PATHOGEN REDUCTION TECHNOLOGY PRESS RELEASE

NEWS RELEASE

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SHEPEARD COMMUNITY BLOOD CENTER INCREASES PROTECTION FROM TRANSFUSION-TRANSMITTED INFECTIONS THROUGH USE OF PATHOGEN REDUCTION TECHNOLOGY

INTERCEPT® Blood System reduces the risk of transmitting infectious disease via blood transfusion by inactivating a broad range of viruses, bacteria and protozoa.

AUGUSTA, GA. (JULY 12, 2016) – Shepeard Community Blood Center is proud to be the FIRST in the State of Georgia to produce pathogen reduced platelet components in which a broad spectrum of pathogens and leukocytes have been inactivated to reduce the risk of transfusion-transmitted infection, including sepsis, and to potentially reduce transfusion-associated graft-versus-host disease. Shepeard supports 21 hospitals in Georgia & South Carolina, and supplies 32,000 components per year.

"Shepeard continuously strives to find ways to utilize the latest innovative technologies to improve the safety and availability of our blood supply," said Kevin Belanger, Shepeard President/CEO. "The INTERCEPT Blood System provides a proactive approach to address the safety of blood transfusion recipients by helping to protect them from transfusion transmitted infections, including those from certain bacteria and emerging pathogens."

Nearly 30 million blood components are transfused each year in the United States.[1] In fact, it is estimated that 40 percent of people[2] will one day need a transfusion to treat a disease, replace blood loss during a traumatic injury or to supplement their own blood during surgery.

In the United States, the incidence of transfusion transmitted infections (TTIs), including HIV, and hepatitis C (HCV), have become rare thanks to donor screenings and advanced disease testing procedures. Recently, the U.S. Food and Drug Administration (FDA) issued a revised draft guidance document which includes pathogen reduction technology as a recommended option to reduce the risk of bacterial contamination in platelets, and transfusion-related sepsis. [8]

In addition, gaps exist for some pathogens for which there are no licensed tests – such as Zika,[9,10] dengue and chikungunya -- or for threats that haven't yet been identified. Adding new commercialized tests to the routine assessment of donated blood can take a significant amount of time due to development and regulatory submissions that must be performed.

Unlike testing, pathogen reduction is a proactive approach to reducing transfusion-transmitted infectious risk, including sepsis, through the comprehensive inactivation of bacteria, viruses, and

parasites in plasma and platelet components. The INTERCEPT Blood System's proprietary pathogen reduction technology is based on a simple premise – platelets and plasma contains no functional DNA or RNA; however, pathogens and harmful white blood cells all do. Pathogen reduction is designed to block the replication process so that these viruses, bacteria, and parasites can no longer multiply and cause disease. The INTERCEPT Blood System inactivates a broad spectrum of pathogens, offering a proactive approach to reducing the risk of transfusion-transmitted infections, even those for which there are currently no commercialized testing methods.

For more information about pathogen reduction technology, please visit shepeardblood.org

Shepeard Community Blood Center was established in 1978 and continues to operate as a 501c3 non-profit blood center, serving hospitals and communities in a 27 county- two state area. Shepeard has three spacious donor centers and a mobile fleet that hosts over 75 drives each month. For more information log onto shepeardblood.org, call 706.737.4551 or email: info@shepeardblood.org.

1. Centers for Disease Control and Prevention. Blood Safety Basics. Accessed 28Oct14 at: www.cdc.gov/bloodsafety/basics.html
2. Shepeard Community Blood Center. About Blood Donations. Accessed 12July16 at: www.shepeardblood.org/TypesofDonations
3. Kleinman S et al. *Transfusion* 2013; 53:1603-1618.
4. Benjamin RJ. *ISBT Science Series* 2014;9:124-130.
5. Stramer SL, Hollinger FB, et al. *Transfusion* 2009;49(Suppl 2):1S-29S.
6. Dodd RY. *Practical Transfusion Medicine. 4th ed.* Chichester: Wiley; 2013;161-7.
7. Dumont, LJ et al. *Transfusion.* 2010 Mar;50(3):589–99.
8. "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," FDA Draft Guidance for Industry, March 2016.
9. Data for pathogen reduction of Zika by INTERCEPT Blood System, pathogen reduction system has not been submitted for FDA review.
10. FDA Zika Guidance for Industry February 2016.

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