

International Standards & Guidelines

Across the world, centers that collect, process and store umbilical cord blood differ in the organizational and processing methods that they use. While government laws and regulations govern the overall operation of cord blood banks, many are also accredited through a variety of mechanisms. Here are a few globally standardized and consistently applied regulations, formed with the aim of benefiting both the cord blood banks and the end users.

AABB Accreditation

The [AABB \(American Association of Blood Banks\)](#) Accreditation Program strives to improve the quality and safety of collecting, processing, testing, distributing and administering blood and blood products. It assesses the quality and operational systems in place at the cord blood banking facility and ensures it's compliance with Standards, Code of Federal Regulations and federal guidance documents.

This independent assessment of a facility's operations helps the facility to prepare for other inspections and serves as a valuable tool to improve both compliance and operations. AABB Accreditation is usually granted for collection, processing, testing, distribution and administration of blood and blood components; hematopoietic progenitor cell activities; cord blood activities; perioperative activities; parentage testing activities; immunohematology reference laboratories and SBB schools.

US FDA Standards

The [United States Food & Drug Administration \(US FDA\)](#) is the largest governmental regulatory body responsible for the protection of public health. During the early years of cord blood banking, the only regulation that the FDA imposed was mandatory screening for certain diseases such as HIV. But since 2005, the US FDA has framed a full body of regulations outlining the procedures and methods that banks and laboratories must follow. These regulations cover the appropriate collection, processing, packaging, labeling and distribution of cord blood stem cells.

In the United States, it is therefore mandatory for all cord blood banks to adhere to the FDA's regulations, which ensure the safe handling and storage of cord blood stem cells. And when a cord blood bank also has AABB Accreditation, it is further evidence of the bank's commitment to quality.

FACT (formerly FACHT)

Founded in 1996, the [Foundation for the Accreditation of Cellular Therapy \(FACT\)](#) is a non-profit, voluntary organization that develops, maintains and updates comprehensive standards for all aspects of hematopoietic stem cell collection, processing and transplantation. Co-founded by the International Society for Cellular Therapy (ISCT) and the American Society of Blood and Marrow Transplantation (ASBMT) for voluntary inspection and accreditation in cellular therapy, FACT's main objective is to promote high quality patient care and laboratory performance.

NETCORD

An international network of cord blood banks, [NETCORD](#)'s main goal is to promote international standards for cord blood banking and to provide unified access to high quality cord blood units from member banks. NETCORD's "Virtual Office" provides Transplant Centers access to all the cord blood units currently available in NETCORD-affiliated cord blood banks. NETCORD in collaboration with FACT, has established the NETCORD-FACT Standards for Cord Blood Banks (internationally adopted minimal standards for cord blood banks) and a mechanism to inspect and accredit cord blood banks in the United States and internationally.