The NIH CIT Consortium Chemistry Manufacturing Controls Monitoring Committee: J. Ansite, A.N. Balamurugan, B. Barbaro, J. Battle, D. Brandhorst, J. Cano, X. Chen, S. Deng, D. Feddersen, A. Friberg, T. Gilmore, J.S. Goldstein, E. Holbrook, A. Khan, T. Kin, J. Lei, E. Linetsky, C. Liu, X. Luo, K. McElvaney, Z. Min, J. Moreno, D. O'Gorman, K.K. Papas, G. Putz, C. Ricordi, G. Szot, T. Templeton, L. Wang, J.J. Wilhelm, J. Willits, T. Wilson, X. Zhang

The NIH CIT Consortium

Emory University: J. Avila, B. Begley, J. Cano, S. Carpentier, E. Holbrook, J. Hutchinson, C.P. Larsen, J. Moreno, M. Sears, N.A. Turgeon, D. Webster

Massachusetts General Hospital: S. Deng, J. Lei, J.F. Markmann

NIAID: N.D. Bridges, C.W. Czarniecki, J.S. Goldstein, G. Putz, T. Templeton, T. Wilson

NIDDK: T.L. Eggerman

Northwestern University: P. Al-saden, J. Battle, X. Chen, A. Hecyk, H. Kissler, X. Luo, M. Molitch, N. Monson, E. Stuart, A. Wallia, L. Wang, S. Wang, X. Zhang

University of Alberta, Edmonton: D. Bigam, P. Campbell, P. Dinyari, T. Kin, N. Kneteman, J. Lyon, A. Malcolm, D. O'Gorman, C. Onderka, R. Owen, R. Pawlick, B. Richer, S. Rosichuk, D. Sarman, A. Schroeder, P.A. Senior, A.M.J. Shapiro, L. Toth, V. Toth, W. Zhai

University of California–San Francisco: K. Johnson, J. McElroy, A.M. Posselt, M. Ramos, T. Rojas, P.G. Stock, G. Szot

University of Illinois, Chicago: B. Barbaro, J. Martellotto, J. Oberholzer, M. Qi, Y. Wang

University of Iowa (Data Coordinating Center): L. Bayman, K. Chaloner, W. Clarke, J.S. Dillon, C. Diltz, G.C. Doelle, D. Ecklund, D. Feddersen, E. Foster, L. G. Hunsicker, C. Jasperson, D-E Lafontant, K. McElvaney, T. Neill-Hudson, D. Nollen, J. Qidwai, H. Riss, T. Schwieger, J. Willits, J. Yankey

University of Miami: R. Alejandro, A.C. Corrales, R. Faradji, T. Froud, A.A. Garcia, E. Herrada, H. Ichii, L. Inverardi, N. Kenyon, A. Khan, E. Linetsky, J. Montelongo, E. Peixoto, K. Peterson, C. Ricordi, J. Szust, X. Wang

University of Minnesota: M.H. Abdulla, J. Ansite, A.N. Balamurugan, M.D. Bellin, M. Brandenburg, T. Gilmore, J. V. Harmon, B.J. Hering, R. Kandaswamy, G. Loganathan, K. Mueller, K.K. Papas, J. Pedersen, J.J. Wilhelm, J. Witson

University of Pennsylvania: C. Dalton-Bakes, H. Fu, M. Kamoun, J. Kearns, Y. Li, C. Liu, E. Luning-Prak, Y. Luo, E. Markmann, Z. Min, A. Naji, M. Palanjian, M. Rickels, R. Shlansky-Goldberg, K. Vivek, A.S. Ziaie

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University of Wisconsin: L. Fernandez, D.B. Kaufman, L. Zitur
Uppsala University: D. Brandhorst, A. Friberg, O. Korsgren

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Address correspondence to: Camillo Ricordi MD, Chairman, CIT Steering Committee, ricordi@miami.edu

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Document Title:

PURIFIED HUMAN PANCREATIC ISLETS WITH EXENATIDE, CERTIFICATE OF ANALYSIS

(PRODUCT CODE PHPI-E-01)

Manufacturing Facility: _____

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

Recipient Medical Record Number: _____

Product Formulation:

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

Number of Bags in Lot: _____

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

COMPONENT	CONCENTRATION
Islet Equivalents (IEQ)	≥ 4.0 X 10^3 IEQ/kg of Recipient Body Weight (Total IEQ/infusion)
Albumin Human USP	2.5%
Exenatide	20 nM
CMRL 1066 Transplant Media, Contains HEPES and without Sodium Bicarbonate	q.s. to 200 mL per bag

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: ≥ 5.0 X 10^3 IEQ/kg of Recipient's Body Weight (Total IEQ/infusion) Subsequent Infusions: ≥ 4.0 X 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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PURIFIED HUMAN PANCREATIC ISLETS WITH EXENATIDE, CERTIFICATE OF ANALYSIS
(PRODUCT CODE PHPI-E-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: _____
Endotoxin	≤ 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
Islets Purity Levels Gram Stain (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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