ENHANCED GENETIC SCREENING PLAN FOR THE B.C. MOLECULAR GENETICS LABORATORY: A FIVE YEAR BUSINESS PLAN

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Management of Biotechnology, Management of Technology

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ABSTRACT

Technological advances in research science have made the identification and diagnosis of genetic dysfunctions possible, and economically viable. This paper explores the growth in the genetic testing industry, and examines the social and fiscal benefits of an increased offering of genetic testing services for the British Columbia Molecular Genetics Laboratory. This study has effectively created a business case, or rationale, for expanding genetic testing services domestically by demonstrating that doing so will lead to a reduction in overall expenditures, an increase in revenues for the Molecular Genetics Laboratory, and a decreased reliance the outsourcing of services. In addition, this paper provides a comprehensive analysis of the genetic services industry, offering key findings and recommendations. The recommendations proposed in this paper are supported by in-depth financial projections, which demonstrate that the implementation of this business plan will create an increased social benefit for British Columbians, as well as an economically sustainable future for the Molecular Genetics Laboratory of British Columbia.
EXECUTIVE SUMMARY

The Molecular Genetics Laboratory (MGL), located within the Children’s and Women’s Hospital in British Columbia is the province’s sole provider of services for the identification and diagnosis of predictive genetic disorders. Advancements in molecular genetics and the sequencing of the human genome have instigated rapid growth in the genetic testing industry, and allowed for the development of new technologies to identify genetic lesions and chromosomal abnormalities. Innovative new technologies have driven up the operating costs for genetic testing services at a time when the publicly-funded healthcare system is looking for ways to cut expenditures. This paradox has forced providers of genetic services to find novel solutions to control spending while maintaining rapid, reliable, state-of-the-art services for patients in the province. This paper will be used by the MGL as an informed analysis that can then be passed to the relevant decision makers within the Provincial Health Services Authority (PHSA) and the Ministry of Health Services.

The MGL’s current budgetary constraints have forced the lab to outsource some services, which increases the labs overall expenditures while also sacrificing potential revenues (opportunity costs) that the MGL could generate if the tests were offered in-house. This paper examines the key social and fiscal benefits that would be realized if the MGL were to receive increased funding from the Ministry of Health Services and the PHSA for an expansion in test offerings and lab capacity. The identified social benefits are supported with a solid business case outlining the fiscal benefits of increased resources and the penalties of maintaining the status quo. Financial projections will show that maintaining the status quo, inadequate funding for a
limited test portfolio, is not the best approach for providing British Columbians with accessible genetic testing. In fact, under the current global funding scheme the MGL risks obsolescence because of an inability to innovate or to respond to external threats.

The recommendations proposed by this paper will include:

- an immediate injection of funds from the Ministry of Health Services to address the imbalance between actual expenditures and the MGL's operating budget
- the immediate hiring of additional laboratory technicians, thereby removing labor constraints;
- the development of a research and development arm at the MGL, charged with the mandate of identifying and implementing innovative technologies and solutions;
- the purchasing of additional laboratory equipment, which will remove a bottleneck in the sample processing pathway and allow the lab to realize increases in overall productivity;
- and, the formation of informal links between inter-provincial labs to enhance collaboration and facilitate coordination of testing services with the goal of achieving reduced transaction costs and the elimination of service redundancies.

The comprehensive analysis described herein has demonstrated that an increase in funding to the MGL will substantially increase British Columbia's social benefits while concurrently creating an economically sustainable future for the MGL.
ACKNOWLEDGEMENTS

We would like to thank both of our readers, Dr. Aidan Vining and Dr. Sudheer Gupta, for their support and mentorship throughout the development of this paper. We would also like to thank both Simon Fraser University and the Molecular Genetics Laboratory of British Columbia for the opportunity to present this business plan, and for considering the findings that have been outlined.
# TABLE OF CONTENTS

