

Appendix 15

Laboratory Space Requirement for SCID TREC ASSAY (Enlite Kit)

Two separate rooms, the pre-PCR and post-PCR rooms will be used for the TREC assay. These rooms will be used exclusively for PCR analysis and no other assays should be run. Each room should have only one entry point. It is desirable that the rooms be connected through a pass-through window for ease of sample transfer.

1. Specifications for pre-PCR room:

The pre-PCR room is the clean room. This room will be designated for preparation of reagents, mixing, dispensing of liquids and blood-spot punching. To maximize cleanliness of this room, DBS blood-spot punching should be done in a separate room.

The specific requirements for this pre-PCR room are:

- a. Dimension: at least 10 ft. by 15 ft.
- b. Electrical outlets: 110 volts
- c. Water requirement: outlet for NCCLS type 1 water
- d. Additional requirement: PCR workstation with hood or a space for bench-top for PCR workstation with UV light

2. Specification for post-PCR room:

The working and back-up thermal cyclers and Victor Enlite instruments will be located in this room. DNA products and any other post-PCR DNA products prepared in this room should not go back to the clean room. A mild negative air pressure should be maintained in this room.

The specific requirements for this room are:

- a. Dimension: at least 10 ft. by 10 ft.
- b. Electrical outlets: 110 volt
- c. Water requirement: None