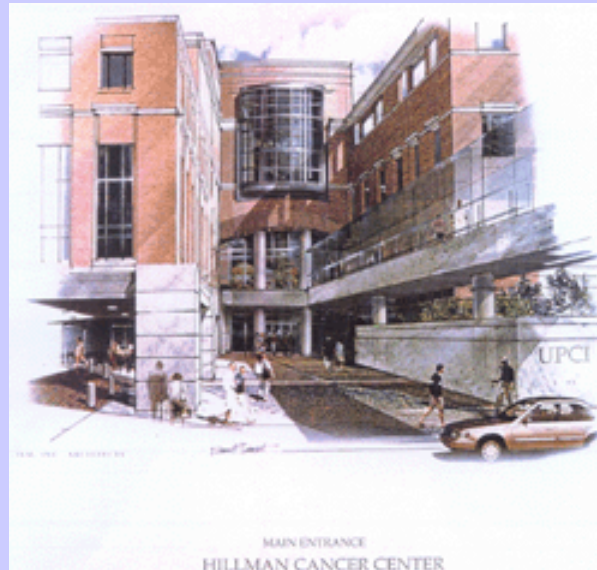


Pitt Facilities



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Hillman Cancer Center

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University of Pittsburgh Medical Center



Manufacturing labs

- ↪ Facilities at the University of Pittsburgh consist of two separately run but interconnected departments
 - ↪ IMCPL
 - ↪ HSCLab
- ↪ Share QA Manager
- ↪ Long history of interaction – both labs have been in continuous operation for over 20 years



Manufacturing labs

Cell Processing Laboratory (CPL) in IMCPL

- Provides cell manufacturing for a variety of clinical trials with internal and external investigators, specializing in cell culture

Hematopoietic Stem Cell Laboratory (HSCLab)

- Provides cell processing for the stem cell transplant program and several other departments, specializing in cell separation

IMCPL & HSCLab at the Hillman Cancer Center

- ↳ Built in 2003
- ↳ Share a single Class 100,000 air-handling system that in static operation functions closer to 10,000.
- ↳ Share same facilities management, clinical engineering, administrative support
- ↳ Under the umbrella of the Pathology Department of the UPMC



Environment

- ↳ Designed after discussions with the FDA
- ↳ Stainless steel casework
- ↳ Coved sprayed resin floors with a seamless join with the wall
- ↳ Solid ceilings
- ↳ Water-resistant epoxy paint
- ↳ Preliminary and terminal HEPA filtration
- ↳ Positive and negative air pressure areas
- ↳ Temperature and humidity controlled
- ↳ Secured area with restricted access