- Approval .................................................................................................................. ii
- Abstract .................................................................................................................... iii
- Executive Summary ................................................................................................. iv
- Acknowledgements .................................................................................................. vi
- Table of Contents ...................................................................................................... vii
- List of Figures ........................................................................................................... ix
- List of Tables ............................................................................................................. x
- Glossary and list of abbreviations ............................................................................ xi

1 Purpose of the Business Plan .................................................................................. 1
   1.1 Evolution of Genetic Testing .............................................................................. 2
   1.2 Incidence of Genetic Abnormalities ................................................................. 3
   1.3 Providers of Genetic Testing in B.C. ................................................................. 4
      1.3.1 The B.C. Molecular Genetics Laboratory ................................................... 5
      1.3.2 The B.C. Cancer Agency ........................................................................... 5
      1.3.3 The Academic Laboratory Genetics Program ............................................ 5
   1.4 The Molecular Genetics Laboratory ................................................................. 6
      1.4.1 History of the MGL .................................................................................... 7
      1.4.2 Reorganization and Finance Restructuring ................................................ 7
   1.5 The Aim ............................................................................................................. 9
   1.6 Scope ................................................................................................................ 10

2 Social and Fiscal Case for Increased Funding ....................................................... 11
   2.1 Growth in Genetic Testing .............................................................................. 11
   2.2 Social Benefits for Enhanced Genetic Testing ............................................... 12
      2.2.1 An Example of Social Benefits from Genetic Testing ............................... 13
      2.2.2 Realizing Social Benefits for B.C. ............................................................. 13
      2.2.3 Shadow Metrics for Social Benefits ......................................................... 15
      2.2.4 Social Costs of Heritable Genetic Defects in Canada and B.C. ............... 17
   2.3 Fiscal Benefits for Enhanced Genetic Testing .................................................. 20

3 Service Expansion Plan ............................................................................................ 23
   3.1 Synergies of Additional Testing ..................................................................... 25
   3.2 Service Identification Checklist ..................................................................... 26
   3.3 Most Demanded Tests .................................................................................... 28
   3.4 Boutique Test Selection ................................................................................... 37

4 Industry Analysis ...................................................................................................... 42
LIST OF FIGURES

Figure 1.0 B.C. Genetic Testing Facilities Structure ................................................................. 5
Figure 2.0 Synergies of Additional Genetic Tests ........................................................................ 26
Figure 3.0 The MGL's Current Organizational Structure ............................................................... 52
Figure 4.0 The MGL's Proposed Organizational Structure ............................................................ 53
Figure 5.0 Positioning Diagram 1 ................................................................................................. 56
Figure 6.0 Positioning Diagram 2 ................................................................................................. 56
Figure 7.0 Total Samples Received (2002-2007) ........................................................................ 61
Figure 8.0 Outsourcing (Referral) Expenditures (2002-2007) ......................................................... 62
Figure 9.0 Total Annual Budget ................................................................................................... 62
Figure 10.0 Total Budget vs. Actual vs. CPI Adjusted Budget ......................................................... 63
Figure 11.0 Non-Labor Funding .................................................................................................... 64
Figure 12.0 Budgeted Expenditures vs. Actual Expenditures ......................................................... 64
Figure 13.0 Actual Referred Out vs. Actual Revenue ................................................................... 65
Figure 14.0 Actual Budget Projections .......................................................................................... 67
Figure 15.0 Projected Outsourcing Demand ............................................................................... 68
Figure 16.0 Historical Demand for Proposed New Services (2004-2007) ..................................... 68
Figure 17.0 Projected Demand for Proposed New Services ............................................................ 69
Figure 18.0 Projected Revenues ..................................................................................................... 70
Figure 19.0 Referral (Outsourcing) Projections .......................................................................... 70
Figure 20.0 Projected Outsourcing of Samples .......................................................................... 71
Figure 21.0 Projected Labor Expenses ......................................................................................... 72
Figure 22.0 Billable Price for Services ......................................................................................... 73
Figure 23.0 Opportunity Costs (Lost Potential Revenues) ............................................................ 75
Figure 24.0 Projected Budget and Actual Spending (2008-2012) ............................................... 75
Figure 25.0 Identified MGL Bottlenecks ...................................................................................... 84
LIST OF TABLES

