MAYO CLINIC
Mayo Medical Laboratories

Solving Problems before Construction & Consolidation

Lessons Learned from Design, Build-Out, and Relocation of Multiple Labs into One Facility

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New Orleans, LA
Tuesday, October 24th, 2017

Disclosures

- None

Presentation Outline

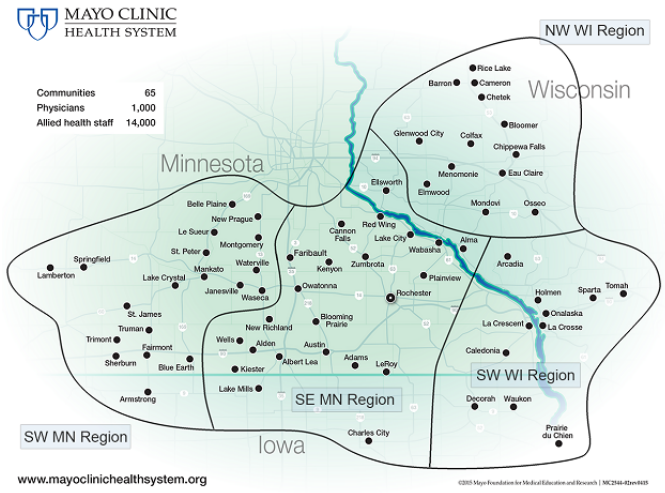
- Institutional Overview
- Laboratory Medicine at Mayo Clinic
- Lab Facilities Status
- Strategic Planning
- Relocation Project and Oversight
- LEAN Process Engineering
- Lab Reorganization
- Relocation Planning and Execution
- Lessons Learned

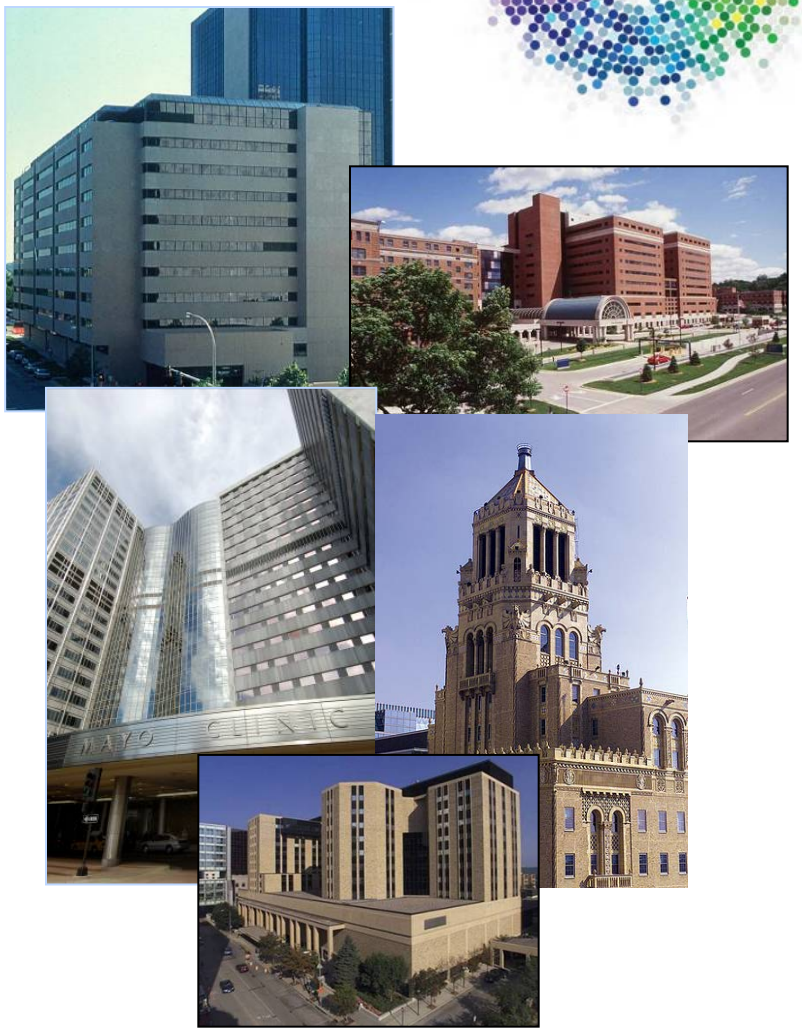
Institutional Overview
Mayo Clinic

- Locations
  - Rochester, MN
  - Scottsdale, AZ
  - Jacksonville, FL
  - Mayo Clinic Health System in MN, IA, WI
- Three Shields
  - Patient Care, Education, Research
- Education
  - Schools of Medicine, Graduate School, Health Sciences, Continuous Professional Development
- Research
  - >4,000 researchers and 11,000 IRB studies

Institutional Overview
Patient Care

- 4,590 staff physicians and scientists
- 58,488 Administrative and Allied Health Staff
- 1.3 million total patients





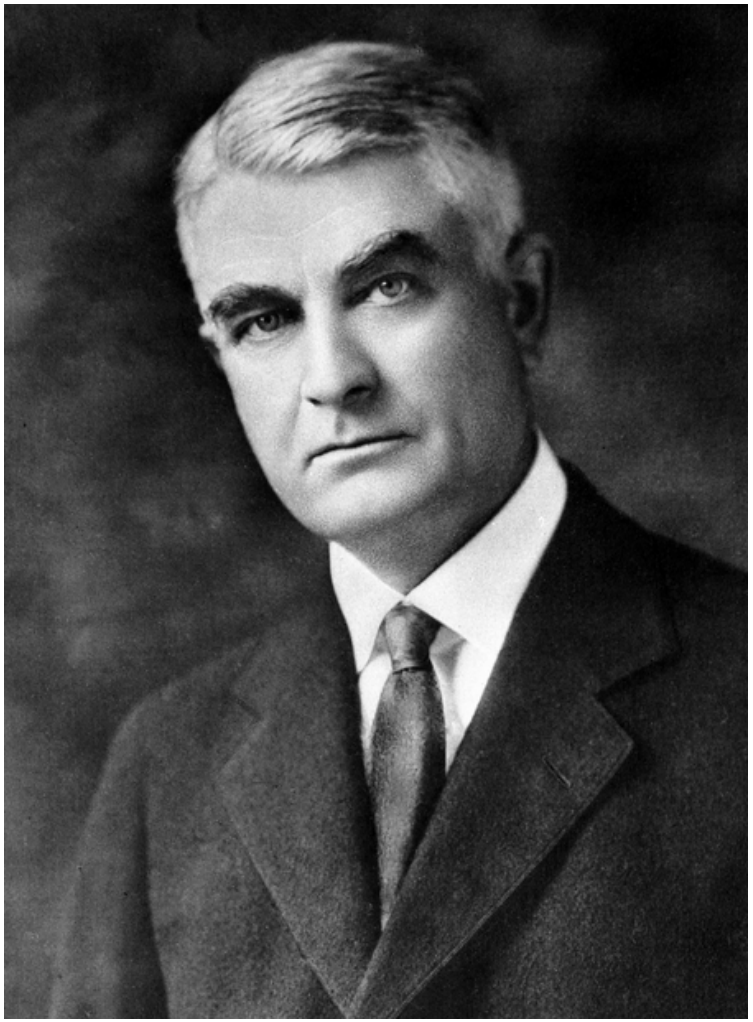
Institutional Overview
Mayo Clinic Care Network

AN INTERNATIONAL NETWORK

- 46 members
- Provides access to Mayo Clinic providers and services
  - Collaboration
  - Virtual consultations
  - Disease management protocols
  - Care guidelines
  - Clinical and business consulting services

Dr. William J. Mayo
1910

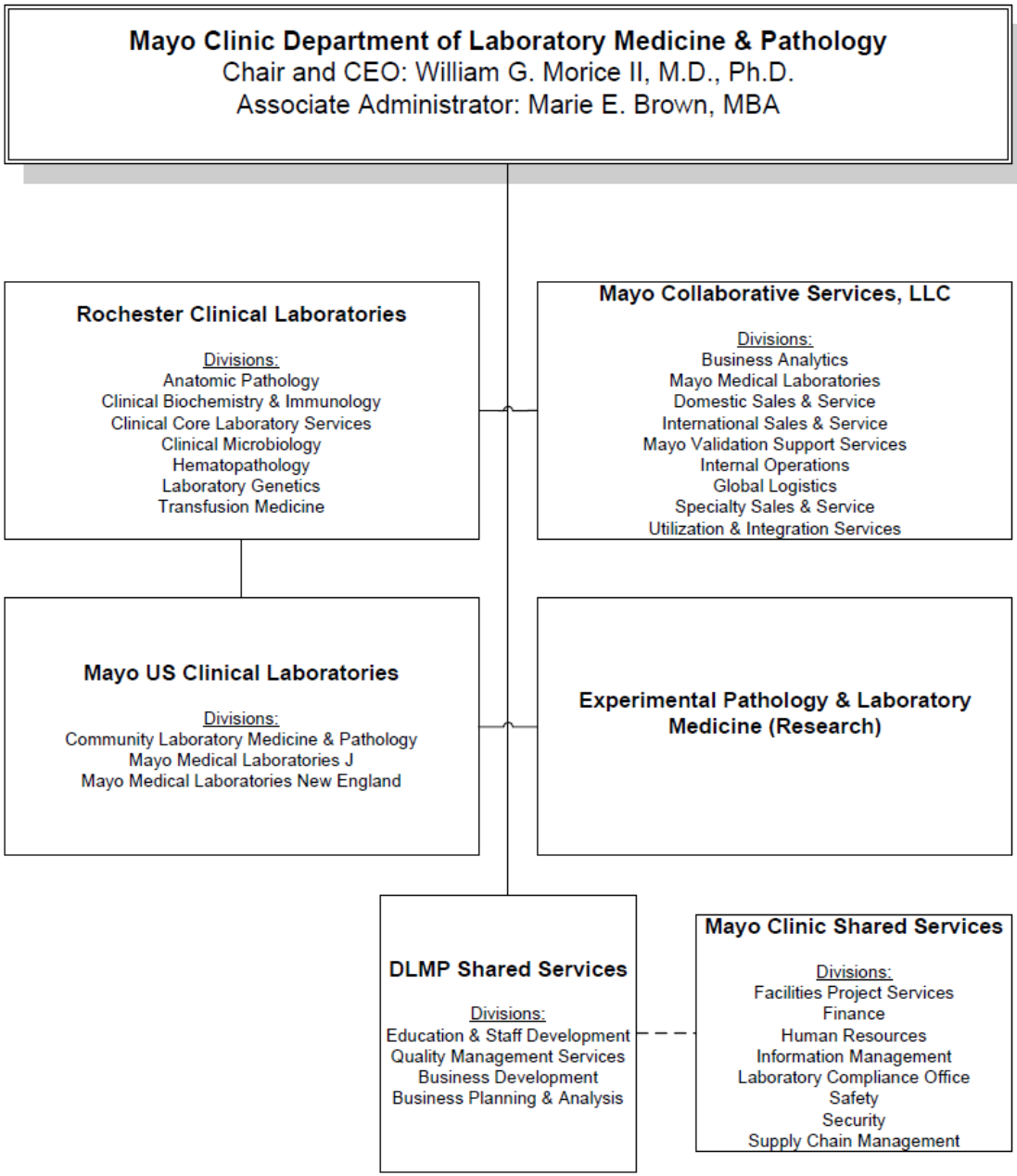
"The best interest of the patient is the only interest to be considered. In order that the sick may have the benefit of advancing knowledge, union of forces is necessary."



