

# Pitt Facilities



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# 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 epoxy terrazzo floors with a seamless joint 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

# Hillman Blueprint

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



# IMCPL

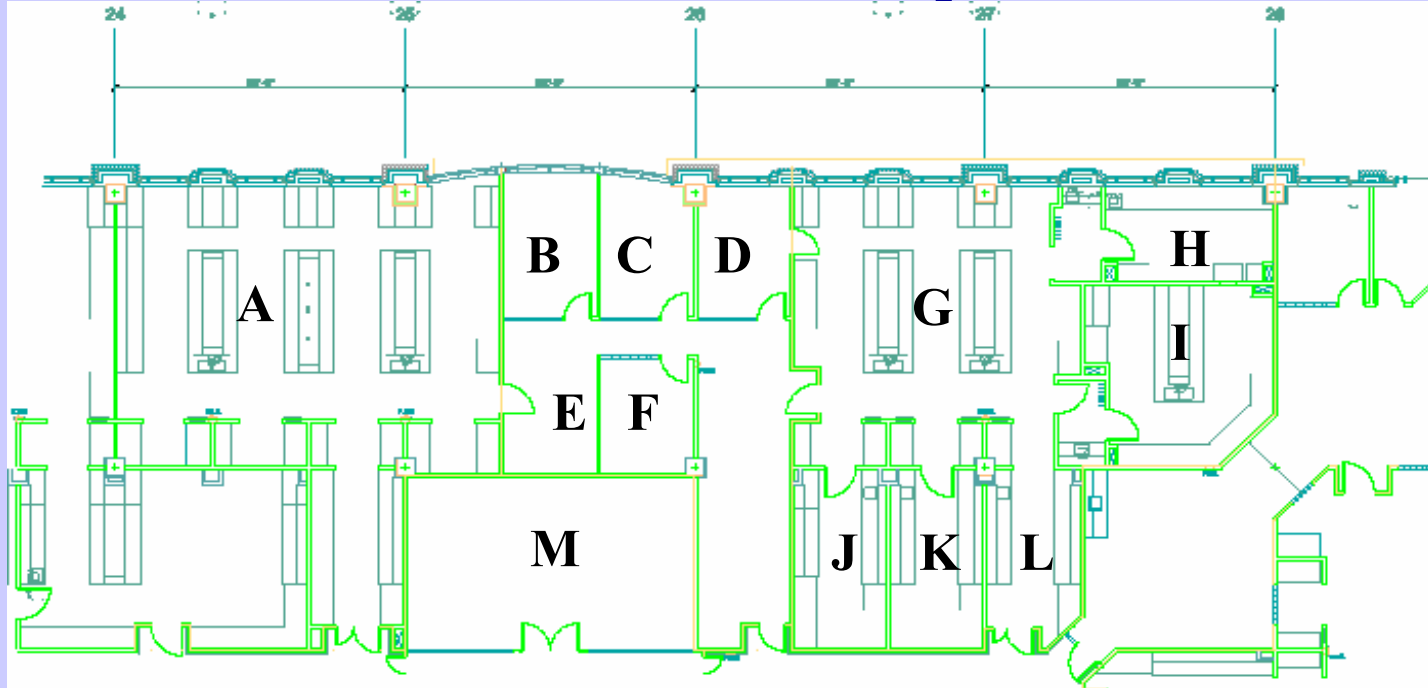
- ↳ CPL consists one large testing laboratory with several smaller attached labs and two cleanrooms
- ↳ Main laboratory contains
  - ↳ Flow Cytometer
  - ↳ Centrifuges
  - ↳ Incubators
  - ↳ Microscopes
  - ↳ Refrigerators & Freezers
  - ↳ Controlled-rate Freezers



