

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

University of Wisconsin: L. Fernandez, D.B. Kaufman, L. Zitur

Uppsala University: D. Brandhorst, A. Friberg, O. Korsgren

Supported by grants from the National Institute of Allergy and Infectious Diseases and the National Institute for Diabetes and Digestive and Kidney Diseases.

- At Emory University, U01AI089317.
- At Northwestern University, U01AI089316.
- At the University of Alberta, Edmonton: U01AI065191.
- At the University of California, San Francisco, U01DK085531.
- At the University of Illinois, Chicago, 5U01DK070431-10.
- At the University of Iowa, U01DK070431.
- At the University of Miami, U01DK070460.
- At the University of Minnesota, U01AI065193.
- At the University of Pennsylvania, U01DK070430.
- At Uppsala University, U01AI065192.

In addition, the study was supported by the following GCRC and CTSA awards:

- At Emory University: UL1TR000454.
- At Northwestern University: 5UL1RR025741 and 8UL1TR000150.
- At the University of California, San Francisco, UL1TR000004.
- At the University of Illinois, Chicago, UL1TR000050.
- At the University of Miami: 1UL1TR000460.
- At the University of Minnesota: 5M01-RR000400 and UL1TR000114.
- At the University of Pennsylvania: UL1TR000003.

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

To cite this article

Raw Material Specification, Islet Gradient 1.108, Sterile – Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium

CellR4 2016; 4 (3): e2010

DAIT, NIAID, NIH

SOP APPENDIX



Document No.
SOP 3102, A39

Revision No.
00

Effective Date
25 October 2010

Supersedes Date
NA

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Document Title:

RAW MATERIAL SPECIFICATION, ISLET GRADIENT 1.108, STERILE

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container labeling and Certificate of Analysis must both specify: "Islet Gradient 1.108, sterile," "Catalog No. 99-692-CIS" and same lot number.
Vendor	Visual Inspection	Manufacturer & Distributor: Mediatech
Review of Certificate of Analysis	Visual Inspection	The following criteria must be met: Density 1.108 ± 0.002 g/mL @ 20 – 25°C pH 7.3 ± 0.2 @ 20 – 25°C Osmolality 330 – 530 mOsm/kg H ₂ O Endotoxin ≤ 2.0 EU/mL Mycoplasma Tested Negative Sterility Pass USP Safety Test Pass Appearance: Clear, almost colorless solution

2.0 Storage

2 – 30°C

3.0 Formulation:

NA