitigation of transfusion-transmitted babesiosis during a May 2015 meeting and previously suggested nationwide year-round antibody screening of donors for *B. microti*, in addition to nucleic acid testing (NAT) in high-risk states. Babesia donor testing began in August 2012 in certain endemic areas under IND. Most individuals that become infected with *B. microti* are asymptomatic, while others display flu-like symptoms. In a recent development, Roche and Grifols, in collaboration with several U.S. blood centers, have begun IND testing of nucleic acid assays compatible with instrumentation in use in current U.S. donor testing laboratories.

(Source: U.S. Food and Drug Administration News Release, 3/6/18)
WORD IN WASHINGTON

Regulators appeared before the House Energy and Commerce Committee’s Subcommittee on Oversight and Investigations at a hearing to review the effectiveness of the flu vaccine and the response of federal agencies to this year’s flu outbreak. Members of Congress sought explanations from The Centers for Disease Control and Prevention’s (CDC) Anne Schuchat, MD, the Food and Drug Administration’s (FDA) Scott Gottlieb, MD, the National Institute of Allergy and Infectious Diseases’ (NIAID) Anthony Fauci, MD, and the Biomedical Advances Research and Development Authority’s (BARDA) Rick Bright, PhD in the wake of reports from CDC that this year’s flu vaccine’s adjusted vaccine effectiveness (VE) against influenza A and influenza B virus infection was 36 percent (95 percent confidence interval [CI] = 27 percent–44 percent). “Unlike in other seasons when flu activity varied in timing and intensity across states, during this 2017-2018 season, many states experienced widespread and high flu activity at the same time,” said Anne Schuchat, MD acting director at CDC in a news release from the House Energy and Commerce Committee. “We cannot predict how long this season will last.” The Committee urged the agency leaders to continue to explore ways to reduce the number of hospitalizations and fatalities attributed to flu going forward. Anthony Fauci, MD added that NIAID “has made the development of universal influenza vaccines a high priority, and in this regard, has begun a concerted effort to galvanize research in the field.” A recording of the hearing is available.

(Source: House Energy and Commerce Committee News Release, 3/8/18)

The U.S. Department of Health and Human Services’ (HHS) Secretary Alex Azar stressed the importance of value-based healthcare during a speech this week at the Federation of American Hospitals’ public policy conference. His address outlined four areas of emphasis, “giving consumers greater control over health information through interoperable and accessible health information technology, encouraging transparency from providers and payers, using experimental models in Medicare and Medicaid to drive value and quality throughout the entire system, and removing government burdens that impede this value-based transformation.” ABC issued comments to the FDA, as reported in ABC Newsletter Issue #7, to address burdensome regulations on behalf of member blood centers. ABC members can find additional information on the submission in MCN 18-009. Mr. Azar added, “[T]his administration is unafraid of disruption in the way many political actors are. President Trump is a man of courage and vision. He has seen and heard how the high cost of healthcare is burdening working-class Americans, and he has given us a mandate to do something about it…In order to bring down costs and increase quality, we have to put patients in charge of their own data; provide them with useful, transparent price and quality information; use Medicare and Medicaid to shift toward a value-based system; and get government out of the way of such a system.”

(Source: Alex Azar Statement, 3/5/18) 🔹
56th ABC Annual Meeting Registration

Registration remains open for ABC’s 56th Annual Meeting in Scottsdale, Ariz. March 17th – 19th at the Scottsdale Plaza Resort. Don’t miss an exclusive opportunity for blood community leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Celso Bianco, MD Lectureship, the Scientific, Medical, and Technical Forum, and the 21st Annual Awards of Excellence. Additionally, ABC member Blood Systems Inc. will host a networking event at the Musical Instrument Museum. Click here for additional details. Contact Leslie Maundy for available sponsorship opportunities.
INSIDE ABC (continued from page 3)

**Human Resources and Training & Development Workshop Registration**

ABC invites all human resources and training and development professionals to register for the 2018 ABC Human Resources and Training & Development Workshop in Dallas, Texas May 8<sup>th</sup> – 10<sup>th</sup> at the Fairmont Dallas. Attendees will have the opportunity to discuss industry challenges and trends with their peers and partake in joint sessions that will explore the current state of the blood industry, critical thinking skills, and disaster training/preparedness. View the workshop schedule [here](#). Time will also be devoted for separate sessions focusing on hot topics specific to each discipline such as Human Resources as a Business Partner, Intermittent FMLA/ADA/LOA, Training Video Production, and Mobile Learning/Micro-Learning. HRCI and P.A.C.E. credits will be offered. Please contact Leslie Maundy for additional details and sponsorship opportunities. Registration rates are below:

