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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.

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To cite this article

Raw Material Specification, OptiPrep – Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium

CellR4 2016; 4 (3): e1928

DAIT, NIAID, NIH

SOP APPENDIX



Document No.
SOP 3102, A16

Revision No.
01

Effective Date
02 May 2011

Supersedes Date
07 July 2008

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Document Title:

RAW MATERIAL SPECIFICATION, OPTIPREP

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "OptiPrep" and must have same lot number.
Vendor	Visual Inspection	Qualified Supplier
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirements on the Certificate of Analysis must be met. Density: 1.320 ± 0.001 g/mL (20°C) Osmolality: 170 ± 15 mOsm Endotoxin: < 1.0 EU/mL Sterility: Pass The Certificate of Analysis must be signed and dated.

2.0 Storage

4°C to 24°C (Protect from light while in storage)

3.0 Formulation:

60% Iodixanol (w/v) in water