

TECHNICAL NOTES

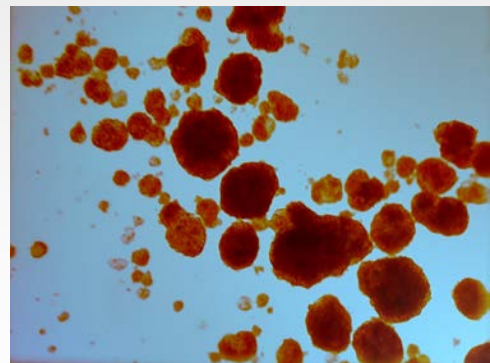
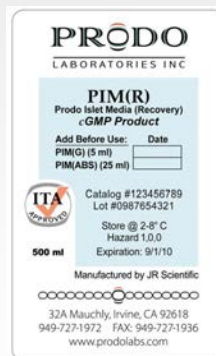
PIM(R)[®]: cGMP Prodo Islet Media (Recovery)

Description

PIM(R)[®] is a new Prodo Labs islet specific media that is manufactured under cGMP conditions for tissue culture use in immediately recovering human islets following their processing and purification from pancreases. It is designed for the first 48 hours of tissue culture at 37°C. It accelerates the recovery of the islets as demonstrated by rapid rounding up with increased glucose responsiveness, insulin content, and suitability for implantation. This starts to occur in the first 12-18 hours. It currently is designed to be used with 5% Human AB Serum that is pretested for islet suitability. It does not contain any animal proteins or growth factors and has a glucose concentration of 5.8 mM.

Uniqueness

- cGMP Manufactured with QC/QA Specifications
- Permits rapid recovery from islet processing damage
- Use with prescreened 5% Human AB Serum
- Glutamine / Glutathione mixture as separate additive
- Approved for use in clinical and research applications
- Tested superiority in islet recovery, function, and insulin content over other islet specific media available for first 48 hours, but can lead to islet chaining with longer use
- Each lot ITA Approved by Islet Testing Authority prior to release for sale
- Part of Biological Master File application with the FDA
- Similar effectiveness in non-human primate islet culture
- Does not contain any animal products

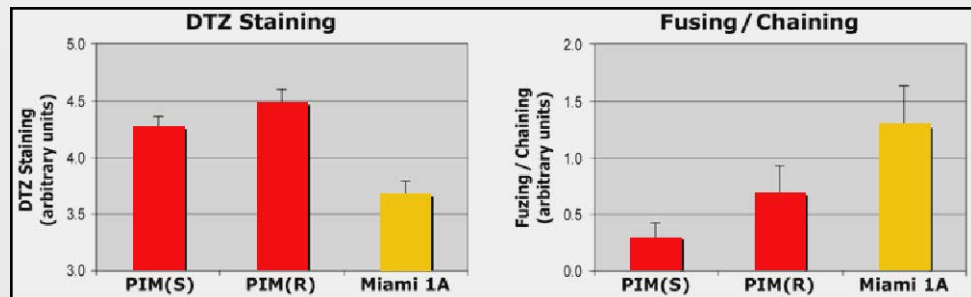
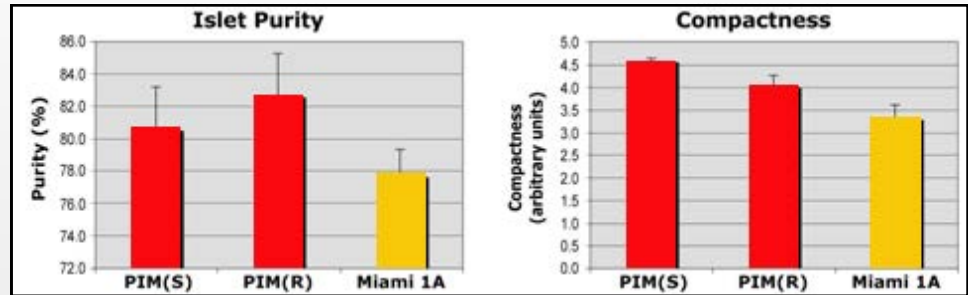


Comparative Outcomes

Morphologic Human Islet Results from Culture in Different Media: PIM(S)[®], PIM(R)[®], & Miami 1A

Results in culturing islets in different media at 37°C up to 7 days:

- Superiority of PIM(R)[®] & PIM(S)[®] in Islet Purity, Compactness, Insulin Staining, & reduced Fusing / Chaining over use of Miami 1A media
- Short term use of PIM(R)[®] increases recovery with long term use of PIM(S)[®] advised



Functional Human Islet Results from Culture in Different Media: PIM(S)[®], PIM(R)[®], & Miami 1A

Results in culturing islets in different media at 37°C up to 7 days:

- Superior islet function of PIM(R)[®] followed by PIM(S)[®]; Miami 1A media with lowest function response
- Insulin content highest in PIM(R)[®] and PIM(S)[®] with lower levels in Miami 1A media

