Subject Screening

Blood products are collected from individuals (subjects) screened in accordance with the FDA's current requirements and recommendations for donors of blood products intended for transfusion in the US. Health history of prospective subjects is assessed prior to each collection by soliciting the individual's responses to 50+ questions on Key Biologics' Health History Record which includes all questions on the current FDA-approved health history questionnaire used to screen donors of transfusable components. Key Biologics' Health History Record also includes several questions approved by the FDA to screen donors of tissue for transplantation. Specific questions related to potential exposure to Zika virus are also included.

Most blood products are collected under IRB-approved protocols with specific inclusion/exclusion criteria that must also be assessed to determine the potential subject's eligibility to provide a specific blood product. Subjects must be found eligible in accordance with all the guidelines for screening donors of transfusable products unless the final use of the product and protocol's inclusion/exclusion criteria allow an exception. Screening materials and protocol inclusion/exclusion criteria will be provided to the customer for review upon request and may be modified to meet customer specifications if subject safety would not be adversely impacted by the changes.

Infectious disease screening is performed with each product collection using blood samples collected concurrently with the product. Infectious disease screening is outsourced to an FDA regulated laboratory. Test results are generally received and provided to the customer on the day following collection, usually before noon. If requested by the customer, infectious disease screening can be performed in advance of collection, e.g. subject tested within seven days of collection, with products released for shipment based on those results. Additionally, a customer may request additional testing of prospective subjects to qualify them for the intended use of the product.

The test panel listed below and frequency of testing are the same as required/recommended by the FDA for screening blood products intended for transfusion.

Test	Frequency
Hepatitis B virus (HBV) surface antigen	**Each donation**
Antibody to hepatitis B virus core antigen (Anti-HBc)	**Each donation**
Hepatitis C virus (HCV) antibody	**Each donation**
Human T-cell lymphotropic virus types I and II antibody (HTLV I/II)	**Each donation**
Human immunodeficiency virus (HIV) type 1- Groups M and O and/or type 2 antibody	**Each donation**
HIV–1 RNA by NAT pooled testing*	**Each donation**
HCV RNA by NAT pooled testing*	**Each donation**
HBV DNA by NAT pooled testing*	**Each donation**
West Nile Virus (WNV) RNA by NAT pooled testing*	**Each donation**
Zika Virus RNA by NAT single donor testing**	**Each donation**
Serological test for syphilis	**Each donation**
Red cell antibody screen (ABS)	**Each donation**
Blood ABO group and Rh type (ABO/Rh)	**Each donation**
***T. cruzi* antibody**	**Performed once and blood products released based on historic results unless repeat requested by customer**
Cytomegalovirus antibodies (CMV)	**Upon customer request**

***Tissue donor level screening using single donor unit testing can be performed at customer's request**

**** Performed under Roche Molecular Diagnostics IND**

If upon a subsequent donation, a subject is found to have a reactive infectious disease test, customers who received a blood product collected from this subject are notified in accordance with FDA guidelines for transfusable blood components.