STRATEGIC PLAN

Laboratory Medicine at Mayo Clinic
DLMP

- Mayo Clinic in Rochester, MN
- Department of Laboratory Medicine & Pathology (DLMP)
  - 160 physician scientists
  - 3,000 Allied Health Staff
  - 60 laboratories
  - >23 million tests/year
  - Test menu >3,000
- Internal and Extramural testing


Mayo Clinic Department of Laboratory Medicine & Pathology
Chair and CEO: William G. Morice II, M.D., Ph.D.
Associate Administrator: Marie E. Brown, MBA
Rochester Clinical Laboratories
Divisions:
Anatomic Pathology
Clinical Biochemistry & Immunology
Clinical Core Laboratory Services
Clinical Microbiology
Hematopathology
Laboratory Genetics
Transfusion Medicine
Mayo Collaborative Services, LLC
Divisions:
Business Analytics
Mayo Medical Laboratories
Domestic Sales & Service
International Sales & Service
Mayo Validation Support Services
Internal Operations
Global Logistics
Specialty Sales & Service
Utilization & Integration Services
Mayo US Clinical Laboratories
Divisions:
Community Laboratory Medicine & Pathology
Mayo Medical Laboratories J
Mayo Medical Laboratories New England
Experimental Pathology & Laboratory Medicine (Research)
DLMP Shared Services
Divisions:
Education & Staff Development
Quality Management Services
Business Development
Business Planning & Analysis
Mayo Clinic Shared Services
Divisions:
Facilities Project Services
Finance
Human Resources
Information Management
Laboratory Compliance Office
Safety
Security
Supply Chain Management

Laboratory Medicine at Mayo Clinic
MML

- Mayo Medical Laboratories (MML)
- Global reference laboratory services

Our Laboratory Locations

Minnesota
3050 Superior Drive NW
Rochester, MN 55901

Florida
4500 San Pablo Road
Jacksonville, FL 32224

Fast Facts

4.5 million
Patients worldwide

150
New tests launched annually

165
Physicians and scientists specializing in laboratory medicine and pathology

70
Countries served monthly

104,000
People reached through education programs annually

90+
Subspecialty pathologists

560
Peer-reviewed articles published annually

23 million
Tests performed annually

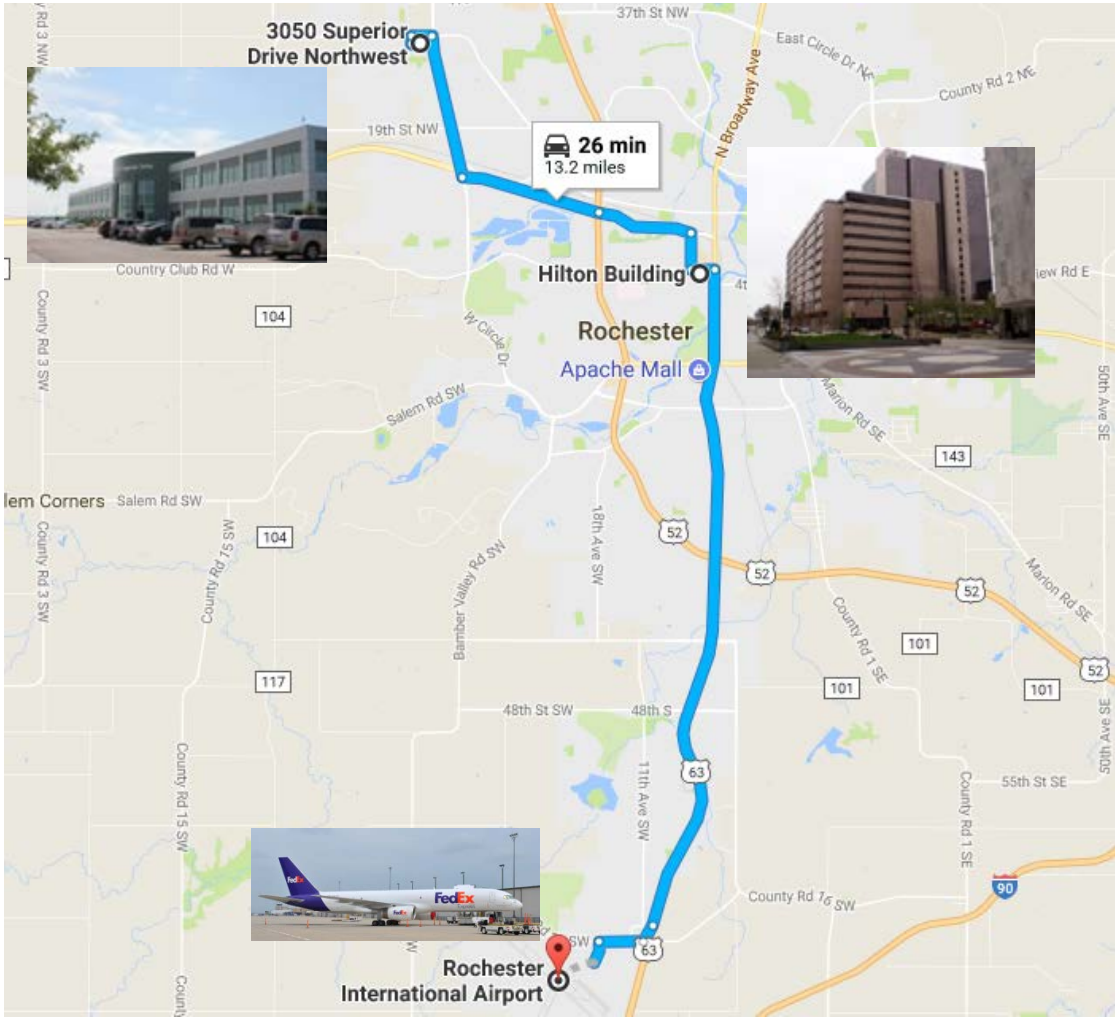
3,000+
Tests and pathology services

Laboratory Medicine at Mayo Clinic
MML Value to Mayo Clinic Practice

- Extends Mayo Clinic's reach
- Provides Mayo patients/physicians with access to a large, esoteric test menu
- Infrastructure to support MML volumes results in decreased internal TAT
- MML testing exposes DLMP consultants to complex case loads with benefits to practice
- Financial contributions that support the three shields through reinvestment

Laboratory Medicine at Mayo Clinic

MML Infrastructure



Laboratory Medicine at Mayo Clinic
Reference Laboratory Environment in 2013-2014

- Lab testing accounts for 3-5% of annual healthcare costs in the United States
- 60-70% of treatment decisions are made in part on the basis of laboratory tests
- Increasing costs
  - Next Gen Sequencing, Molecular Diagnostics, compression of Test Life Cycle, increasing regulatory overhead
- Change to reimbursement landscape
  - Shift from Fee-for-Service to Value Based models
  - PAMA
- Other challenges including qualified staff

Laboratory Medicine at Mayo Clinic
MML Approaches to Changing Lab Environment

- Test Utilization strategies
  - The right test at the right time
  - Some tests ordered unneccessarily, creating waste and increased costs
  - Others, particularly new, high-complexity tests, underutilized
  - Optimal test ordering is associated with more rapid interventions, improved outcomes, and reduced mortality rates
- Partnership with Optum Labs
- Leverage internal practice to build care algorithms
- Expansion of service to physician practices
- CareSelect Decision Support

Dr. Charles H. Mayo
1939

"Today, the only thing that is constant is change."