Table 1.0 Frequency of Genetic Disorders ................................................................. 4
Table 2.0 Social and Economic Benefit Shadow Metrics ........................................ 16
Table 3.0 Checklist for Most Demanded Tests ......................................................... 40
Table 4.0 Checklist for Boutique Tests ........................................................................ 40
Table 5.0 Average Annual Referral Frequency ......................................................... 41
Table 6.0 Strategic Alternatives ................................................................................ 57
Table 7.0 Financial Results Table ............................................................................. 76
Table 8.0 Sensitivity Analysis .................................................................................... 78
Table 9.0 Financial Summary .................................................................................... 82
Table 10.0 Additional Expenditures .......................................................................... 83
## GLOSSARY AND LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Term / Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td><strong>Phenotype</strong></td>
<td>The observable characteristics of an organism, collectively determined by the interactions of genes and the environment in which the organism is raised.</td>
</tr>
<tr>
<td><strong>Recessive</strong></td>
<td>A concept from Mendelian genetics, whereby a disease gene must be present in two copies in order for the disorder manifest itself. A single copy of the non-disease gene is sufficient to protect against onset of the disease.</td>
</tr>
<tr>
<td><strong>PHSA</strong></td>
<td>Provincial Health Services Authority Laboratory Services Authority</td>
</tr>
<tr>
<td><strong>MGL</strong></td>
<td>Molecular Genetics Laboratory at the Children's and Women's Hospital</td>
</tr>
<tr>
<td><strong>C &amp; W</strong></td>
<td>The Children's and Women's Hospital of British Columbia</td>
</tr>
<tr>
<td><strong>B.C.CA</strong></td>
<td>The British Columbia Cancer Agency</td>
</tr>
<tr>
<td><strong>MSP</strong></td>
<td>Medical Services Plan</td>
</tr>
<tr>
<td><strong>PLCO</strong></td>
<td>The Provincial Laboratory Coordinating Office</td>
</tr>
<tr>
<td><strong>PCR</strong></td>
<td>Polymerase Chain Reaction</td>
</tr>
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</table>
1 PURPOSE OF THE BUSINESS PLAN

Advancements in molecular genetics and the sequencing of the human genome have facilitated the development of novel technologies that are capable of identifying genetic defects not only perinatally, but also in mature individuals. This has created a shift in demand for genetic testing from mainly diagnostic testing to predictive testing. In addition, innovations in sequencing technologies have permitted testing to be carried out in high-throughput manners for large sections of the population. This has created the need for facilities with the capacity to carry out rapid, reliable genetic tests with state-of-the art technologies for the general population. However, Canada, along with several other nations, must be able to meet the demand for accurate testing within the confines of a publicly-funded healthcare system. This is the challenge facing our client, the Molecular Genetics Laboratory (MGL) at B.C.'s Children's and Women's Hospital in Vancouver, a tertiary-level laboratory that offers services to the entire province. The current population-based funding formula does not address the high fixed costs associated with providing specialized genetic testing services.

The MGL currently outsources approximately 7.2% of all tests performed which not only increases the labs expenditures, but also generates a reliance on external genetic laboratories that may have conflicting incentives. Thus the purpose of this business plan is to examine the social and fiscal costs and benefits of allocating additional healthcare dollars to the MGL. This additional funding will allow the MGL to increase the range of genetic testing performed in-house, thereby decreasing the need to outsource genetic testing.
1.1 Evolution of Genetic Testing

Ever since the DNA puzzle was solved by James Watson and Francis Crick in the 1950's, it has been accepted that DNA is the material that stores the blueprint for human life. Researchers now know that the sequence of DNA is transcribed into an intermediate molecule, RNA, and then translated into a linear arrangement of amino acids which form proteins, the structural molecules of cells. Slight changes to the sequence of DNA can have deleterious effects on the entire organism. These alterations, or mutations, can occur at the level of the gene or the chromosome. They can take the form of massive chromosomal rearrangements or simple point deletions (or insertions) resulting in the change of a single amino acid at the protein level. Despite the differences in scale, both types of mutations can have the same negative effect on the person.