# 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

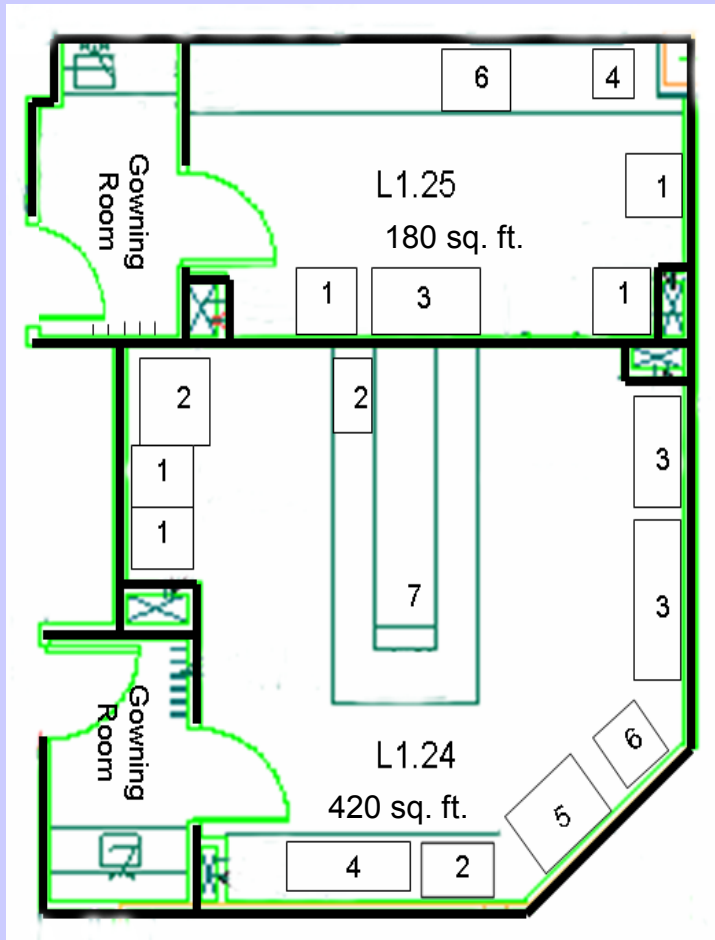
# CPL Floor plan



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

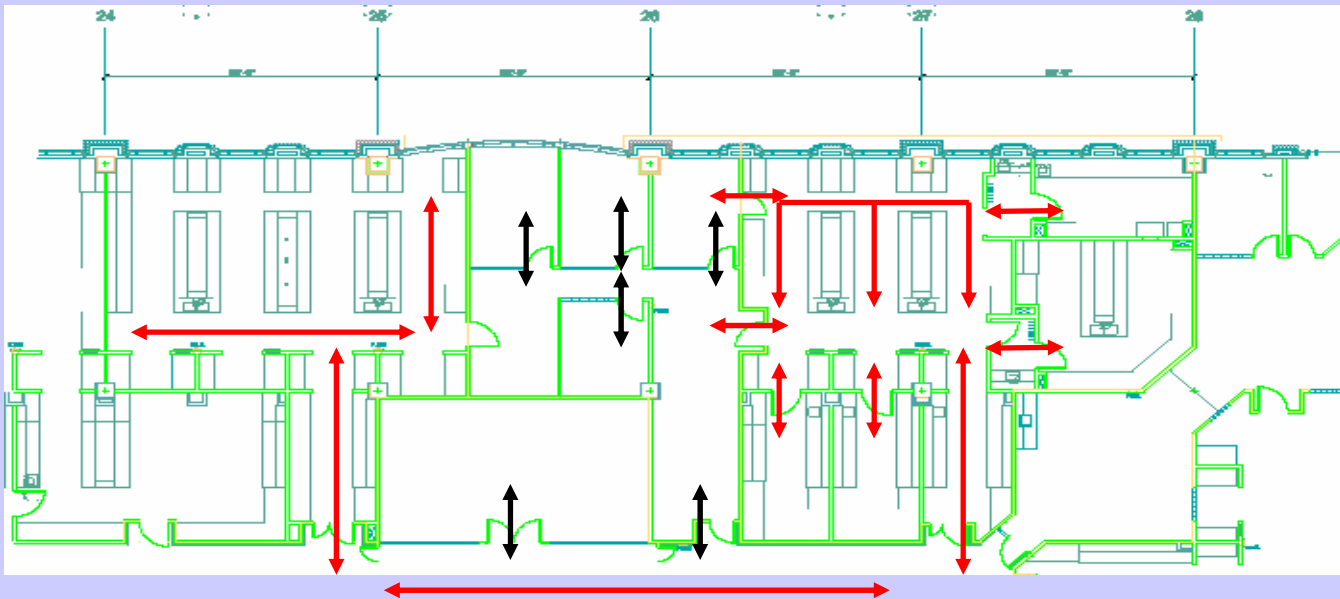
6 = Refrigerators

7 = Microscopes