Lab Facilities Status
Hilton Building

- Located in downtown Rochester, MN near Mayo Clinic buildings, Methodist Hospital, St. Marys Hospital
- Home to 45 DLMP laboratories
- Known requirement to update facility for efficiency
- Other challenges
  - 2012 Facility survey projected 100% utilization by 2017
  - Limitations to physical structure of building constructed in 1974 to accommodate some efficiencies
  - OSHA Flammable Solvent limits (vertical structure)
  - Many labs with >75% extramural volume requiring large specimen distribution operation

Lab Facilities Status
Superior Drive Support Center (SDSC)

- Located in NW Rochester near US Highway 52
- Headquarters for MML business and lab operations and home to 4 extramural-focused (>85%) laboratories
- Extramural specimens shipped from RST to SDSC
  - FedEx, UPS, commercial flights, courier
  - 30,000-35,000 specimens per day sorted and delivered to SDSC labs and via truck to Hilton
  - Extramural specimens received and sorted at SDSC
  - Truck transports extramural samples from SDSC to Hilton and intramural samples from Hilton to SDSC hourly
- Existing “wet lab” space at SDSC fully utilized

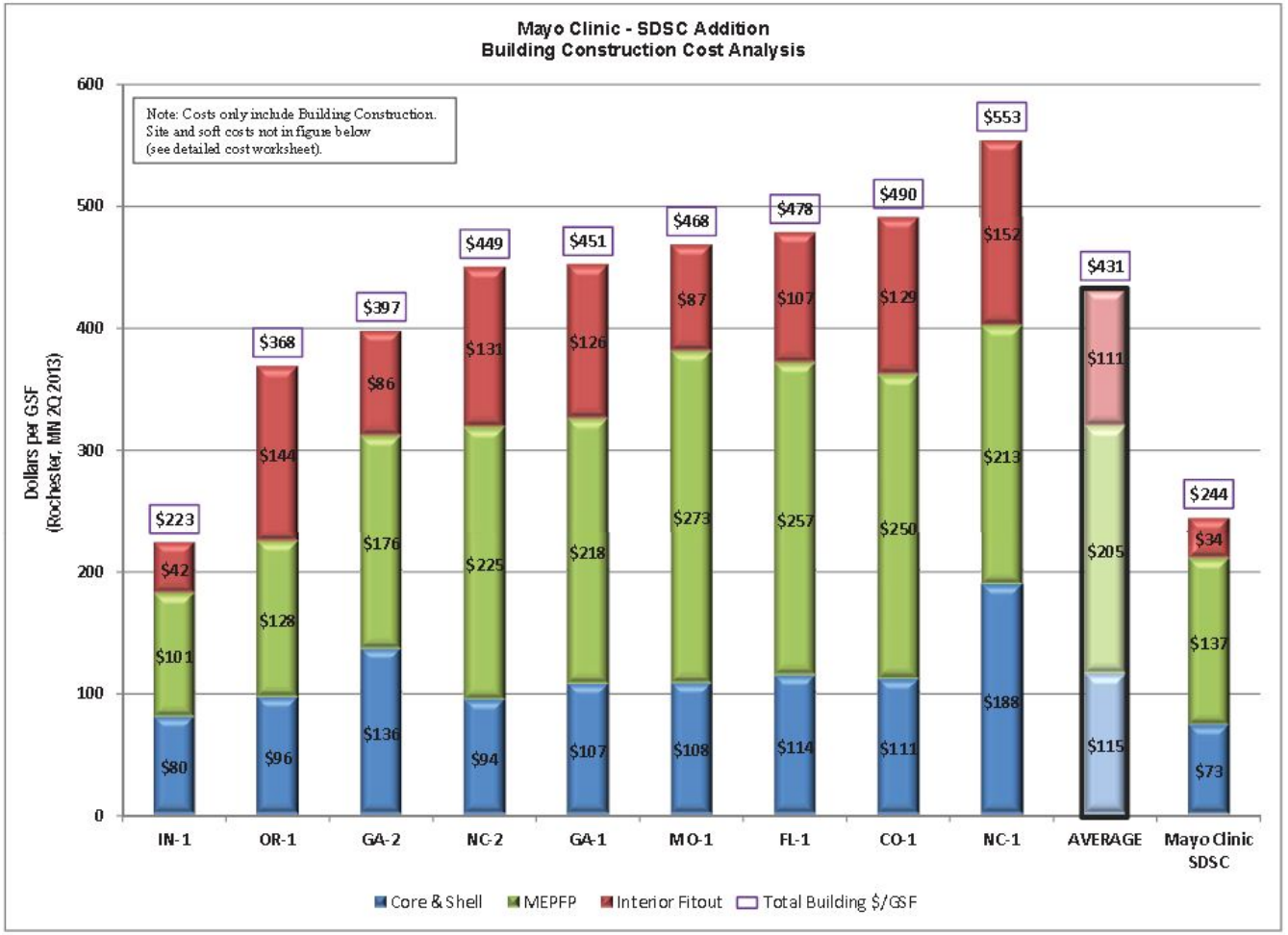
Strategic Planning
Hilton Master Plan

- DLMP Leadership identified requirement to clear 23,000 square feet of space in Hilton Building
- Only achievable through relocation of some operations off-site
- Challenge to “Think Differently”
  - Reduce redundancy
  - Increase instrument utilization
  - Automate where possible
  - Share services and equipment where possible
- DLMP Divisions reviewed future space requirements and potential candidates for relocation

Strategic Planning
Facility Options

- New construction downtown
- “Green Field” option near RST
- IBM Rochester
- SDSC Expansion
  - Converted from Lease to Ownership in 2012
  - Co-location of MML Internal Operations
  - Some existing logistical and infrastructure support
  - Increased centralization of extramural practice
- Construction of 2-story, 50,000 square foot facility at SDSC approved in 2013 with budget of $23 million

Building Cost Analysis



Strategic Planning
Relocation Candidates

- DLMP Facilities & Space Committee challenged all Divisions to propose candidates for relocation
  - Preference to clear a complete floor of Hilton
  - Labs with >80% extramural MML volumes
  - Non-STAT testing for intramural practice
  - Efficiency opportunities to be investigated and implemented at time of move
  - Standardize processes and equipment wherever possible
  - At or near full space utilization in Hilton Building
- Many Divisions offered no candidates
  - Hematopathology, Anatomic Pathology poor candidates due to reliance on consultant staff
  - Clinical Core Lab Services heavily focused on intramural operations and not a candidate for relocation

Relocation Candidates
Division of Clinical Biochemistry & Immunology

	Endocrine Laboratory	Toxicology & Drug Monitoring Laboratory
Location	Hilton 7th Floor	Hilton 7th Floor, Hilton CL
Staff	88	78
Hours of Operation	Mon-Fri: 6:00 AM – Midnight Sat-Sun: 7:00 AM – 5:00 PM	Mon-Sun: 24/7
Annual Test Volumes	1,050,000	550,000
Extramural Volume %	90%	85%
Testing Platforms	LC-MS/MS HPLC Equilibrium Dialysis Manual Immunoassays Recombinant Bioassay	LC-MS/MS HPLC GC-MS Automated Immunoassay
Test Menu Size	60	110
STAT Tests?	No	Yes
Testing	Endocrinology, Soluble Tumor Markers, Monoclonal Antibodies	Therapeutic Drug Monitoring, Clinical/Forensix Tox, Chain of Custody

Relocation Candidates
Organizational Opportunities

- Significant similarities between labs
  - Push to LC-MS/MS since 2000
  - Instrument models and extraction techniques broadly similar
- Equipment efficiency improvement
  - Different maintenance criteria and procedures
  - Discrepancies in purchased services and consumable parts between labs
  - Significant instrument downtime in Endocrine on overnight shifts
- Two CBI Labs already located at SDSC
  - Clinical Immunoassay Laboratory
  - Metals Laboratory

Relocation Candidates
Endocrine/TDML LC-MS/MS Evaluation

Instrument	Endocrine Laboratory	Toxicology & Drug Monitoring Laboratory
AB Sciex 3200	0	5
AB Sciex 4000	4	3
AB Sciex 5000	10	2
AB Sciex 5500	2	0
AB Sciex 6500	3	4
Agilent 6400 Series	0	5
Thermo QExactive	2	1

Relocation Candidates
LC-MS/MS Utilization Evaluation

	Endocrine Lab - AB Sciex 4000				TDM Lab - AB Sciex 4000		
Hour	The Hulk	Godfather	Sunny D	Simon	Paris	Yukon	Otis
12:00 AM	Metanephrines					Opiates	Maintenance
1:00 AM	Metanephrines					Opiates	Maintenance
2:00 AM						Opiates	Maintenance
3:00 AM						Maintenance	
4:00 AM						Maintenance	
5:00 AM						Maintenance	
6:00 AM			Maintenance	Maintenance	Maintenance		
7:00 AM		Maintenance	Maintenance	Maintenance	Maintenance		
8:00 AM		Maintenance	25-Hydroxyvitamin D	Glucocorticosteroids	Immunosuppresants		
9:00 AM	Maintenance	Serotonins	25-Hydroxyvitamin D	Glucocorticosteroids	Immunosuppresants	Immunosuppresants	Opiates
10:00 AM	Maintenance	Serotonins	25-Hydroxyvitamin D	Glucocorticosteroids	Immunosuppresants	Immunosuppresants	Opiates
11:00 AM	N-Methyl Histamines	Serotonins	25-Hydroxyvitamin D	Glucocorticosteroids	Immunosuppresants	Immunosuppresants	Opiates
12:00 PM	N-Methyl Histamines	Serotonins	25-Hydroxyvitamin D	Maintenance	Immunosuppresants	Immunosuppresants	Opiates
1:00 PM	N-Methyl Histamines	Maintenance	25-Hydroxyvitamin D	Maintenance	Immunosuppresants	Maintenance	Opiates
2:00 PM	N-Methyl Histamines	Maintenance	25-Hydroxyvitamin D	Maintenance	Immunosuppresants	Maintenance	Opiates
3:00 PM	N-Methyl Histamines	Maintenance	25-Hydroxyvitamin D	Fluticasone 17-Beta	Immunosuppresants	Opiates	Opiates
4:00 PM	N-Methyl Histamines	Alpha-1 Antitrypsin	25-Hydroxyvitamin D	Fluticasone 17-Beta	Immunosuppresants	Opiates	Opiates
5:00 PM	Maintenance	Alpha-1 Antitrypsin	25-Hydroxyvitamin D	Fluticasone 17-Beta	Maintenance	Opiates	Opiates
6:00 PM	Maintenance	Alpha-1 Antitrypsin	25-Hydroxyvitamin D	Fluticasone 17-Beta	Maintenance	Opiates	Opiates
7:00 PM	Maintenance	Maintenance	25-Hydroxyvitamin D	Maintenance	Maintenance	Opiates	Opiates
8:00 PM	Metanephrines	Maintenance	25-Hydroxyvitamin D	Maintenance		Opiates	Opiates
9:00 PM	Metanephrines	Maintenance	Maintenance	Maintenance		Opiates	Opiates
10:00 PM	Metanephrines		Maintenance			Opiates	Opiates
11:00 PM	Metanephrines		Maintenance			Opiates	Opiates

