

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

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ATTACHMENT**



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Document Title:

**PURIFIED HUMAN PANCREATIC ISLETS,
CIT TRANSPLANT WASH MEDIA**

Manufacturing Site: _____ Date: _____

1. **Materials:**

Material	Source	Lot #	Expiration Date	Quantity Required	Quantity Used
CMRL 1066 Transplant Media, contains HEPES and without Sodium Bicarbonate	Mediatech 98-291-L			500 mL	mL
Albumin Human USP, 25% Solution				50 mL	mL
Heparin Sodium Injection USP	_____ Units/mL			5,000 units (_____ mL)	mL

*Or other qualified vendor.

2. **Procedure**

- 2.1 In a BSC place a 500 mL bottle of CMRL 1066 Transplant Media, contains HEPES and without Sodium Bicarbonate.
- 2.2 Add 50 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 Cap the bottle and mix by gentle inversion at least five times.
- 2.5 Label the bottle with:
 - "CIT Transplant Wash 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
- 2.6 Store the bottle of solution at 2°C to 8°C before use.

Total volume prepared: _____ mL

Prepared by: _____ **Date:** _____

Reviewed by: _____ **Date:** _____

Islets Lot Number: _____