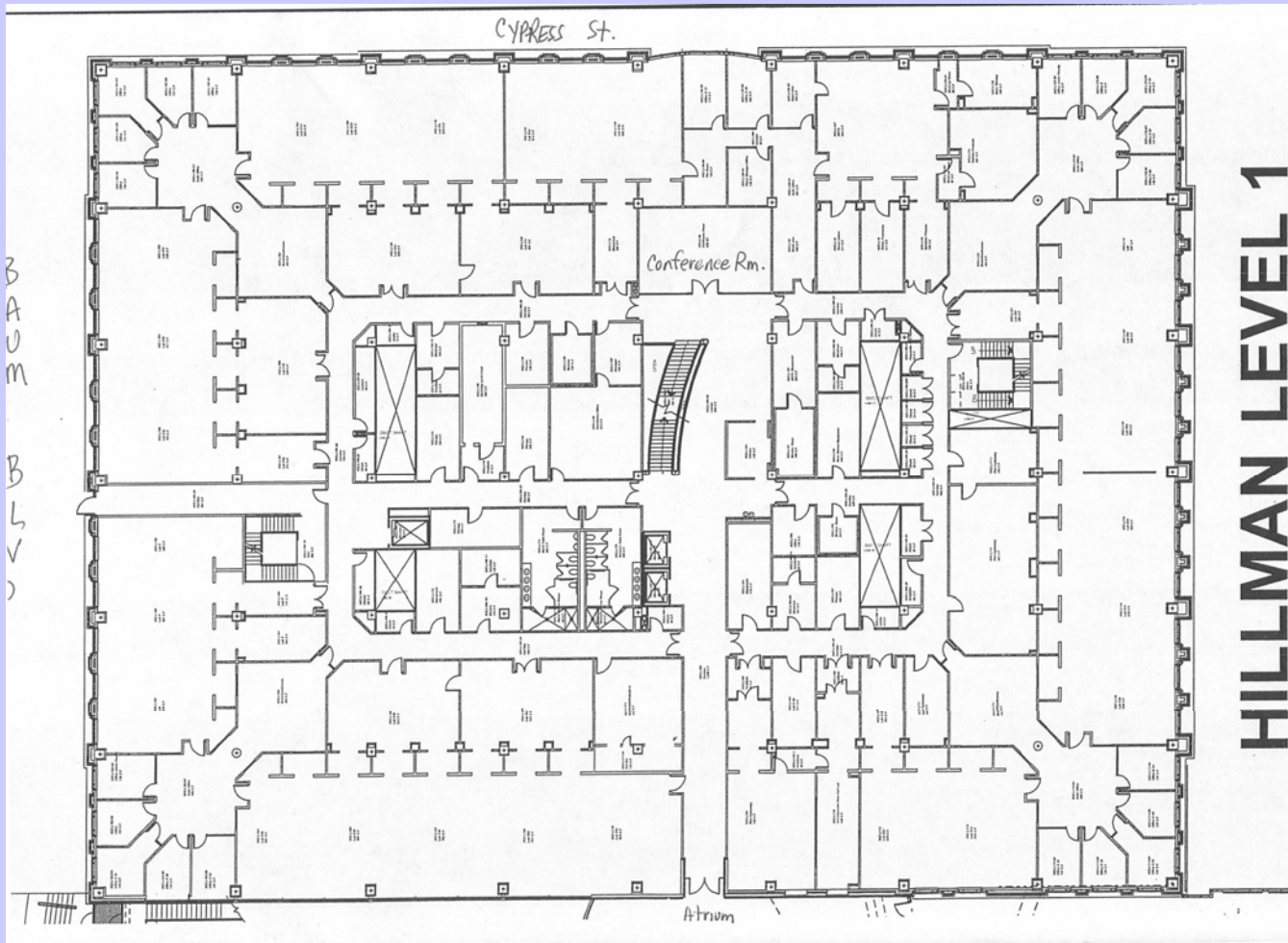
Facility Design

- ↪ Separate, defined areas for each operation of the laboratories:
 - ↪ Accessioning of products
 - ↪ Product labeling
 - ↪ Processing
 - ↪ Storage of products, short-term and long-term
 - ↪ Waste disposal
 - ↪ Supply and reagent storage
 - ↪ Testing
- ↪ Interlocked anterooms between outer labs and cleanrooms
- ↪ Surfaces are non-shedding and non-porous
- ↪ Card-key access to authorized-user areas



Hillman Blueprint

🌀 Laboratories are on the first floor, across the hall from each other.



