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

CellR4 2015; 3 (1): e1448