- 2014 average daily run times for *seven* AB Sciex 4000 instruments
- Minimum 49 hours of downtime per day

Relocation Candidates
LC-MS/MS Utilization Proposal

	Endocrine Lab - AB Sciex 4000			TDM Lab - AB Sciex 4000	
Hour	Godfather	Sunny D	Simon	Paris	Otis
12:00 AM	Opiates	Metanephrines			Opiates
1:00 AM	Opiates	Metanephrines			Opiates
2:00 AM	Opiates				Opiates
3:00 AM	Opiates	Maintenance		Maintenance	Maintenance
4:00 AM	Maintenance	Maintenance	Maintenance	Maintenance	Maintenance
5:00 AM	Maintenance	Maintenance	Maintenance	Maintenance	Maintenance
6:00 AM	Maintenance	25-Hydroxyvitamin D	Glucocorticosteroids	Immunosuppresants	Immunosuppresants
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1:00 PM	Alpha-1 Antitrypsin	25-Hydroxyvitamin D	Fluticasone 17-Beta	Immunosuppresants	Opiates
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8:00 PM	Opiates	Metanephrines	N-Methyl Histamines		Opiates
9:00 PM	Opiates	Metanephrines	N-Methyl Histamines		Opiates
10:00 PM	Opiates	Metanephrines	N-Methyl Histamines		Opiates
11:00 PM	Opiates	Metanephrines	N-Methyl Histamines		Opiates

- Future daily run times for ***five*** AB Sciex 4000 instruments
- Minimum 14 hours of downtime per day
- Potential $1.2 million in equipment replacement avoidance

Relocation Candidates
Operational Opportunities

- Over 700 controlled documents utilized by Endocrine and TDM Labs
  - >150 identified as being potentially redundant
- 3 separate supply rooms at Hilton, with significant duplication
  - Potential for reduction in supply-on-hand by $50,000
- Non-standardized quality and proficiency testing practices
- Development processes not standardized
  - Little history of collaboration or knowledge sharing
  - No standardization of equipment, reagents, or processes
  - Variability in validation standards and practices

Relocation Candidates
Staffing Opportunities

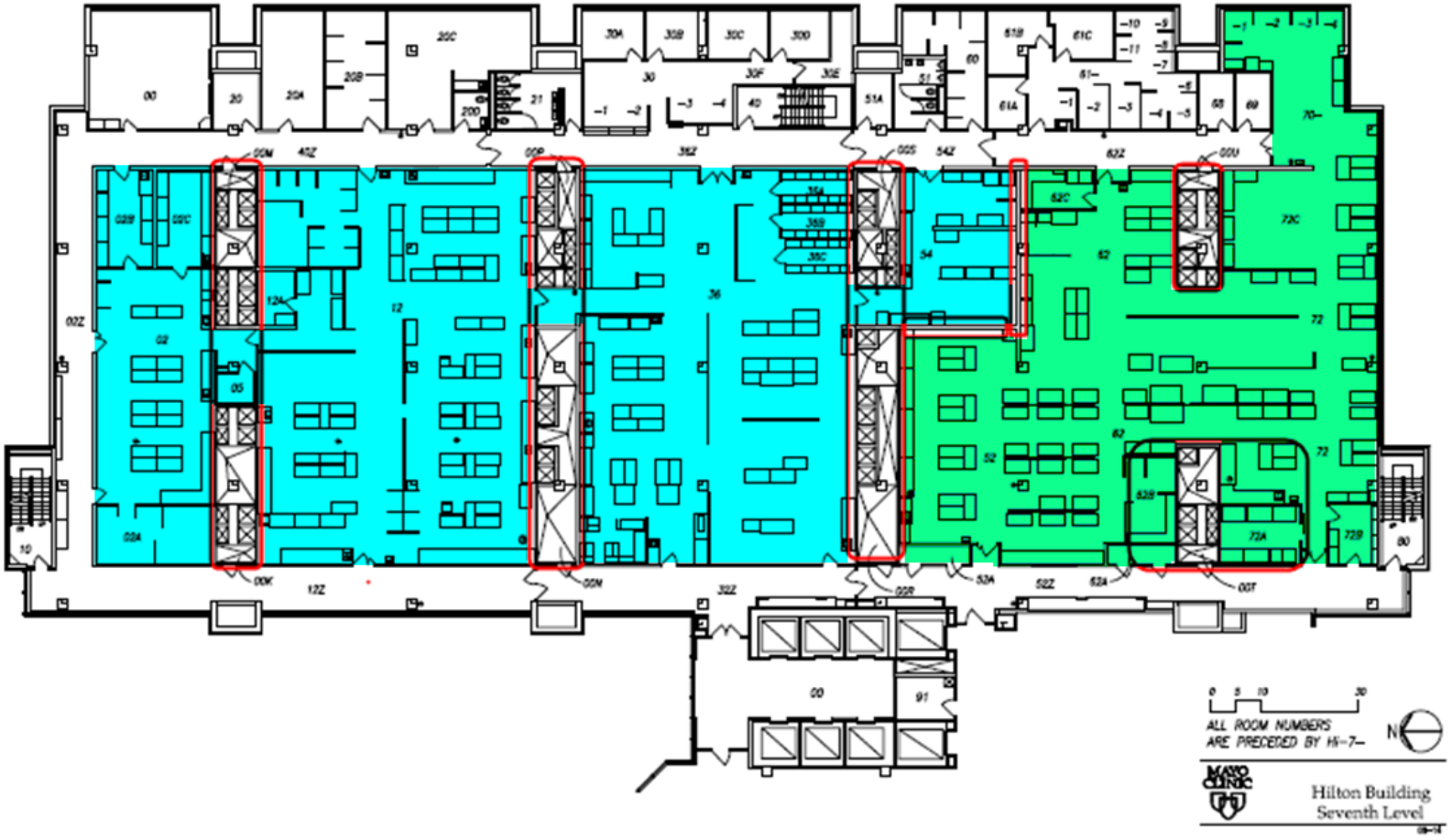
- Imbalance in technologist staffing between labs
  - Available instrument time on Overnights in Endocrine
  - High workload variability on Overnights in TDM often left technologists with available capacity
- Imbalance in Specialist staffing between labs
  - Technical Specialist/Technologist Ratio
    - 1 to 3 in TDM Lab
      - Technical staff on clinical bench 20-50% of time
      - Technologist staff putting in overtime with high burnout
    - 1 to 6 in Endocrine Lab
      - Technical staff putting in overtime with high burnout
      - Technologist staff taking on Technical work
    - Combined ratio would be 1 to 4.5
      - DLMP average: 1 to 5

Relocation Candidates
Facility Opportunities

- Hilton 7 space evaluated as inadequate for future growth
- Annual 5-10% volume growth for both labs
- LC-MS/MS, HPLC, and GC-MS technology requires large quantities of flammable solvents
  - Significantly above OSHA limits for 7th floor
- Segmented floor plan with utility galleys prevents open space concept, limiting opportunities for collaboration
  - TDM split between two floors
  - Endocrine test development relocated to borrowed space on Hilton 5th Floor

Relocation Candidates

Hilton 7 Floorplan – 23,480 square feet



Project Direction and Oversight
Leadership Structure

- Steering Team
  - DLMP Executive Committee
  - DLMP Facilities & Space Committee
- Leadership Team
  - CBI Division Chair and Lab Directors
  - CBI Division Administration
  - Supervisors
  - Project Manager
  - Systems Engineer
- Facilities Project Team
  - Facilities Project Manager
  - Flad Architects from Madison, WI

Project Direction and Oversight

Project Goals

- Defined by Leadership Team
  - Design operation to sustain 20% growth in 10 years
  - Reorganize operations around technology rather than clinical specialty
  - Increase instrument utilization
  - Staff-to-workload and shift run-times to match instrument availability and staffing
  - Standardize
    - Instrument and reagent purchases
    - Policies, procedures, document control
    - Validation procedures
  - Maintain or improve quality metrics (TAT, Repeat Rate, PT)
  - Maintain business continuity and complete relocation without impact to patient care