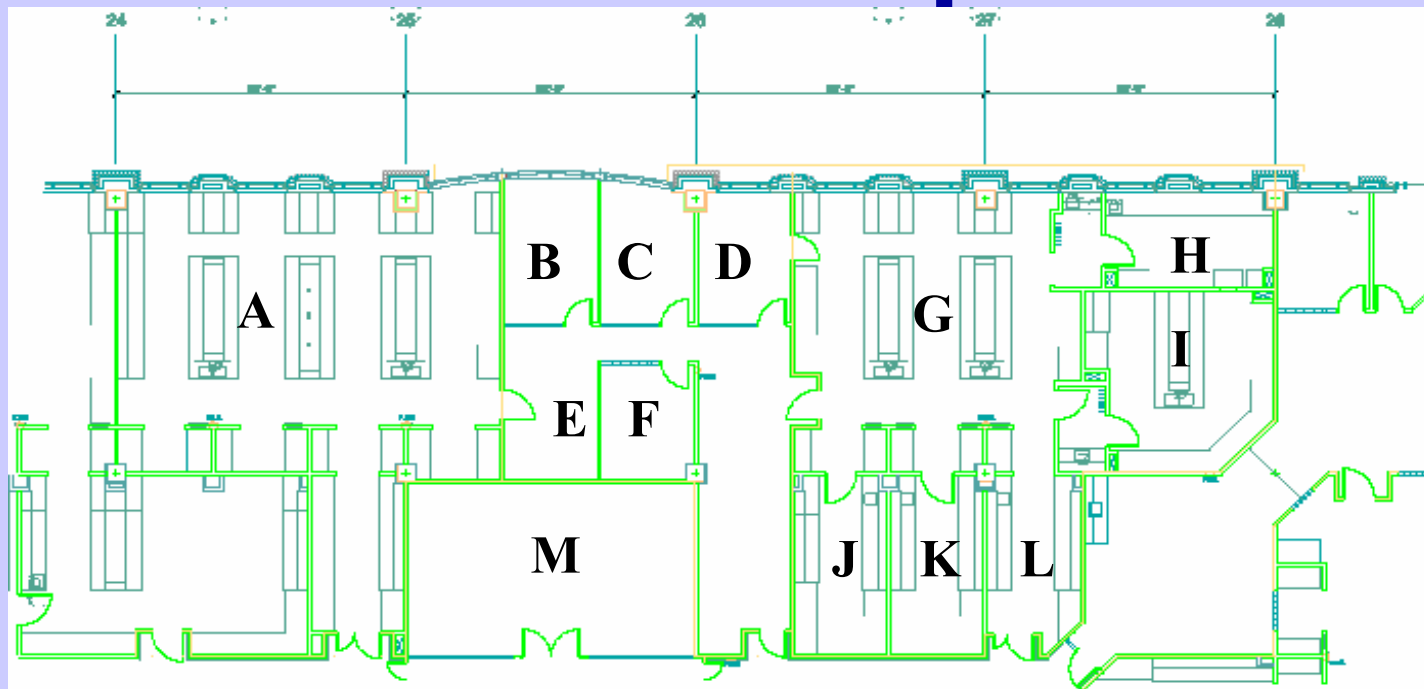
IMCPL

- ↳ CPL consists one large testing laboratory with several smaller attached labs and two cleanrooms
- ↳ Main laboratory contains
 - ↳ Flow Cytometer
 - ↳ Centrifuges
 - ↳ Incubators
 - ↳ Microscopes
 - ↳ Refrigerators & Freezers
 - ↳ Controlled-rate Freezers

IMCPL

- ↳ CPL consists one large testing laboratory with several smaller attached labs and two cleanrooms
- ↳ Cleanrooms contain
 - ↳ Biological safety cabinets
 - ↳ Centrifuges
 - ↳ Incubators
 - ↳ Microscopes
 - ↳ Elutra
 - ↳ Aastrom Replicell System

CPL Floor plan

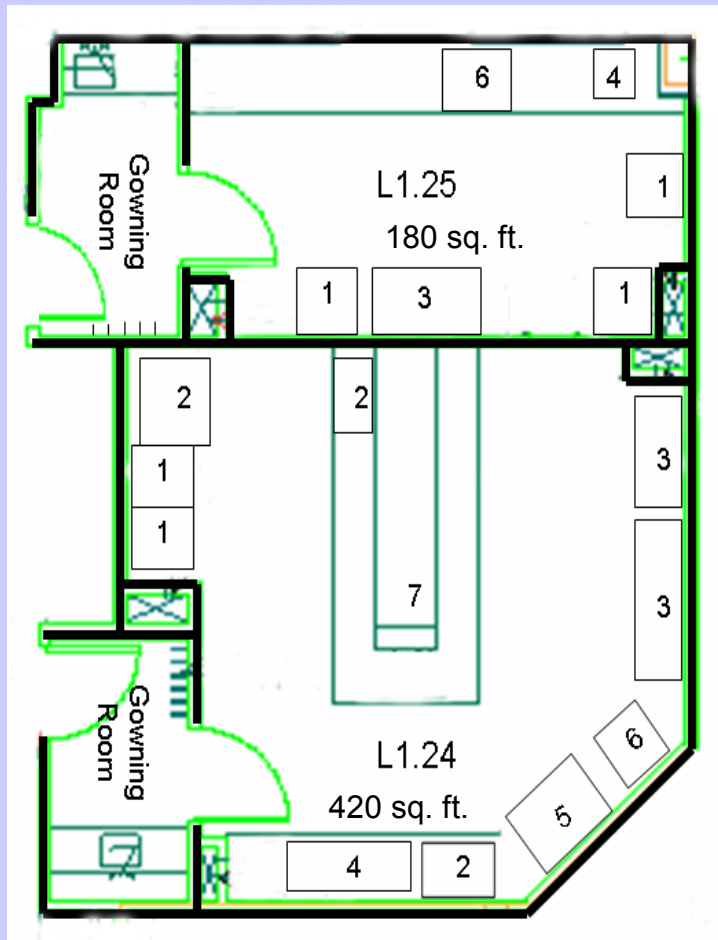


A = Monitoring laboratory (IML) (Rm. L1.31)
 B = Laboratory Director's office (Rm. L1.27d)
 C = Computer facility (Rm. L1.27c)
 D = Laboratory Supervisor's office (Rm. L1.27b)
 E = File storage / records (Rm. L1.27)
 F = Administrator's office (Rm. L1.27)
 G = Research and development laboratory/Support Services (Rm. L1.26)

