Purified Human Pancreatic Islets, CIT Culture Media – *A Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium*

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Document Title:

PURIFIED HUMAN PANCREATIC ISLETS, CIT CULTURE MEDIA

Manufacturing Site: _____ Date: _____

1. Materials:

Material	Source	Lot #	Expiration Date	Quantity Required	Quantity Used
CMRL 1066 Supplemented				500 mL Bottle	Bottle
Albumin Human USP, 25% Solution				10 mL	mL
Heparin Sodium Injection USP	_____ Units/mL			5,000 units (_____ mL)	mL
Hydrochloric Acid, 1 N				0.2 mL	mL
Sterile Water for Injection				20 mL	mL
IGF-1, 1 mg/vial	Cell Sciences Cat. #CM001			50 µL	µL

*Or other qualified vendor.

2. Procedure

2.1 In a BSC place a 500 mL bottle of CMRL 1066, Supplemented.

2.2 Add 10 mL of Albumin Human USP, 25% Solution to the bottle.

2.3 Add Heparin to the bottle to obtain a final concentration of 10 Units/mL (5,000 Units total).

2.4 Separately, add 0.2 mL of 1 N Hydrochloric Acid to 20 mL of Sterile Water for Injection to make 10 mM HCl solution. Reconstitute one 1 mg vial of IGF-1 with 1.0 mL of the 10 mM HCl solution. Add 50 µL of the IGF-1 solution to the bottle. Aliquot the remaining IGF-1 solution into 19 small sterile vials and store below -20°C. Cap the bottle and label it with:

- "CIT IGF-1 Solution, 50 µL, "
- Islet Lot Number (for traceability of preparation record)
- "Store below -20°C"
- Date Prepared
- Expiration Date (3 months after preparation)
- Initials of the person who prepared the solution

Islets Lot Number: _____

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2.5 Cap the bottle and mix by gentle inversion at least five times.

2.6 Label the bottle with:

- "CIT Culture Media"
- Islets Lot Number
- "Store at 2°C to 8°C"
- Date Prepared
- Expiration Date (the end of the day after preparation)
- Initials of the person who prepared the solution

2.7 Store the bottle of solution at 2°C to 8°C before use.

Total volume prepared: _____ mL

Prepared by: _____ **Date:** _____

Reviewed by: _____ **Date:** _____

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