



Indiana University Health

Cellular Therapy Laboratory

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## SOP, Form, Label and Regulatory Update Review

F-028 v.04.17.2021

Document Type	Change Control #	Document #	New	Revision	Document Title
SOP					
Form					
Label					
Other	Novartis Leukapheresis Reference Manual G3				

Staff Education / Changes to Review:	Effective Date:
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EDUCATION LEVEL	<input type="checkbox"/> I	<input checked="" type="checkbox"/> II	<input type="checkbox"/> III	<input type="checkbox"/> IV
1) Minor wording changes throughout manual 2) Contact Novartis in case of sterility failures, COI discrepancies, or instrument malfunctions. 3) Updated optimal range for cryopreservation cell concentration target 4) Do Not Write on cryobag or canister 5) Cryopreserved product must be in LN2 vapor phase for 1 hour prior to shipment to Novartis (decreased from 8 hours) 6) Best practice suggestions of centrifugation at 2-8° C during centrifugation, dilute to <200e+06 TNC/mL prior to over night storage, limit DMSO exposure to <20 minutes, and suggestion to freeze cells the same day when possible (currently not implemented into our SOP)				

12/10/2021
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CTL Staff Review:	Initials	Review Date
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