- 3-day HR/TD Workshop (Tue-Thu) $540
- 2-day Training & Development (Tue-Wed) $465
- 2-day Human Resources (Wed-Thu) $465

(Source: MCN 18-011)

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**RESEARCH IN BRIEF**

Factors associated with the failure of reentry among blood donors with false positive infectious diseases testing quantified. Investigators at ABC member Héma-Québec have studied permanently deferred blood donors with pre-defined false positive infectious diseases testing for predictors of “re-deferral” after completing reentry testing. Hepatitis C virus, HIV, hepatitis B virus and syphilis false positives were included. The percentage of invited donors who participated in reentry was 42.1; 26.6 percent failed to qualify, but the failure rates were only 2.7 percent for donors tested with a second manufacturer’s platform

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compared to 42.9 percent tested on the platform responsible for their initial deferral. Among donors who initially qualified for reentry, deferral after three years for a second false positive test was 8.4 percent in aggregate, but only 1.8 percent when using a different platform than the index, compared to 21.4 percent due to the index platform.


Can patients needing massive transfusion and other aggressive interventions for trauma be identified early in their clinical course? Early, appropriate triage after trauma is considered critical for optimal outcomes. Authors from the University of Ottawa (Canada) and Leiden University (Netherlands) have performed a systematic literature review and meta-analysis of factors predictive of a need for massive transfusion. The bulk of the available literature was described as being of “poor quality” according to standardized assessment tools. The predictors identified by the most reliable data included: penetrating trauma as the mechanism of injury, the presence of systolic hypotension, tachycardia, low hemoglobin, severe lactic acidosis, coagulopathy (assessed with the international normalized ratio), and imaging findings consistent with the presence of free fluid using focused abdominal sonography for trauma (FAST). Their conclusions highlight the poor quality of the available literature, the consistency of the predictors identified in the review with “expert guidelines,” and their potential to inform future derivation of valid prediction models.


Stem cells and regenerative medicine. The international authors, from academia and industry, of a formal Lancet Commission argue “that a combination of poor quality science, unclear funding models, unrealistic hopes, and unscrupulous private clinics threatens regenerative medicine’s social license to operate.” They “recommend a solution that lies in a coordinated strategy with four pillars: better science; better funding models; better governance; and better public and patient engagement.” For cell and gene therapies and tissue engineering, clinical trial imperatives, health economic, access, ethical and stakeholder perspectives are included.


How to do patient blood management? Two programs with different approaches and outcomes. The first paper, from New York University, the Cleveland Clinic, and Johns Hopkins was a compilation of the facilities’ best practice recommendations defined as red blood cell (RBC) transfusion in stable adult hospitalized patients at a hemoglobin level of <7 g/dL, restriction of RBC transfusion during orthopedic or cardiac surgery or in patients with underlying cardiovascular disease to a hemoglobin level of <8 g/dL, and using single-unit RBC transfusions followed by reassessment as the standard of care. The patient blood management (PBM) program had nine elements, support from health system leadership, engage a multidisciplinary team of clinicians and stakeholders, provide education emphasizing randomized clinical trials, harmonized health systems transfusion guidelines, provide clinical decision support and best practice advisories, acquire and analyze data generated, use of guideline compliance dashboards, guideline compliance audits with feedback, and other methods for improving blood use (e.g. “Why give 2 when 1 will do” Choosing Wisely campaign).

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RESEARCH IN BRIEF (continued from page 5)

The second was a paper from Leiden University, the Medical Center Leeuwarden, and Groene Hart Hospital in the Netherlands. It emphasized that increasing evidence supporting PBM does not automatically translate into practice. The Leiden Implementation Study of cost-effective blood management in total hip and knee arthroplasties (LISBOA) focused on cost-effective PBM by attempting to “de-implement” two elements of low-value care, preoperative use of erythrocyte stimulating agents (i.e. erythropoietin) to optimize the RBC mass, and blood salvage to minimize blood loss in total hip and knee arthroplasties. Their five-element systematic strategy, based on published implementation science, to reduce their use was not effective compared to the control group. They suggest that specific de-implementation frameworks may fail to recognize important factors playing roles in clinical decision-making or that the inability to blind clinical staff completely may have driven “de-implementation” at control sites.


