

COMPARISON OF CORD BLOOD BANKING STANDARDS AND VOLUNTARY ACCREDITATIONS

Report of the Quality Standards Committee of the Cord Blood Association – June 2018*

Presented below are observations about the scope and organization of the two sets of standards - AABB and FACT-NetCord - along with a summary of similarities and differences in requirements for facility operations, collection, processing, listing, search, selection, reservation and distribution.

■ Scope

The scope of the two sets of standards is different:

- **FACT** standards are **specific to cord blood banks** and release for administration.
- AABB standards are related to different variety of cellular products.

■ Organization

The organization of the two sets of standards differ:

- **FACT** standards are organized by workflow of cord blood banking and **release for clinical use**.
- AABB standards are structured according to “quality system essentials”

■ Cord Blood Bank Operations

The AABB and FACT standards are similar with respect to operations. Both have requirements for maintaining quality. However:

- **FACT** standards are **specific to cord blood banking**
- AABB standards are intended for a variety of cellular product entities.

Examples:

- Greater specificity in the **FACT** standards **include the processes** for characterization and validation for viability of cord blood cells (specific requirements for CD34+, CD45+) and cord blood units.
- For allogeneic products, **FACT** standards **require validation** that the donor and the recipient are different individuals when there is a complete HLA match. in AABB, traceability is well described standards with a requirement that products be traceable to the donor or source, but there is no requirement for linkage of a cord blood unit to an infant donor.
- The **FACT** standards **specify continuous safe storage, transport and shipping of cord blood units**, while the AABB standards require only an emergency plan.

- The **FACT** standards **address unplanned deviations**. Both sets of standards include procedures for accepting products that have incomplete donor eligibility, but the AABB standards do not require medical histories of first-degree relatives. AABB standards have a general policy on deviations.
- With respect to inventory transfer, both AABB and FACT have requirements for the transfer of products for clinical treatment, as well as procedures for responding to emergencies and disasters. **FACT has additional requirements for inventory transfer if a bank were to cease operations**.
- For interruption of operations, the AABB standards require that banks have emergency procedures to respond to disasters or emergencies. The **FACT** standards provide **specific requirements for interruptions in processing operations and the maintenance of units already in storage**.

■ Cord Blood Processing

The required policies and standard operating procedures for product *processing* are similar but:

- **FACT** standards, being specific to cord blood, are **more detailed**.
- AABB standards address products in general and calls out cord blood when the requirements differ.
- **FACT** standards have **requirements** for sample segments including size, volume, number of maternal samples, retention of samples, product segments, and storage conditions.
- The AABB standards more simply require that two “integrally attached” segments be cryopreserved with the product.

In summary, because the FACT requirements are specific to cord blood banking, compliance can be achieved only by following strict checklists in the standards. The AABB standards are more general.

*Extract by https://cord.memberclicks.net/assets/docs/standards_and_%20accreditation.pdf