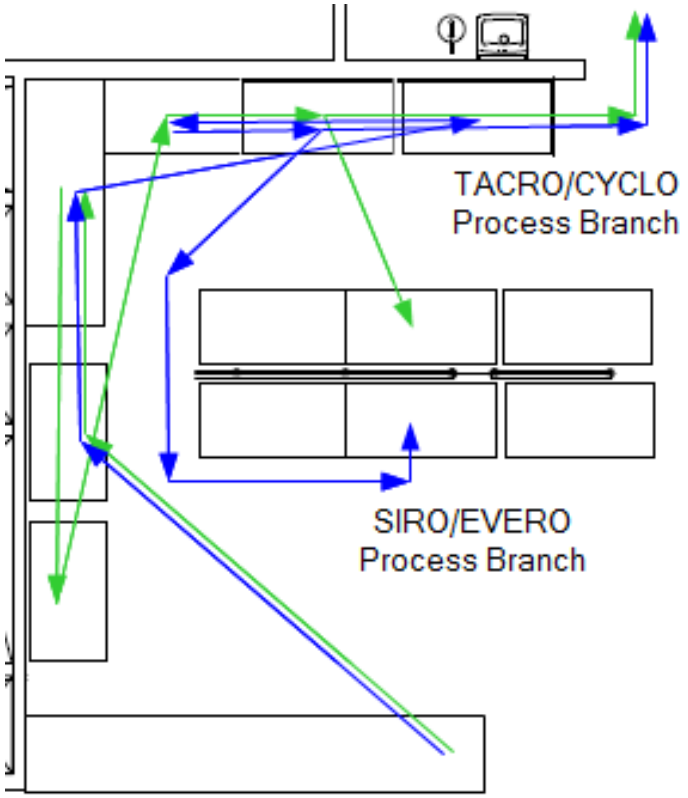
Planning
LEAN Process Engineering

- Systems Engineers engaged to lead LEAN process
  - Map all existing processes with guidance from laboratory technical staff
    - Use results to provide architect team with guidance on layout of workflows
  - 5S of workstations to standardize layouts across labs and remove wasteful steps
  - Led team to design ventilated benchtop concept to address issues with “nuisance” odors
  - Worked with lab staff to develop move schedule
- Requirement to complete majority of work prior to facility design
- Dedicated Systems Engineering staff

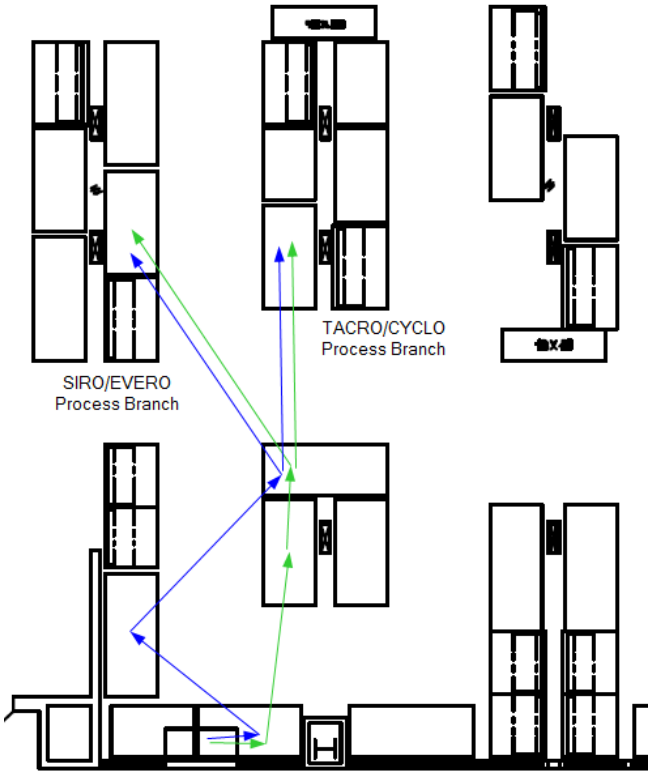
Planning
LEAN – Workflow Design

- Hilton Building fixed utility galleys and structural members limited efficiency opportunities
- Majority of workflows had some inefficiencies
  - Hallway space converted to lab space
  - Some operations on other floors resulting in complex flow of specimens
  - Specimen deliveries required pushing large carts into lab
  - Legacy processes from 10-15 years previous had not been updated to match new technology
- Spaghetti diagramming exercises for each workflow, Current vs. Ideal

LEAN Process Engineering
Immunosuppresants Spaghetti Diagram



- Hilton 7
- 7-8 process steps depending on instrument used



- Future State Proposal
- 5 process steps regardless of instrument used

Planning
LEAN – Staffing to Workload

- TDML staffed 24/7 to cover STAT and Expedited testing
  - Workload highly variable
- Endocrine staffed 6 AM – Midnight M-F, Day Shift Saturday and Sunday
  - Available, non TAT-sensitive work
- Standardization would allow increased instrument utilization and improve TAT for Endocrine tests
  - Transition batched testing and some preventative maintenance to Evening and Overnight shifts
  - Transition staffing to match work hours
  - Added benefit of reducing laboratory congestion during day shift

Planning
LEAN – Equipping to Workload

- Crosswalk of equipment for each test
  - Analytical instrumentation
  - Liquid handler deck layout, tip types
  - Reagent compatibility
- Multiple unrealized opportunities to share resources within and between labs
  - 2 LC-MS/MS system purchases cancelled
  - 1 automated liquid handler purchase cancelled
  - 2 manual liquid handler purchases cancelled
  - Net capital savings of $1.75 million
- Prototype studies carried out for new instrument utilization model

Planning
LEAN – Equipping to Workload

- Transition non-HPLC and LC-MS/MS testing to other laboratories with similar equipment
  - Manual Immunoassays to Clinical Immunoassay Laboratory already at SDSC
- Transition STAT Drug Screens Roche Cobas chemistry platforms in Central Clinical Lab in Hilton Building
- Dedicated Reagent Preparation Facility shared by both labs as well as existing SDSC labs
  - Utilize unoccupied lab facility in existing SDSC building to conserve “wet” space
  - Dedicated staff to maximize potential for cross-training
  - Bulk Solvent delivery system to maximize economies of scale and contracting

Project Scope Proposal
Recommendations from LEAN Process

- Recommendations brought to Leadership Team for review and approval
- Open facility floorplan with flexible space and redesign of all workflows
- Change to historical organization to realize efficiencies
- Some limitations
  - Unique workflow and regulatory requirements for Clinical & Forensic Toxicology testing
  - Unique Roche Cobas and GC-MS instrumentation for drug screens and confirmations
  - Beta Counters used for Free Testosterone analysis tied too closely to Testosterone workflow to be moved to other labs

Organizational Plan
Final Organization

- Clinical Mass Spectrometry Laboratory (CMSL)
  - Merger of Endocrine and Therapeutic Drug Monitoring Labs
- Clinical & Forensic Toxicology Laboratory (CFTL)
  - Toxicology portion of TDML
- Clinical Mass Spectrometry Development Laboratory (CMSDL)
  - Development staff from Endocrine and TDM
- Clinical Immunoassay Laboratory (CIL)
  - Immunoassays
- Laboratory Oversight Team (LOT)

Laboratory Reorganization

	CMSL	CFTL	CMSDL	CIL
Staff	96	44	15	39
Testing	• Endocrine • Tumor Markers • Therapeutic Drugs • Monoclonal Antibodies	• Drugs of Abuse • Clinical tox • Forensic tox • Chain-of-custody • Autopsy	• New test development support for LC-MS/MS	• Allergens • Endocrine • Immunology • Newborn screening
Instruments	• LC-MS/MS • HPLC • Beta Counters	• LC-MS/MS • GC-MS • Immunoassay	• LC-MS/MS	• Automated and Manual Immunoassay • Radiolabeled Immunoassay
Hours of Operation	24/7	24/7	M-F 7 am – 6 pm	M-Sat 6 am-Midnight

Lab Reorganization
Laboratory Oversight Team

- Responsible for:
  - Prioritizing test development resources
  - Reviewing requests for research resources
  - Managing instrument standardization process
- Directors and Supervisors from all labs
- Division Chair as impartial leader
- Operations Manager as secretary
- Managed process for transitioning some testing to other laboratories within DLMP

Lab Reorganization
CMSL Test Volumes

- 2015 CMSL Test Volumes

	Test	Volume
1.	Total Testosterone, S	248,657
2.	25-Hydroxyvitamin D2 and D3, S	216,092
3.	Free Testosterone, S	198,926
4.	1,25-Dihydroxyvitamin D2 and D3, S	134,612
5.	Tacrolimus, B	75,133
6.	Levetiracetam, S	71,965
7.	Lamotrigine, S	38,048
8.	Metanephrines, P	34,321
9.	Estradiol, S	25,014
10.	Nicotine and Metabolites, S	24,032

Lab Reorganization
Operationalizing

- CMSL formation presented a significant challenge
- Different histories and cultures between merging labs
- Lack of trust
- Suspicion regarding reasons for reorganization
- No history of collaboration between the groups
- New Supervisor named from outside the groups to oversee organizational transition and relocation
- Coordinate closely with Supervisors of CFTL
  - Transition of staff
  - Alignment of policies and practice

Lab Reorganization
Operationalizing

- Transition plan
  - Met with all 90 staff members 1:1
  - Utilization of Applied Behavioral Analysis principles to motivate positive and productive behaviors
  - Formed lab standardization teams
    - Delegated responsibility to team leads
    - Deadlines and shared vision
    - Mixed membership between groups
    - Document Control, Quality Management, Preventative Maintenance, Validation/Verification, Education & Training, IT
  - Combined meetings and website
  - Lab and SDSC Facility Tours
  - Lecture program by laboratory directors

Lab Reorganization
Operationalizing

- Staff surveys and small-group meetings
- Used opportunities for collaboration to create opportunities for teamwork
- Joint happy hours and holiday parties
- Instituted cross-training program for new hires to build collaboration as normality
- Crucial Conversations
- Develop a sense of urgency
  - Publicly posted timelines
  - Hold staff accountable to deadlines