Contributed by Richard Gammon MD, Medical Director, OneBlood (Orlando, Fla.)

Gene therapy in hemophilia B (factor IX (FIX) deficiency) successful. An adeno-associated virus vector with a liver-specific promoter sequence was used to deliver a single dose of the wild-type human FIX gene in a multicenter study in the European Union and U.S. No prospective subjects needed exclusion for a preexisting antibody to the vector. To date, the ongoing study has demonstrated an 81 percent decrease in annualized factor infusion requirements and a reduction of the annualized spontaneous bleeding rate from 9.8 to 4.6 percent among 10 adults with FIX levels ≤ 1.5 IU/dL. Toxicity was acceptable and FIX levels were stable during follow-up to one year. Cellular immune responses to the vector were not detectable.


RECENT REVIEWS

A review from the Netherlands and Australia describes “barriers and facilitators” to blood donation by sub-Saharan minorities and migrants to the developed Western world. Minority donors are critical for a robust supply of phenotype compatible blood donors. Reviewing 31 published studies, evaluating target donor cohorts including African-Americans and specific migrant nationalities, hemoglobin deferral, fear of needles, social exclusion, lack of awareness, lack of accessibility were commonly described barriers. Facilitators included altruism, health check-ups, and specific awareness initiatives.


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. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 393-1282. 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.
BRIEFLY NOTED

The U.S. Food and Drug Administration’s (FDA) Blood Products Advisory Committee (BPAC) will be holding a joint meeting with the Microbiology Devices Panel of the Medical Devices Advisory Committee. The meeting will take place on March 21st-22nd at the FDA Campus in Silver Spring, Md. Additional information is available including the announcement and meeting materials. The Joint Committee will “discuss and make recommendations regarding the device reclassification from Class III to Class II of nucleic acid and serology-based point-of-care and laboratory-based in vitro diagnostic devices indicated for use as aids in the diagnosis of human immunodeficiency virus (HIV) infection, hear an overview of the research presentations on the research programs of the Laboratory of Emerging Pathogens, the Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents, and the Laboratory of Molecular Virology in the Division of Emerging Transfusion-Transmitted Diseases, Office of Blood Research and Review Center for Biologics Evaluation and Research, and discuss and make recommendations regarding the reclassification from Class III to Class II of nucleic acid and serology-based in vitro diagnostic devices indicated for use as aids in diagnosis of hepatitis C virus (HCV) infection and/or for use as aids in the management of HCV infected patients,” according meeting announcement. Blood donor screening assays are not included.

(Source: Federal Register Meeting Notice, 2/22/18)

Keagan Lenihan has been appointed as the associate commissioner for strategic initiatives according to Politico. She previously worked as a senior adviser of former Department of Health and Human Services secretary Tom Price, MD, and as the director of government relations at McKesson, a pharmaceutical company. Ms. Lenihan will be responsible for “big-picture projects that combine her background on the Hill, the agencies, and in pharma,” stated the Politico report.

Source: (Politico, Patients’ bills may surge due to new drug coupon policies, 3/5/18) ▶
REGULATORY NEWS

Scientists at the National Institute of Allergy and Infectious Diseases (NIAID) examined the ability of three “unstudied” prion protein mutations to be transmissible according to a news release from the National Institutes of Health. Prion diseases are a family of rare progressive neurodegenerative disorders that affect both humans and animals. Familial prion diseases such as genetic Creutzfeldt-Jakob disease are “passed within families” and “associated” with 34 known prion mutations. In the study, investigators exposed mice to brain samples from three individuals who died due to familial prion disease. They observed the mice for two years finding that two of the mutations were transmissible. According to the study, “[t]he finding illustrates the hardiness of prion infectivity and the potential risks associated with prion transmission, potentially through surgery, blood transfusion or tissue donation.”

