U.S. Food and Drug Administration

Center for Biologics Evaluation and Research
Laboratory Quality System

Laboratory Quality Product Testing Plan (TP)

Title: *ALLOCORD (Hematopoietic Progenitor Cells) HPC, Cord Blood*

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Testing Plans document how CBER currently anticipates regulating licensed products including the circumstances under which CBER testing may be used to evaluate a lot of licensed product. It is the responsibility of each Product Office to develop Lot Release Testing Plans for the licensed products under its purview.

Product Trade Name:	ALLOCORD
License Product Name (Proper Name):	HPC, Cord Blood
Product ID (LQDB):	002309
License Number:	1873
STN (RMS-BLA):	125413
Applicant (Supplier):	SSM Cardinal Glennon Children's Medical Center

Signatures Required to Approve or Update Testing Plan

Product Office Director (or designee), OCTGT:	Celia Witten, Ph.D., M.D.
Director, DBSQC/OCBQ:	William McCormick, Ph.D.
Director, DMPQ/OCBQ:	John A. Eltermann, Jr., M.S., R.Ph.
Center Lab Quality Mgr:	Sheila Smith

Mode of Product Regulation

Based upon Product Office assessment of the product, including relevant manufacturing, safety, clinical and other considerations, determine which form of CBER review and or release of manufactured product lots is necessary.

Lot Release – Manufacturer may not distribute product until receiving lot-specific release from CBER.

Surveillance – Manufacturer may distribute product without lot-specific release from CBER. Manufacturer is required, according to the terms of the license, to periodically provide CBER with lot-specific testing information and possibly samples.

Exempt – Manufacturer is free to distribute product post-licensure without supplying any additional information or samples to CBER.

Lot Release	
Protocol Review	☐
Protocol Review and Confirmatory CBER Testing	☐
Alternative to Lot Release	
Surveillance	☐
Exempt	☒

Justification for Mode of Regulation:

Briefly, describe how the indicated Mode of Regulation supports CBER's mission to ensure the purity, potency, safety, efficacy, and availability of this biological product including justification for any confirmatory CBER product testing, per 21 CFR 610.2(a). Additionally, for products on Surveillance, summarize the requirements for submission of lot-specific information and sample (if required) as described in the license.

Brief Description:

Hematopoietic progenitor Cells, (HPC, Cord Blood) manufactured by St. Louis Cord Blood Bank (SLCBB) of the SMM Cardinal Glennon Children's Medical Center are volume reduced and partially red cell and plasma depleted. The final cell suspension (~25 mL) is cryopreserved in a final concentration of 10% DMSO and 1% Dextran 40. The cryopreserved product is frozen -----(b)(4)------ and stored in liquid nitrogen (-(b)(4)-). The product is shipped frozen to the end-user.
Cord blood used to prepare the HPC, Cord Blood is collected from newborns with maternal consent. Mothers who consent to donate their newborn's cord blood for public banking, are screened and tested for communicable infectious diseases per regulations cited in 21 CFR 1271.45 through 21 CFR 1271.90. Cord blood is collected from mothers who screen and test negative for the listed infectious disease markers. The sponsor (supplier) has arrangements with 29 hospitals in the metropolitan St. Louis region (includes eastern Missouri and southern Illinois) to collect cord blood and designated couriers to transport the collected cord blood to their manufacturing facility.

ALLOCORD is an allogeneic cord blood hematopoietic progenitor cell therapy indicated for use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.

Patients are HLA-matched to the donors.

The following discussion forms the rationale for the testing plan based on potential safety risks:

ALLOCORD will be exempt from Lot Release including no requirement for submission of lot release protocols or product samples to CBER for the following reason:

- Each lot is a single HPC, Cord Blood unit that will treat a single patient. Additional Lot release requirements including confirmatory testing at CBER may negatively impact the often limiting quantity of cells available to the patient and failure of a single lot has a minimal potential impact on public health.
- Confirmatory testing for potency and HLA typing to verify and confirm product identity are performed by SLCBB at the time of release for infusion.

Anticipated confirmatory CBER product testing: List laboratory evaluations to be performed at CBER.			
Document ID number	Test Method	Test Specifications	Testing Frequency
n/a	n/a	n/a	n/a

Lot Testing algorithm(s):
For each Test Method listed above describe how the indicated frequency of testing supports CBER's mission of protecting public health. For each method with testing frequencies other than 100%, describe how lots are pre-selected for testing, i.e. random number table, every n^{th} lot submitted, first X lot(s) submitted per time period, decision tree, etc.
n/a

Conditions anticipated to require temporary over-ride of algorithm:
Specify conditions justifying algorithm over-ride; i.e. Public Health Considerations (e.g. temporary product shortage, sudden increase in demand), Operational Considerations (e.g. temporary unavailability of resources), Lot-specific Compliance Considerations (e.g. questions raised during lot release protocol review).
None anticipated

Changes since the last revision

N/A New Document