# CPL Workflow

## Personnel Workflow

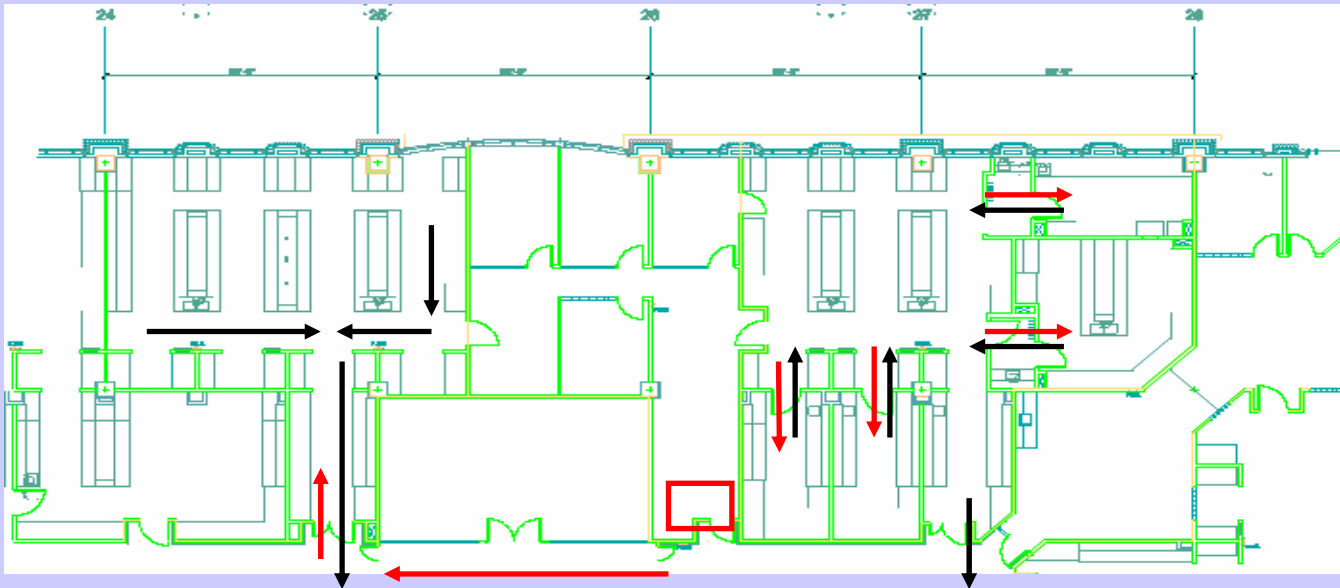
Lab Staff    Office Staff



# 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

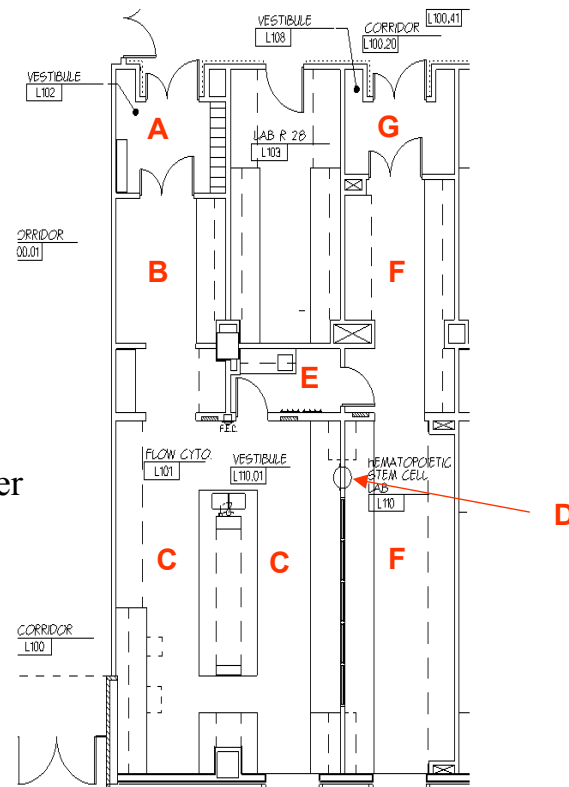
# HSCLab

- ↳ 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 ft<sup>2</sup>)

