Purified Human Pancreatic Islets, Certificate of Analysis (Product Code PHPI-A-01) – *Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium*

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DAIT, NIAID, NIH				
	SOP ATTACHMENT			
Document No. SOP 3100, B02	**Revision No. 02**	**Effective Date 21 July 2009**	**Supersedes Date 02 June 2008**	**Page 1 of 2**

Document Title:

PURIFIED HUMAN PANCREATIC ISLETS, CERTIFICATE OF ANALYSIS

(PRODUCT CODE PHPI-A-01)

Manufacturing Facility: _____

Islets Lot Number: _____ **Recipient Study ID #:** _____

Recipient Medical Record Number: _____

Product Formulation:

COMPONENT	CONCENTRATION
Islet Equivalents (IEQ)	$\geq 4.0 \times 10^3$ IEQ/kg of Recipient Body Weight (Total IEQ/infusion)
Albumin Human USP	2.5%
CMRL 1066 Transplant Media, Contains HEPES and without Sodium Bicarbonate	q.s. to 200 mL per bag

Manufacture Date: _____
(Date 1st Infusion Bag filled)

Number of Bags in Lot: _____

Storage Condition: **+ 15ºC to + 30ºC**

TEST	REQUIREMENT	RESULTS
	IDENTITY	
Recipient Identity	Recipient Study ID # and Recipient Medical Record Number on this CoA and on each infusion bag label are identical to that in the Production Batch Record, Section 12.3	Bag 1: _____ Bag 2: _____ Bag 3: _____
Islets Identity	Islets are present in each product bag	Bag 1: _____ Bag 2: _____ Bag 3: _____
	VOLUMES IN BAGS	
Suspension Volume	200 mL per product bag ≤ 600 mL total in three product bags	Bag 1: _____ mL Bag 2: _____ mL Bag 3: _____ mL Total: _____ mL
Settled Tissue Volume	≤ 7.5 mL per product bag ≤ 15.0 mL total in three product bags	Bag 1: _____ mL Bag 2: _____ mL Bag 3: _____ mL Total: _____ mL
	POTENCY	
High Purity Islets GSIR Index (Pre-culture Sample)	For Information Only	GSIR Index: _____
High Purity Islets GSIR Index (Post-culture Sample)	Glucose Stimulated Insulin Release Index > 1	GSIR Index: _____
Islets Quantity	First Infusion: $\geq 5.0 \times 10^3$ IEQ/kg of Recipient's Body Weight (Total IEQ/infusion) Subsequent Infusions: $\geq 4.0 \times 10^3$ IEQ/kg of Recipient's Body Weight (Total IEQ/infusion)	Bag 1: _____ IEQ/kg Bag 2: _____ IEQ/kg Bag 3: _____ IEQ/kg Total: _____ IEQ/kg

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Document Title:

PURIFIED HUMAN PANCREATIC ISLETS, CERTIFICATE OF ANALYSIS
(PRODUCT CODE PHPI-A-01)

Islets Lot Number: _____ **Recipient Study ID #:** _____

Recipient Medical Record Number: _____

TEST	REQUIREMENT	RESULTS
POTENCY (CONTINUED)		
Viability	≥ 70% in each product bag	Bag 1: _____ % Bag 2: _____ % Bag 3: _____ %
PURITY		
Islets Concentration	≥ 20,000 Total IEQ/mL Total Settled Tissue Volume	Bag 1: _____ IEQ/mL Bag 2: _____ IEQ/mL Bag 3: _____ IEQ/mL Total: _____ IEQ/mL
SAFETY		
Appearance	Light yellow to amber liquid with visible aggregates in each product bag	Bag 1: _____ Bag 2: _____ Bag 3: _____
Endotoxins	≤ 5.0 EU/kg of Recipient's Body Weight (Total EU/infusion)	Bag 1: _____ EU/kg Bag 2: _____ EU/kg Bag 3: _____ EU/kg Total: _____ EU/kg
Gram Stain (Islets Purity Levels Pre-combination Samples)	No Organisms Seen	High Purity: _____ Middle Purity: _____ Low Purity: _____
Sterility (21CFR610.12 or validated alternate)	No Growth in each product bag	Bag 1: _____ Bag 2: _____ Bag 3: _____

All Test Results Meet Requirements: Yes No (Circle One)

_____ Date: _____
Recorded By

_____ Date: _____
Laboratory Director, Operations Manager, or Designee

_____ Date: _____
Quality Unit

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