



## Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood

**Keeping the United States blood supply the world's safest** is the ultimate responsibility of the nation's more than 3,000 blood establishments, which collect and process 14 million units of whole blood donated by volunteers each year. The Food and Drug Administration, however, has the vital role of ensuring that the 3.5 million patients who receive a blood transfusion in a year are protected by five layers of overlapping safeguards. This FDA blood-safety system includes the following measures:

- **Donor screening:** Donors are informed about potential risks and are required to answer questions about factors that may have a bearing on the safety of their blood. For example, donors with a history of intravenous drug abuse are routinely deferred. Since November 1999, the FDA has requested the blood industry to defer potential donors who had lived in European countries with

### Testing Blood

The FDA reviews and approves all assay test kits used to detect infectious and transmissible diseases in donated blood. Each unit must be tested for: **Hepatitis B and C viruses (HBV and HCV)**, which cause inflammation of the liver. The three tests used identify current and previous infection with HBV and HCV; detect a person who has recovered from a hepatitis B infection but continues to be a carrier for HBV; and identify carriers of even symptomless HCV.

**Human Immunodeficiency Virus (HIV 1 and 2)**, which cause immunodeficiency disease, or AIDS. One test detects antibodies to proteins of both types of HIV virus, and another detects one of the viral proteins of the HIV-1 virus.

**Human T-Lymphotropic Virus, Types I and II**, which can cause infections that can lead to leukemia or a variety of neurologic diseases.

**Syphilis.** The test detects ongoing and previous infections with the bacterium that causes syphilis.

In addition, the FDA has licensed the first nucleic acid test systems for screening donors of whole blood and blood components, including fresh plasma, red cells and platelets. The semi-automated, highly sensitive systems can directly and rapidly recognize the genetic material of HCV and HIV, and thereby detect the infections before the appearance of their symptoms.

reported or suspected cases of BSE, the "mad cow disease," and who might be carriers of the BSE agent.

- **Blood testing:** After donation, each unit of donated blood undergoes a series of tests for infectious diseases.

- **Donor lists:** Blood establishments must keep current a list of deferred donors and use it to make sure that they do not collect blood from anyone on the list.

- **Quarantine:** Donated blood must be quarantined until it is tested and shown to be free of infectious agents.

- **Problems and deficiencies:** Blood centers must investigate manufacturing problems, correct all deficiencies, and notify the FDA when product deviations occur in distributed products.

If any one of these safeguards is breached, the blood product is considered unsuitable for transfusion and is subject to recall.

**For more information**, call 301-827-2000 or visit [www.fda.gov/cber/blood.htm](http://www.fda.gov/cber/blood.htm).