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FDA approves Immucor's PreciseType® HEA Test to be used for screening blood donors for Sickle Cell Trait (SCT)

- Now recognized as a tool to identify SCT negative units in addition to extended antigen typings all in one test
- Reduces the time and expense of selecting units for patients requiring frequent transfusions, such as those with sickle cell disease
- Improves the decision-making process of which blood components to collect from donors

NORCROSS, Ga. - October 21, 2016 - Immucor, Inc., a global leader in transfusion and transplantation diagnostics, announced that the U.S. Food and Drug Administration (FDA) has approved the use of its PreciseType HEA test to screen blood donors for Sickle Cell Trait. The PreciseType HEA test is the only FDA-approved molecular assay designed to provide clinicians and blood banks with the detailed genetic matching information they need to reduce the risk of alloimmunization and serious hemolytic reactions, which is especially problematic for patients receiving frequent blood transfusions. The added utility of screening donors for Sickle Cell Trait addresses the desire to avoid transfusing red blood cells from SCT donors to sickle cell disease patients or neonates.

SCT screening has traditionally been performed by solubility testing of Sickle Hemoglobin (Hbs) in buffer, but blood centers have been looking for an alternative due to limitations in this method. A molecular approach using PreciseType HEA can overcome throughput limitations and reduce false positive rates, both of which act to limit the potential donor pool.

"We've successfully demonstrated the clinical benefits of our PreciseType HEA Test, and this is evident in the FDA broadening its approved use," said Immucor Vice President of Medical Affairs Dr. Michael Spigarelli. "The use of PreciseType HEA to screen donor units for patients with sickle cell disease, neonates or any individual that may require SCT negative blood provides a great improvement over previously used methods, and offers the first FDA approved molecular method specifically for screening units."

"We had already validated the PreciseType HEA test for this purpose in our lab," said the New York Blood Center's Executive Scientific Director of Immunohematology, Genomics, and Rare Blood Connie Westhoff, SBB, Ph.D. "Our previous screening method required manual testing and interpretation of the results and had high false positive rates. About 1 in 12 minority donors possess the sickle trait, so accurate results are important to us to avoid unnecessary notifications to donors and deferred blood units. We are now able to identify SCT in our donors utilizing the same PreciseType HEA test we are already running on many of our donors without running additional tests."

Dr. Westhoff is an expert in transfusion therapy for patients with sickle cell disease and in the application of molecular diagnostics to transfusion medicine. She oversaw a clinical trial of the PreciseType HEA at the New York Blood Center, and she is also an adjunct assistant professor at the University of Pennsylvania and is associate editor of the journal Transfusion blood group genomics and hematology section. "Patients with sickle cell disease can require frequent transfusions, and clinicians desire to maximize the efficacy of these transfusions. This molecular method provides a readily accessible way to make this desire a reality. Now, when SCT negative units are requested by a physician for a sickle cell patient, laboratory directors have access to an FDA approved method to rapidly perform this testing to fulfill that request and allow the patient to receive the blood that was ordered," Spigarelli added.

Blood from SCT donors can also present a problem when performing the required filtration of white cells from the blood donation. The use of a molecular test will allow these units to be identified prior to filtration. Early and accurate identification allows blood center staff an opportunity to decide how best to utilize the various components of a valuable whole blood donation to provide the best blood products to patients who need them.

About the PreciseType HEA test
The Immucor PreciseType HEA test rapidly and accurately predicts blood compatibility between donors and patients to help prevent mismatches that can cause serious, potentially life-threatening reactions. The test works by detecting genes that govern the expression of 35 antigens that can appear on the surface of red blood cells. The test is manufactured by Immucor wholly owned subsidiary, BioArray Solutions.

About Immucor
Founded in 1982, Immucor is a global leader in transfusion and transplantation diagnostics that facilitate patient-donor compatibility. Our mission is to ensure that patients in need of blood, organs, or stem cells get the right match that is safe, accessible, and affordable. With the right match, we can transform a life together. For more information on Immucor, please visit our website at www.immucor.com.

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