H = GTL (Rm. L1.25)
 I = CPL (Rm. L1.24)
 J = TPL (Rm. L1.29)
 * Gowning rooms
 K = Tissue culture
 L = Specimen acceptance and Processing (access to G)
 M = Conference room
 N = IMCPL Reception (access to the office suite)
 O = entry to A



CPL Floor plan



The floor plans and equipment in the two cleanrooms

Legend:

* indicates the pass-through

1 = CO2 incubators

2 = Aastrom Replicell System

3 = Biosafety cabinets

4 = Centrifuges

5 = ELUTRA system

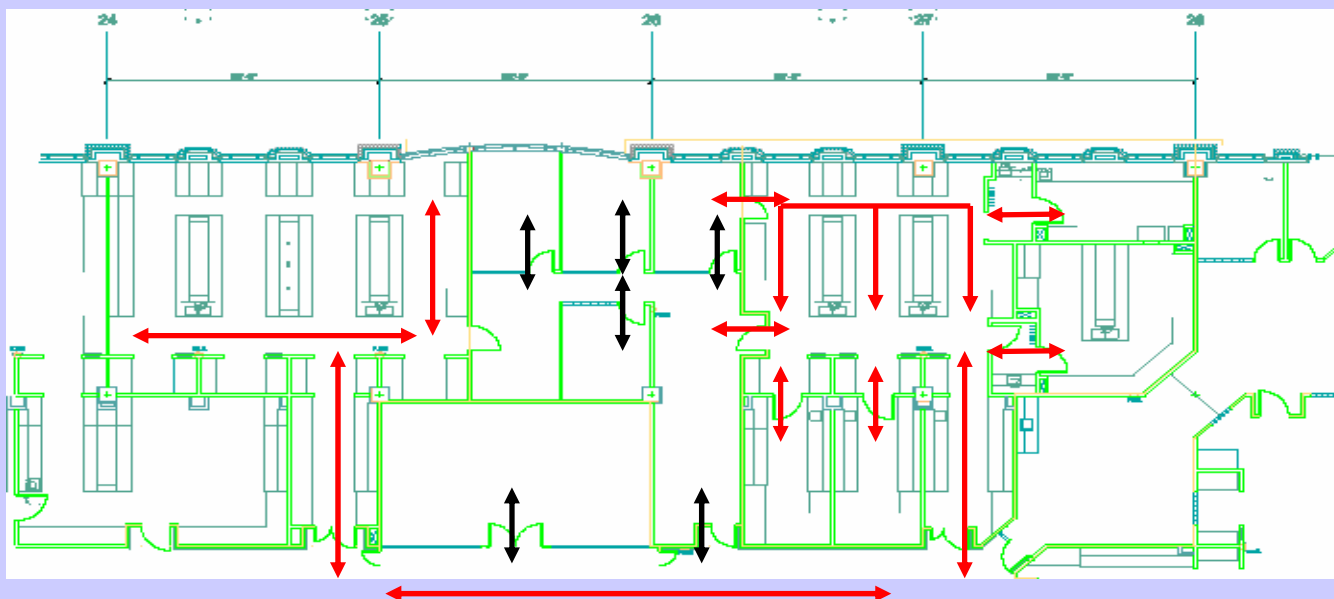
6 = Refrigerators

7 = Microscopes

CPL Workflow

Personnel Workflow

