STANDARD OPERATING PROCEDURE (SOP)
Microbiology Testing for Islets for Distribution
(For IIDP Centers)
Version: QA-003-04
Standard Operating Procedure for Microbiology Testing

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1.0 Objective

1.1 To be a model for site-specific SOPs that define the assay method for microbiology testing of the Purified Human Pancreatic Islet product manufactured for use in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) sponsored research in the Integrated Islet Distribution Program (IIDP).

1.2 Samples may be taken from the final preparation post purification.

2.0 Scope and Applicability

2.1 This SOP applies to the IIDP Coordinating Center (CC) and to any center using funds from the NIDDK that manufactures purified human pancreatic islets for basic research studies for IIDP approved investigators.

2.2 This SOP will require participation from all participating IIDP centers.

3.0 Responsibilities

3.1 It is the responsibility of the IIDP CC to both follow and ensure adherence to the procedures outlined in this SOP. In order to accomplish this, the IIDP CC will interact with the relevant personnel from each of the participating centers.

3.2 It is the responsibility of each IIDP center to follow the procedures listed in this SOP and to work to the best of their ability to follow all requirements.

4.0 Definitions

4.1 Integrated Islet Distribution Program (IIDP): The IIDP is a contracted program commissioned and funded by the NIDDK to provide quality human islets to the diabetes research community to advance scientific discoveries and translational medicine. The IIDP consists of the NIDDK Scientific and Project Officers, the External Evaluation Committee and the CC at City of Hope (COH). The IIDP CC integrates an interactive group of academic laboratories including the subcontracted IIDP centers.

4.2 IIDP Coordinating Center (CC): Joyce Niland, Ph.D. is the Principal Investigator for the IIDP CC and leads staff from the Department of Research Information Sciences at COH to coordinate the activities of the IIDP and assist the participating centers and investigators in the distribution of human islets.
5.0 Materials

5.1 The following supplies and equipment is necessary to perform microbiology testing for human islet distribution. (Following is a list of example supplies. You may follow your own center specific protocol for microbiology testing however we do require testing for Aerobic, Anaerobic, and Fungal Contamination.)

5.1.1 Final Islet Preparation

5.1.2 Sterile Pipet(s) and pipetter for sample taking

5.1.3 Sterile tube(s) for samples

5.1.4 Microbiology Worksheet for tracking of samples and recording of the results.

6.0 Procedures

6.1 Assemble all items described in 5.0-Materials in laminar flow environment. (Following is an example procedure. You may follow your own center specific protocol for microbiology testing however we do require testing for Aerobic, Anaerobic, and Fungal Contamination.)

6.2 Samples for microbiology may be taken after the isolation or post culture. Sampling should be repeated of the final product, prior to packaging for shipment. Follow your center specific protocol for sterility testing

6.2.1 Allow 100ml final islet preparation to settle for 5 minutes.

6.2.2 Remove >2ml (or whatever amount is necessary for your testing center) of supernatant and place in a sample tube under sterile conditions.

6.2.3 Replace the volume that is removed from the final preparation supernatant with similar media that is used for culture.

6.2.4 Have sterility testing performed for aerobic, anaerobic and fungal contamination.

6.2.5 Document your results and add to the broadcast system as both preliminary and final data are received.
7.0 References


8.0 Attachments

8.1 Microbiology Tracking Worksheet