



Executive Summary

- Molecular testing is a large and growing market
- Size and scope of this opportunity requires a departmental level initiative
- Investment will produce a payback in 6.3 years, return on investment of 112%, and provide synergies with other CCF lab testing
- Our patients (here and around the world) and their physicians will benefit through personalized molecular medicine & synergies in integrated institute-based patient care
- CCF will be poised to have the premier clinical diagnostic molecular pathology laboratory both domestically and internationally

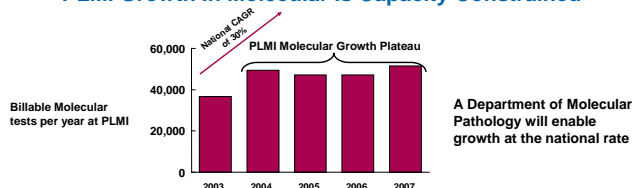
Proposal

- A new Department of Molecular Pathology (DMP) in the Pathology & Laboratory Medicine Institute located at the Main Campus but serving physicians and patients both in CCHS and globally
- Testing will include Pharmacogenomics, Cancer markers, Molecular basis for diseases (Cardiovascular, Inflammatory, Oncologic diseases, and others)
- Molecular testing is being done already, but will now be enhanced, coordinated and focused in one Department
- A DMP will allow us to bring in currently outsourced testing, with significant associated cost savings (Currently the top ten "Send Out" Molecular Tests = \$3.1 M Paid Out to reference labs in 2007)
- Increasing demand for molecular testing provides excellent opportunities for growth and for innovative & individualized patient care

Rationale / Opportunity Analyses

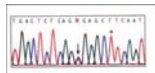
- Molecular Test Growth Outpaces Routine Clinical Laboratory Testing. The G2 survey of 300 laboratories estimated that 1/3rd of their total revenue will come from molecular testing during the next five years
- However, 1/3 of surveyed laboratories plan **no molecular assay implementation** during the next five years indicating a regional/national/international need that can be met
- There has been a 30% increase in molecular test volumes for laboratories in the last 2 years. Molecular testing for many cancers is becoming best clinical practice. Pharmacogenomics is becoming best practice for some drugs, providing therapeutic efficacy while minimizing adverse drug reactions & toxicity
- Scaling up to a national reference lab with increased demand is feasible
- Given that some space (L3) and some personnel are already in place, an exit strategy is not cost prohibitive

PLMI Growth In Molecular Is Capacity Constrained



Molecular Testing

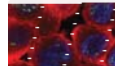
DNA and RNA-based diagnostic testing



DNA Sequencing – Mutation analysis



Detection of single nucleotide polymorphisms (SNPs)
- Diagnosis, pharmacogenomics, disease risk assessment



In situ hybridization with molecular probes
- cytogenetic studies & detect translocations associated with malignancy



Expression arrays
- mRNA expression measurement, association with prognosis and treatment response

SWOT Analysis

Strengths

- Integrated molecular pathology model
- Develop a new area of expertise for the Clinic
- Capture >\$1 M in current send out testing
- Scale up to a national reference lab
- Recruitment of molecularly skilled Professional Staff

Weaknesses

- Equipment, space, and personnel may be insufficient for the expansion
- Patchwork renovation history for space development
- Devoting FTEs/training/resources to rarely used tests
- Low MD awareness of new molecular tests
- Expensive assays

Opportunities

- Provide physicians with sophisticated diagnostic testing results, enabling individualized patient care
- Expand revenue from the most rapidly growing component of diagnostic testing
- Integrate subspecialty expertise with molecular testing not available from our competitors
- Expand into other burgeoning areas: Pharmacogenomics, direct clinical sequencing, and genomic microarray
- Core lab for research studies & collaboration
- Further enhance reputation of CCF & PLMI

Threats

- Inaction and falling behind
- Exclusive licensing granted to other reference laboratories
- Excessive royalty obligations erode profitability
- Excessive government regulation
- Other established reference labs
- Anticipated volume does not materialize

Proposal Budget

	Personnel	Capital
2008	\$171,000	\$450,000
2009	1,262,000	1,360,000
2010	895,000	2,490,000
2011	872,000	750,000
2012	260,000	0
Total	\$3,460,000	\$5,050,000

An Investment
is Required

Financial Performance

Year	Molecular Pathology		DPLM		% Molecular Margin of Total Revenue	% Molecular of Total Net Contribution Margin
	Net Revenue	Contribution Revenue	Net Margin	Contribution Revenue		
2002	1,046,393	(54,083)	139,141,420	69,471,499	0.75%	-0.08%
2003	1,213,969	(144,549)	148,466,152	73,415,951	0.82%	-0.20%
2004	1,576,413	91,112	160,753,185	77,383,686	0.98%	0.12%
2005	2,034,455	380,779	198,894,645	109,635,947	1.02%	0.35%
2006	2,359,662	409,706	223,752,331	124,757,821	1.05%	0.33%
2007	2,753,312	453,275	237,691,869	128,233,875	1.16%	0.35%

A New DMP Pays Back on Its Own

- Net present value: 0.5 M
- Payback: 6.3 Y
- Profitability Index: 1.1
- Return on Investment: 112%

Plan Implementation 2008-2012

- Reconfigure space in L3 to house Department
- Recruit additional physicians and technologists
- Two pronged approach to marketing locally and nationally
- Formally survey physicians and enhance stakeholders with specific molecular needs based on disease process
- Promote Integrated Molecular Medicine model in multiple clinical arenas
- Enhance educational paradigms for trainees and medical students