Facility Design
Architectural Concepts

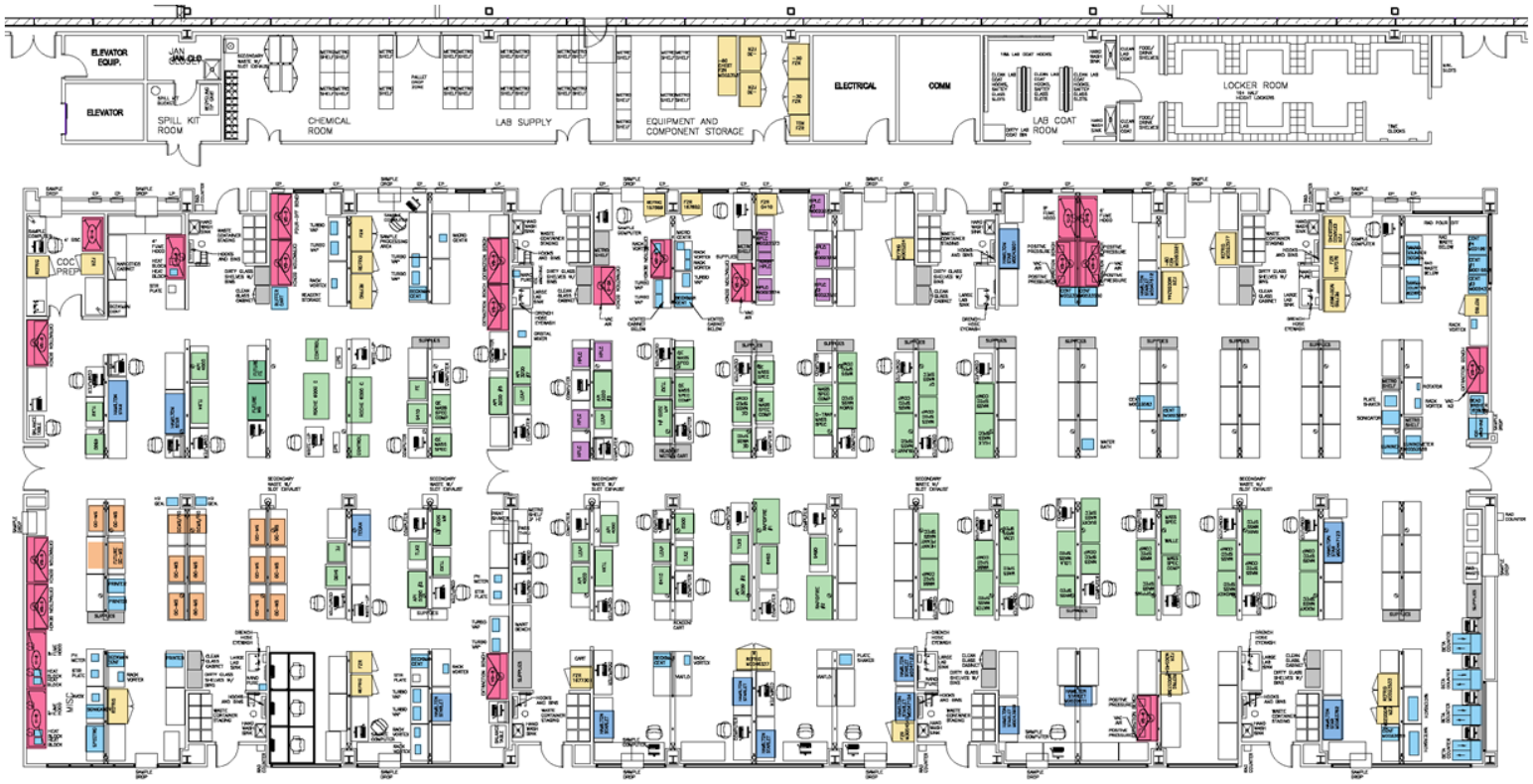
- Design process initiated November, 2013 and substantially complete May, 2014
- 2-story, 50,000 square foot building expansion
  - 1st Floor fully occupied
  - 2nd Floor with small MS Development facility, remainder maintained as shell space
- Open, flexible space with limited fixed furniture
- Maximize natural light penetration
- Utilize existing office, breakroom, conference room space as much as possible to maximize wet lab space

Facility Design
Architectural Process

- Shared, centralized supply and freezer storage
- Maintain line of sight
- Dedicated refrigerator/freezer room
- Specimen delivery windows to eliminate carts in the lab
- Delivery indicator light system
- Ventilated benchtops for “nuisance” odors
- Arrange workstations to maximize potential for collaboration
- Specimens are prepped towards the “outside” of the lab; prepared specimens move “inside” for analysis