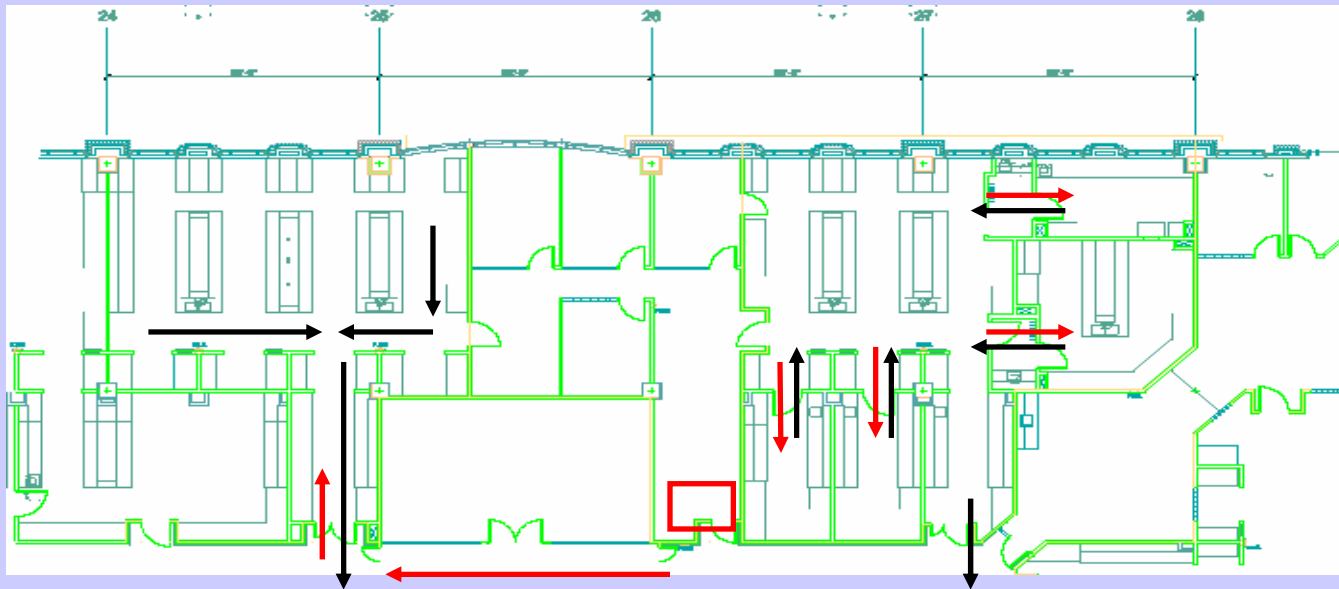
Lab Staff Office Staff



CPL Workflow

Supply and Waste Workflow

Supplies Waste  Supplies reception



HSCLab

- ↳ The HSCLab consists of a main testing lab and a long cleanroom
- ↳ Main testing lab contains
 - ↳ Hematology Analyzer
 - ↳ Flow Cytometer
 - ↳ Incubator
 - ↳ Microscopes
 - ↳ Centrifuges
 - ↳ Serifuges

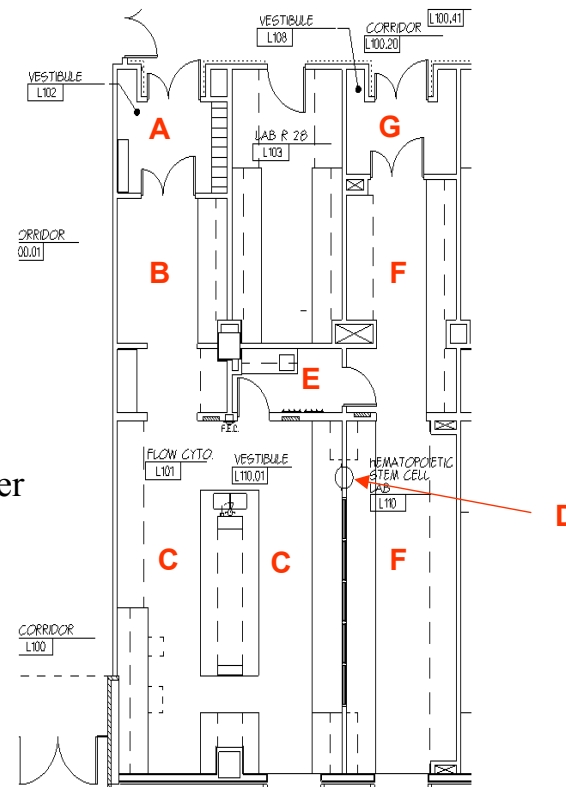
HSCLab

- ↳ The HSCLab consists of a main testing lab and a long cleanroom
- ↳ Cleanroom contains
 - ↳ Biological safety cabinets
 - ↳ Floor model centrifuge
 - ↳ Cell Separator
 - ↳ Cell Washer