Source: (National Institutes of Health News Release, 3/8/18)


INFECTIOUS DISEASES UPDATE

Zika Virus


*Other routes include 47 reported cases that were transmitted through sexual contact (45), laboratory exposure (1), and person-to-person through an unknown route (1)
MEMBER NEWS

Uber, a popular ridesharing service, has announced that Blood Centers of the Pacific (San Francisco, Calif.) is one of several healthcare organizations taking part in their Uber Health beta program according to a March 1st news release. The program aims to remove transportation as a barrier to “provide reliable, comfortable transportation for patients.” Currently, more than 100 healthcare organizations are participating in the service that permits healthcare facilities to summon rides for patients on their behalf, or for patients to schedule rides for themselves. “For many, their first ever Uber ride will be through Uber Health, so we’re committed to providing the necessary education tools that ensure every patient feels comfortable and at ease during their journey,” said Uber Health General Manager Chris Weber to Healthcare IT News. Uber Health is also accessible to those without a smartphone using thanks to text messaging functionality or an opt-in call service that works with mobile and landline phones.

(Sources: Uber News Release, 3/1/18; Healthcare IT News, Uber offers providers, patients new Uber Health transportation app and dashboard, 3/2/18)
MEMBER NEWS (continued from page 9)

**BloodCenter of Wisconsin** (Milwaukee, Wis.), part of Versiti, Inc. is launching the “BloodFLOW – Further Learning On the Web webinar series” in April for continuing education. The webinars will be offered on a quarterly basis with the first examining next generation sequencing (NGS) and its impact on virtual cross matching and its enhancement of donor selection within histocompatibility. It will occur on April 11th at 1 pm CDT with Jennifer Schiller, PhD presenting “NGS technology for HLA typing.” Registration is open. Future topics will include “Discord in the blood bank” (Greg Denomme, PhD) in June, “Diagnostic testing for von Willebrand disease” (Kenneth Friedman, MD) in August, and “Genetic testing in hematology” (Stefanie Dugan, MS, CGC and Jamie McCreery, MS, CGC) in December.

Source: (BloodCenter of Wisconsin News Release, 3/7/18)
CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)

2018


May 8-10. ABC Human Resources & Training/Development Workshop, America’s Blood Centers, Dallas, Texas. More details available here.

May 9-11. ADRP Conference & Expo., Dallas, Texas. More details available here.


Sept. 28. 36th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, MD. More details available here.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC 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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Director of Community Development. Houchin Community Blood Bank is a local, non-profit community blood bank, centrally located in Bakersfield, California, serving all of Kern County for over 60 years. We operate in a state-of-the-art, 42,000 square foot facility. Our Director of Community Development is a key employee of the blood bank and an integral member of the management team. This individual will direct and coordinate activities related to: community development, marketing, field recruiting, and account management. The Director will foster a strong community relationship and a strategic balance between fixed site and mobile collection operations. In doing so, the Director will manage staff, maintain adequately developed goals and plans, and be responsible for the attainment of those goals. Qualifications include a minimum of BS/BA degree in business, marketing, sales, public relations or related field; minimum three years of managerial responsibility; minimum five years of technical experience in sales or a marketing-

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POSITIONS (continued from page 11)

related role; excellent oral and written communication skills, leadership and management skills, business and financial planning skills. We offer a competitive salary, positive work environment, excellent benefits, including two retirement plans, and more. For more information on our company, please visit us at www.hcbb.com. Interested applicants may email resumes to careers@hcbb.com.

Quality Assurance Director. The Blood Bank of Alaska is seeking a Quality Assurance (QA) Director. The Quality Assurance Director is responsible for ensuring all areas of the Blood Bank of Alaska (BBA) are operating in compliance with applicable government regulations, accrediting agency standards or consignee requirements related to the collection, processing, testing and distribution of blood products, cellular therapy products and services. The QA Director participates as a member of the BBA management team in planning, program formulation, and systems development. The QA Director is responsible for designing, implementing, and monitoring the quality assurance program for all operating divisions of BBA. The incumbent for this role must possess excellent conceptual, communication, and analytical skills. Must understand general work flow processes and equipment used in a medical facility. Must have excellent interactive skills necessary in communicating with coworkers and regulatory officials. The Blood Bank is an equal opportunity employer. Qualified applicants are considered for employment without regard to race, color, religion, national origin, age, disability, marital/veteran status or any other legally protected status. Interested candidates please apply via our website at www.bloodbankofalaska.org.