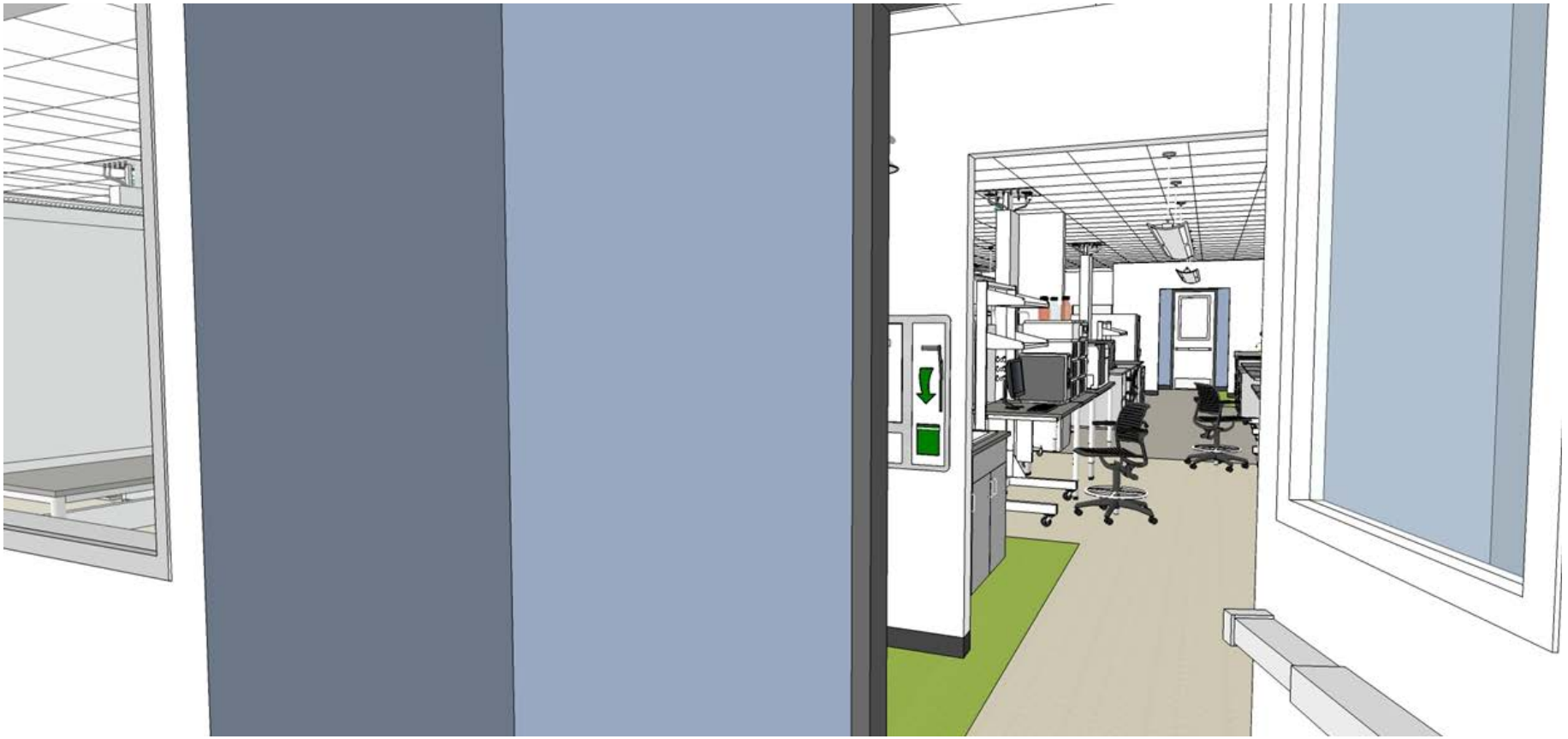
Facility Design
Architectural Process

Facility Design
Architectural Process



Facility Design
Architectural Process

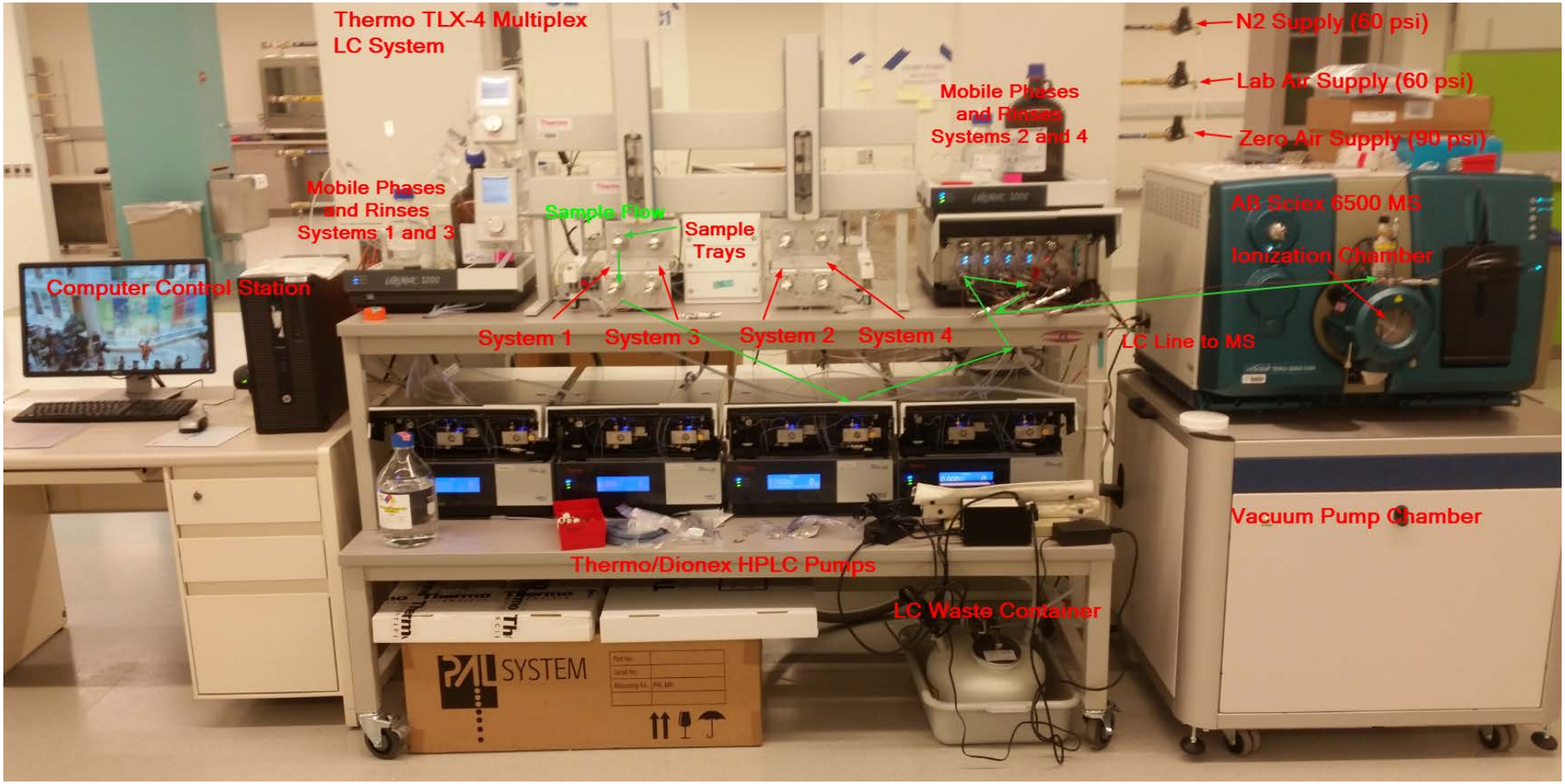
Facility Design
Architectural Process



Facility Design
Architectural Process

- Single-drop utility poles
- Combined power, data, gas, vacuum, ventilation
- Carrier supplies at bench level
- Can be moved within one ceiling tile in any direction
- Balance flexibility with organization to reduce clutter

Facility Design
LC-MS/MS System Orientation



Facility Design
LC-MS/MS System Orientation

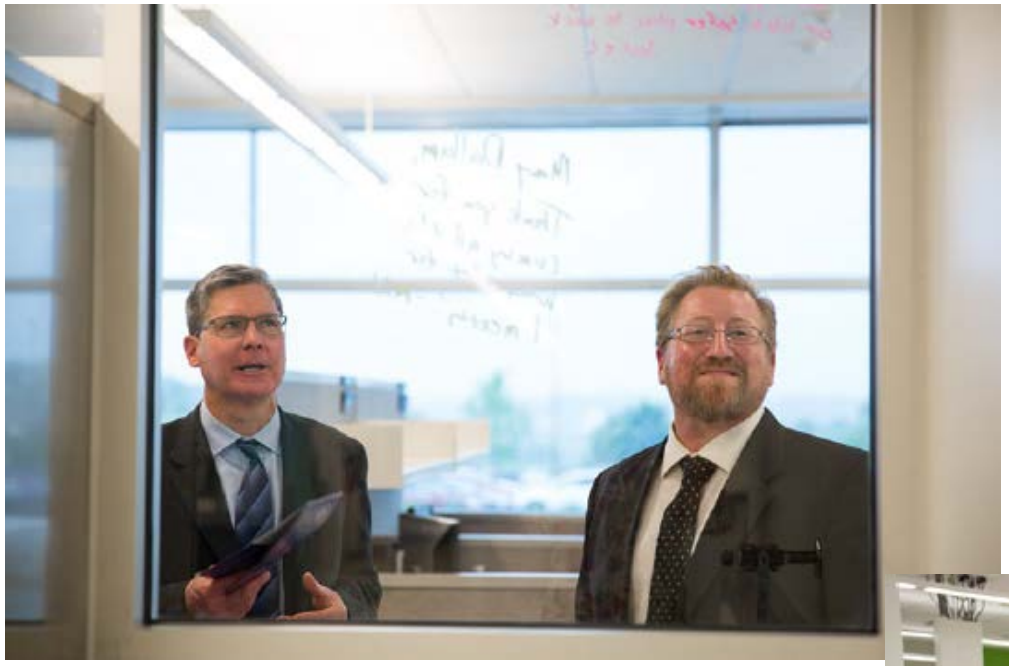
- Additional facility features
  - Shared supply storage
  - 12,000 liquid gallon N2 supply tank
  - 6-manifold redundant Helium supply for GC-MS
  - Dedicated H2 generators for GC-FID
  - 3 dedicated Zero Air generators for LC-MS/MS
  - Underground bulk waste disposal tank
- One wall separating CMSL from CFTL
  - Required due to SWGTOX access regulations
  - Cross-validation of instruments between CMSL and CFTL; some staff can access both labs
  - Windows for off-shift wellness checks and communication

Facility Design
Reagent Room and Bulk Solvents

- Dedicated reagent room to serve CMSL, CFTL, CIL, CMSDL, and other SDSC laboratories (Hep/HIV)
- Unified reagent tracking system
- 3 Chemical Container Prep staff
- Bulk solvent supply system
  - Methanol, Acetonitrile, Hexane, Isopropanol
  - Pressurized by house N_2 system
  - Bulk Solvent supply system
  - Isolated “dead air” scale room

Facility Construction Timeline

- Ground Breaking August 18, 20914
- Final beam emplaced November 11, 2014
- Substantial completion July 17, 2015
- *Lab relocations begin August 3, 2015*
- Grand Opening August 18, 2015



Facility Construction
Necessity for Careful Lab Oversight

- Facility walk-throughs by staff critical in identifying issues
  - Helium supply not completed to plan, causing delay in GC-MS relocations
  - Solvent waste dump relocated to dry supply room
  - Elimination of windows between CMSL/CFTL
  - Ventilation and temperature control
  - Power and data receptacles
- Positives
  - Bright, sunlit facility
  - Significantly improved air quality and cleanliness
  - Extremely conducive to communication and collaboration
  - Improved delivery process for extramural specimens

Relocation Planning
Planning Process

- Formal commencement April, 2014 (15 months in advance)
- Considerations
  - Quality & Regulatory
  - Validation & Verification
  - Move Schedule
  - Logistics
  - Process Changes
  - LIS Test Definition
  - Continuity of Service
  - Staffing
  - STAT contingency

Relocation Planning
Quality & Regulatory

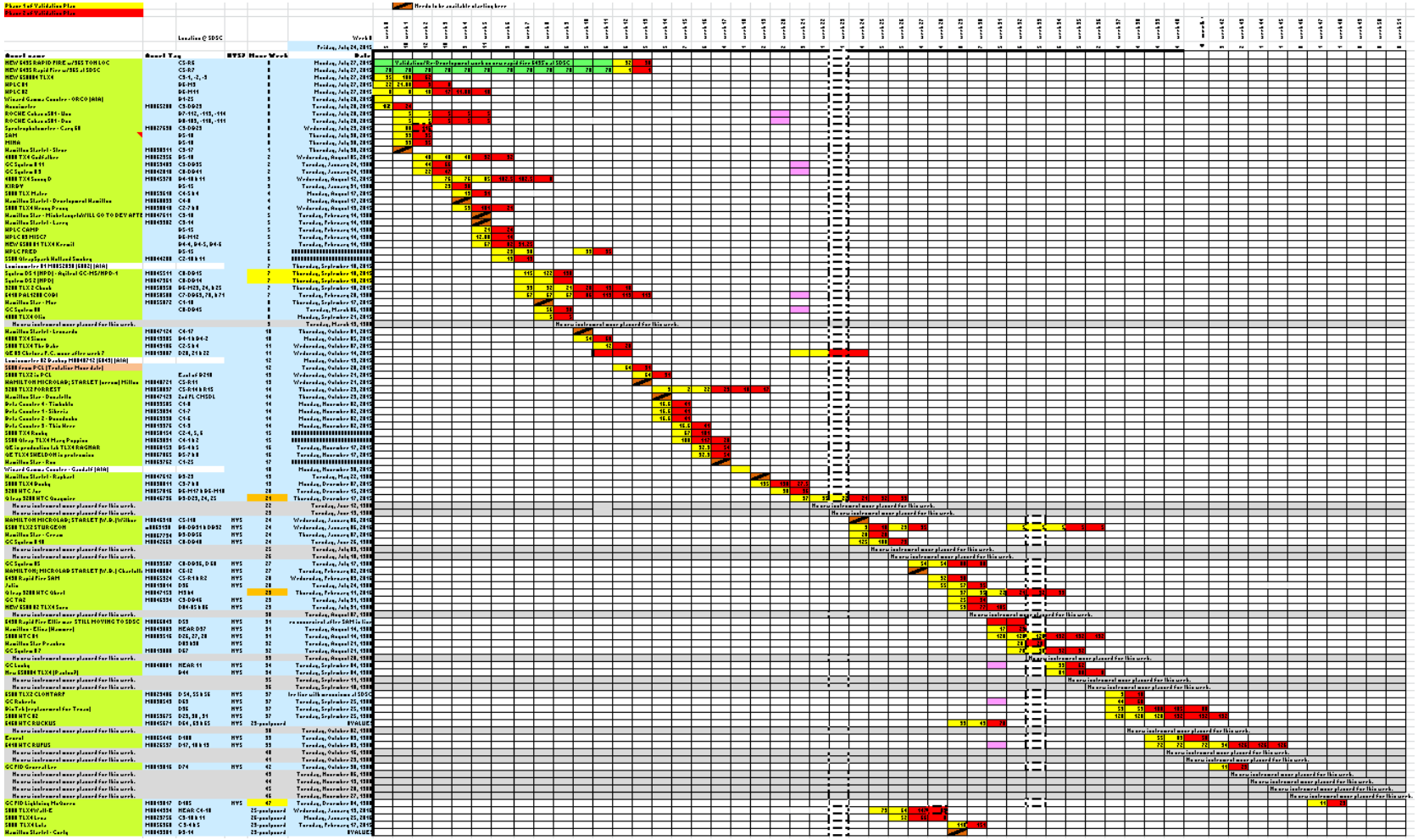
- Quality & Regulatory
  - Hilton and SDSC located under different CAP and NYS PFI numbers
  - Four new NYS categories for SDSC
    - Therapeutic Drug Monitoring
    - Clinical Toxicology
    - Forensic Toxicology
    - Laboratory Genetics
- Proactive communication with Regulatory bodies is key
- Different expectations from CAP vs. NYS
  - NYS requires live testing and inspection prior to granting new categories