HSCLab Floor plan

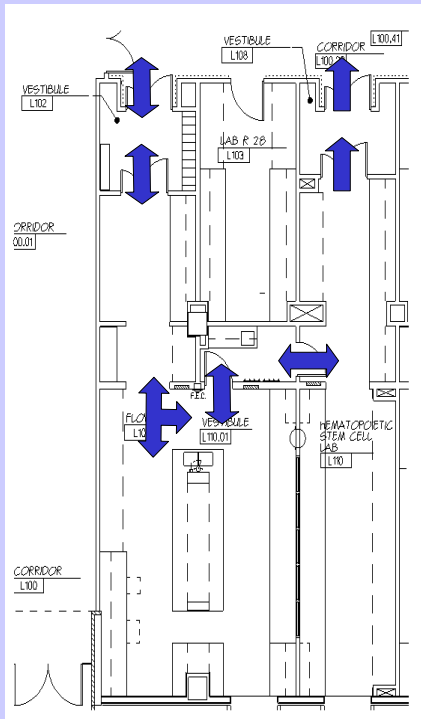
HSCLab Floor Plan (792 ft²)

- A. Vestibule for entrance into the lab
- B. Office area where products and samples are accessioned
- C. Outer laboratory space for WBC enumeration, Flow Cytometry, Preprocessing
- D. Pass-through from outer lab to inner lab
- E. Gowning area between outer and inner labs
- F. Inner laboratory with Isolex and Cobe equipment
- G. Waste vestibule

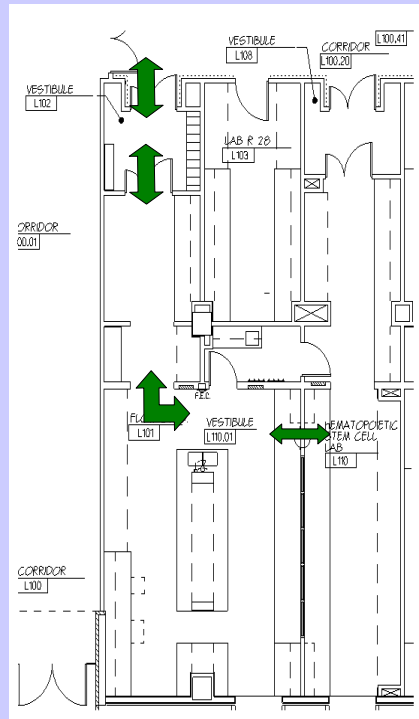


HSClab Workflow

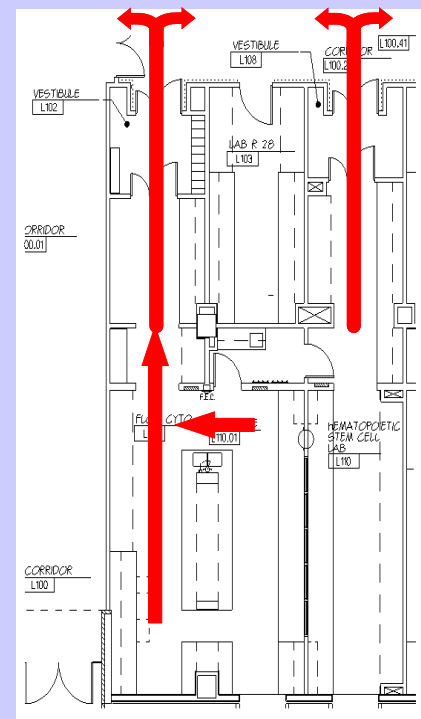
HSClab Personnel Traffic Pattern



HSClab Product Traffic Pattern



HSClab Waste Traffic Pattern



Accessioning Area



Flow Cytometry Area



Cleanroom



Liquid Nitrogen Storage System

- Four “Closets” that contain the LN₂ Banks
- Manifold system that supplies the LN₂ to the vessels
- Freezer room with LN₂ vessels set up for both vial storage and bag storage
- 24 hours monitored alarm systems

Liquid Nitrogen Storage System

- ↳ Common 'closets' for supply of LN₂
- ↳ IMCPL
 - ↳ One large room with attached cold room for storage of media
 - ↳ Additional storage on another floor
- ↳ HSCLab
 - ↳ One large room with 8 full size LN₂ Vessels and one vial vessel for long term storage of vial aliquots

Caveats

- Need to consider the way techs will use the lab prior to designing a lab...input from the techs is always useful!
- HSCLab should have been designed as three modules not one continuous long room
- CPL should not have been built on an outside wall with windows
- Already outgrown both the storage space and the processing lab space
- Plans in place to expand the working areas of the IMCPL
- The HSCLab is also in the planning stages for a satellite laboratory in a nearby hospital, primarily to provide novel therapy products