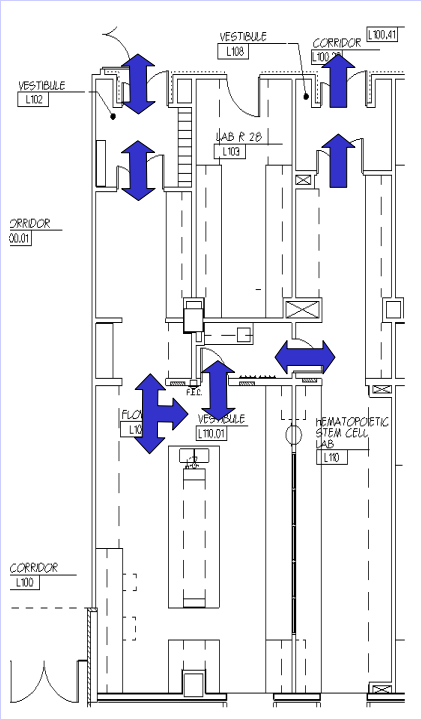
- A. Vestibule for entrance into the lab
- B. Office area where products and samples are accessioned
- C. Outer laboratory space for WBC enumeration, Flow Cytometry, Preprocessing
- D. Pass-through from outer lab to inner lab
- E. Gowning area between outer and inner labs
- F. Inner laboratory with Isolex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





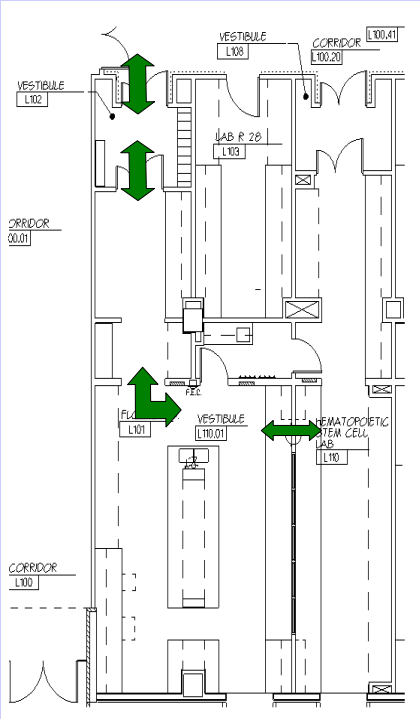
# HSClab Workflow

HSClab Personnel Traffic Pattern



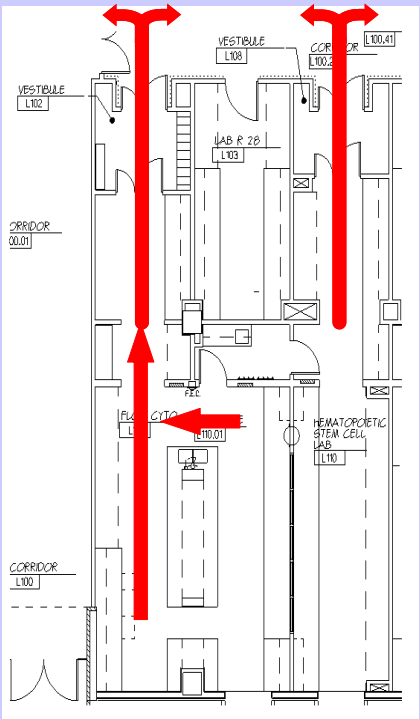
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HSClab Product Traffic Pattern



ADD DLG 10/29/03

HSClab Waste Traffic Pattern



ADD DLG 10/29/03





# Liquid Nitrogen Storage System

- ↳ Common 'closets' for supply of LN<sub>2</sub>
- ↳ 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 LN<sub>2</sub> Vessels and one vial vessel for long term storage of vial aliquots

# Liquid Nitrogen Storage System

-  Blueprint
-  Photos
-  Alarm systems

# 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 space 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