Relocation Planning
Validation & Verification

- Full 20-run validation of all relocated tests
  - PARR-ASAS
  - Ensures CAP and NYS compliance
  - Provides baseline for future work
  - Fills validation gaps in some “legacy” assays
- Aspects not affected by location validated before move if not previously documented
  - Stability studies
  - Interference studies
  - Preservative studies
  - Specimen type studies

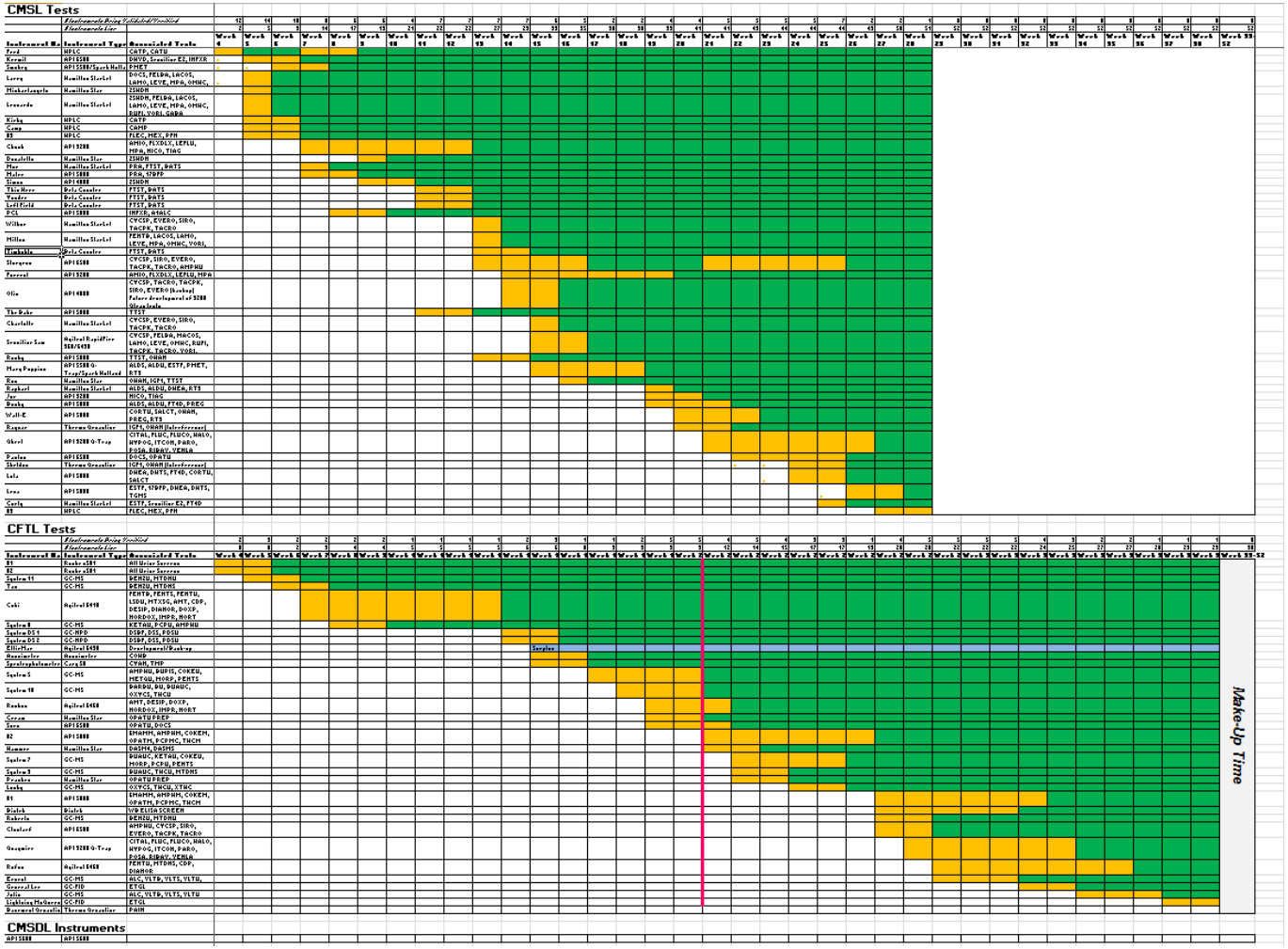
Relocation Planning

Move Schedule



Relocation Planning

Move Schedule



Relocation Planning
LIS, STAT, Process Changes, Continuity

- Used move as opportunity to implement multiple test definition updates
- Established STAT transport process for ER samples
- Process changes
  - Implemented updated methods for multiple high-volume assays
  - Worked with MML Specimen Distribution to define granular specimen delivery sort to improve efficiency of hard-receipt
  - New safety requirements at new facility: use the change as an opportunity to drive home good habits with staff
- Continuity of service
  - MML Referrals pre-built sendout codes for all tests potentially at-risk due to NYS certificate status

Relocation Planning
Logistics

- 9 months prior to move, involved Supply Chain Contracting to put together contracts with vendors
- Instrument move process
  1. Vendor tests functionality at Hilton Building
  2. Vendor shuts down instrument
  3. Vendor secures instrument to cushioned pallet
  4. Local contracted courier service loads and transports instrument
  5. Vendor and lab staff unload and reinstall instrument
  6. Instrument receives full IQ/OQ and must pass all performance tests prior to commencement of validation
  7. Internal Biomedical Engineers handle centrifuges, liquid handlers, scales, balances, etc.

Relocation Planning
Logistics

- Contracting proved very important
- Relocations often not covered under service contracts
- Vendors preferred us to arrange transportation ourselves
- Scale of move caused staffing challenges for vendors; proactive communication allowed us to change our move schedule to fit needs
- Engaging Supply Chain Contracting gave additional negotiating leverage, saving over $100,000 compared to initial quotes
- DoT regulations regarding reagent transportation

Relocation Planning
Staffing

- Arranged temporary parking tags for staff
- Carried out cross-training for some staff to maintain more validation runs
- Offered overtime to interested technologists
- PTO restricted, but front-loading of validation schedule prior to holidays minimized impact
- Carefully monitored burnout; Supervisors spent increased time in the labs
- Positive reinforcement and recognition

Positive Reinforcement and Teamwork

Relocation
Initiation

- Coordinated installation of new LC-MS/MS systems on date of handover to facilitate move
  - Negotiated extended possession of several “replaced” LC-MS/MS systems to extend redundancy
- Weekly Go/No-Go Meetings with project, lab, facilities, and logistical teams
- Welcome bags for employees
- Lab director built tracking and reinforcement plan for timely review of validation/verification data
- Coordinated with NYS DOH for Inspection 6 weeks after

Relocation
Continued

- Validation work carried out every week from August, 2015 through October, 2016
  - MMLNE closure
- Over 70% complete by 2016, 98% complete by June, 2016
  - CMSL move completed in 56 weeks
  - CFTL move completed in 68 weeks
- Maintained positive NOI throughout the move period
- Expense per test decreased compared to pre-move

Relocation
Metrics

Metric	Measure
Validations	>800
Orderable Tests Moved	310
Test Downs Due to Move	4 (1.3%)
Instruments Relocated	91
Instruments Damaged Due to Move	2 (2.2%)
Average Test Volume/FTE	1,339 (up 38% compared to pre-move)
Average TAT During Move	92% meeting goal

Relocation
Current Status

- Closure of MML New England facility
  - Additional 350,000 annual test volumes
  - 6 additional LC-MS/MS systems, 3 liquid handlers
  - Expected 5 year space growth fully utilized
- Importance in instrument utilization to create capacity
- 2018 relocation of Radioimmunoassays to 2nd Floor will clear 2 instrument bays
- Staffing and supply efficiencies paying dividends
- Heavy focus on test redevelopment to improve efficiency, throughput, and TAT
- Staff satisfaction remains high

Future of the SDSC Facility
Master Planning, Round 2

- Hilton 7th Floor now occupied by other laboratories
- Continued volume growth and decompression of Hilton Labs is rapidly consuming freed space
- 2018 relocation of Immunology Laboratory to SDSC 2
- DLMP Facilities & Space Committee carrying out Round 2 of Master Planning
  - Using this project as a model
  - Most likely option is construction of additional facilities at SDSC
  - Relocation of remaining MML-focused labs
  - Eventually >80% of MML extramural volumes will be analyzed at SDSC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Superior Dr NW

Lessons Learned
What did we do well?

- Test Transfer Notifications communications
- Continuity of service plan
- Equipment transportation planning
- Vendor communication and contracting
- Standardized validation/verification format
- Elimination of unnecessary redundancies
- Workflow redesign and LEAN
- Staff morale
  - All Staff Survey conducted at height of move showed *significant improvement* in scores compared to 2013 survey

Lessons Learned

What would we do differently?

- Communication of project vision with laboratory staff
- Initial planning for laboratory reorganization
- Greater involvement of lab staff in facility design, regular review of updates, and facility walk-throughs
- Clarify role of the DLMP Project Manager
- Accept that some level of dissatisfaction will remain with some staff
- Plan for increasing capacity and growth
- Stress testing of instrument sharing plan

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Questions & Discussion