D4.2.2 A minimum of a partial label shall be affixed to the CB unit during all stages of processing.

D4.2.3 Information regarding processing steps that have been completed on a CB unit shall accompany the CB unit during all stages of processing.

D4.2.4 Processing and cryopreservation of CB units shall be performed according to validated Standard Operating Procedures.

D4.2.5 Cryopreservation of unrelated CB units shall be initiated within 48 hours of collection.

D4.2.6 Cryopreservation of directed CB units shall be initiated within 72 hours of CB collection.

D4.2.7 CB unit processing other than simple dilution and/or volume reduction by depletion of erythrocytes and/or plasma shall only be performed according to Applicable Law and:

D4.2.7.1 Using reagents and/or devices approved for that manipulation by the appropriate governmental agency or

D4.2.7.2 With an Institutional Review Board or Ethics Committee-approved protocol or

D4.2.7.3 With an Investigational New Drug Protocol, Investigational Device Exemption, or non-U.S. equivalent.

D4.2.8 Equipment, supplies, and reagents shall not adversely affect the viability of the CB units and shall not permit the introduction of adventitious agents or the transmission or spread of communicable disease.

D4.2.9 Failure of the processing procedure to achieve acceptable end-points shall be evaluated and documented.

D4.3 At the completion of processing prior to cryopreservation, the freezing bag shall be labeled with or be accompanied by the information required in Appendix I, Cord Blood Unit Labeling Table.

D4.4 Records pertinent to the CB unit shall be reviewed by the CB Processing Facility Director or designee.

## D5 REFERENCE SAMPLES AND MATERNAL SAMPLES

D5.1 At a minimum, the following reference samples shall be collected from the CB unit prior to cryopreservation:

D5.1.1 A minimum volume of at least 200 μL in at least two segments with each sealed and integrally attached to the freezing bag.

D5.1.1.1 The contents of each reference sample shall be representative of the CB unit.

D5.1.1.2 When a CB unit is initially requested, one (1) segment shall be used for confirmatory typing and should be used for cell viability and/or potency analysis.

D5.1.2 Additional samples of a minimum of 2 x $10^6$ nucleated cells in at least two (2) vials or additional contiguous segments.

D5.1.2.1 Reference samples intended for viability or potency analysis shall be stored at -150°C or colder.

D5.1.2.2 When reference samples are stored in liquid nitrogen vapor phase at -150°C or colder, the freezers shall be qualified to show that all reference samples are maintained at appropriate temperatures.

D5.1.2.3 Reference samples used for purposes other than viability analysis shall be stored at -70°C or colder.

D5.1.3 A minimum volume of 3.6 mL of serum or plasma from non-heparinized samples in at least two vials.

D5.1.3.1 The serum or plasma should be stored at -70°C or colder.

D5.1.4 Suitable material for preparation of at least 50 μg genomic DNA.

D5.2 Maternal samples to be maintained shall include:

D5.2.1 From the birth mother, a minimum volume of 3.6 mL of serum and/or plasma from non-heparinized samples in at least two vials.

D5.2.1.1 The serum or plasma shall be stored at -70°C or colder.

D5.2.2 From the genetic mother including egg donors, if possible, suitable material for preparation of at least 50 μg genomic DNA.

## D6 CRYOPRESERVATION

D6.1 CB units shall be cryopreserved using controlled rate freezing or an equivalent procedure. If an equivalent procedure is used, it shall be validated to maintain equivalent recovery and viability of nucleated cells.

D6.2 Cryopreservation Standard Operating Procedures shall specify that the following information is recorded for each unit:

D6.2.1 Total nucleated cell concentration within a defined range.