Appendix 6

NEWBORN AND PRENATAL SCREENING LABORATORY SPECIFICS

1. **SPACE** – The contractor shall provide and maintain at least the following space for newborn and prenatal screening services:

Category	Amount NBS	Amount PNS
Total Laboratory floor space (square feet)		5000
Space applicable to screening project	3050	1950
Storage space, shelf (cubic feet)	465	130
Storage space, refrigerated (cubic feet)	115	225
Storage space, frozen (cubic feet)	95	95

These are estimates of the space needed and each laboratory's space will vary somewhat. These estimates include additional space for the required validation studies for new instrumentation. (Include a laboratory floor plan that shows the location of all screening instrumentation and equipment.)

2. **PERSONNEL** – The contractor shall provide newborn and prenatal screening laboratory services with valid California licensed clinical laboratory personnel. Areas of coverage include:

   A. Supervision
   B. Accession and Analysis
   C. Clerical and Data Entry
   D. Shipping and Receiving

3. **NEWBORN SPECIMEN TRANSPORT** – Specimens shall be transported from hospitals and physicians to the contractor via courier or the US mail at CDPH expense.

4. **SPECIMEN TRANSPORT LOG FORMS** - In conjunction with paragraph 3, the contractor shall use Newborn Screening Specimen Transport Log Forms. The contractor shall provide these forms as needed in accordance with CDPH instructions. The contractor shall distribute Newborn Screening Specimen Transport Log Forms to all providers.

   A. The providers shall fill out the log in duplicate, retain one copy, and enclose the other copy with the mailed or couriered specimens.

   B. Upon receipt at the laboratory, the contractor shall date and time stamp all logs received and place a replicate accession label opposite each entry in the Newborn Screening Transport Log.

5. **LABORATORY SPACE REQUIREMENTS FOR SCID TREC ASSAY** – The bidder will need to create two separate rooms, the –pre-PCR and post-PCR rooms, which will be used for the TREC assay.

   Describe in complete detail: space, facilities and physical resources actually available for this work in the laboratory, including office space and storage space; floor space; bench or table top; shelves; equipment; records; plumbing needs; glassware prep and wash; safety measures; disposal areas. Provide a detailed drawing to scale, which shows location and

relationships of furniture, facilities and equipment.

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. 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. 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:

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

Specifications for post-PCR room

The working and back-up thermal cyclers and analytical 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. 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. A mild negative air pressure should be maintained in this room. The specific requirements for this room are:

1) Dimension: at least 10 ft. by 10 ft.
2) Electrical outlets: 110 volts
3) Water requirement: None