Mutations within a genome occur fairly regularly. They can occur as a result of errors during DNA replication or they can be induced by chemical or UV trauma. The cell has mechanisms to guard against DNA damage, but they do not always correct mistakes and these can then be passed on to other generations (assuming the mutations occur in the germline). This can result in several possible scenarios. If mutations accumulate in cell cycle control genes, then a cancer can develop. In contrast, some mutations do not immediately manifest themselves; rather, they are passed on to subsequent generations as heritable diseases.

The discovery and characterization of restriction endonucleases, specialized enzymes that can cut DNA, in the 1970's led to a molecular biology revolution. These enzymes provided researchers with a tool to manipulate DNA sequences in a predictable, reproducible manner. Technologies were developed to identify large mutations within a genome, providing a means to associate specific disease with a patient's genetics. This led to the rise of genetic testing
programs to screen newborn babies for diseases that could be treated if they were identified early enough.

Testing to identify genetic anomalies has been available in Canada for several decades. One of the first hereditary diseases to be studied and assayed for was phenylketonuria during the 1960's, a disease that can severely affect brain development if left untreated. Subsequently, in the 1970's, prenatal testing became available for pregnant women at high risk of carrying children with chromosomal defects like trisomy-21, or Down's syndrome. These tests, along with other perinatal sampling, became standard practice for the next several decades.

Innovations such as the Polymerase Chain Reaction (PCR) and di-deoxy DNA sequencing allowed for a more rapid and refined look at a patient's genome, in so doing creating a market for predictive genetic testing. The rise in predictive genetic testing has resulted in a shift in focus away from chromosomal disorders to local gene changes. This form of pre-symptomatic testing is used to detect gene mutations that appear after birth, often much later in life. These tests are most beneficial for people who have family members with a genetic disorder, but who have no overt phenotype themselves. Predictive testing is used to identify mutations in a patient's genome that increase their risk of developing a genetic disease. The tests can indicate the probability that the individual will express the disease phenotype and help with decisions about medical care.

1.2 Incidence of Genetic Abnormalities

It is estimated that 2-3% of all live births result in babies with congenital defects or genetically-determined diseases (Genetic Interest Group, 2007). This implies that there will be over 10,000 babies born annually in Canada with congenital anomalies, 1200 of which will be in
the province of B.C. Researchers, health officials and government agencies have been trying to assess the costs and benefits of routine genetic testing for some time.

Table 1.0 Frequency of Genetic Disorders

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Frequency per 1000 Births</th>
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<tbody>
<tr>
<td>Neurofibromatosis Type-1/Type-2</td>
<td>0.4/0.05</td>
</tr>
<tr>
<td>Marfan Syndrome</td>
<td>0.1</td>
</tr>
<tr>
<td>Malignant Hyperthermia</td>
<td>0.2</td>
</tr>
<tr>
<td>Familial Periodic Fever</td>
<td>Rare</td>
</tr>
<tr>
<td>Rett Syndrome</td>
<td>0.1</td>
</tr>
<tr>
<td>Myotonic Dystrophy</td>
<td>0.125</td>
</tr>
<tr>
<td>Fascioscapular Humeral Dystrophy</td>
<td>0.05</td>
</tr>
</tbody>
</table>

1.3 Providers of Genetic Testing in B.C

In British Columbia, testing services for inherited and acquired genetic anomalies is carried out by a loose confederation of laboratories (represented in Figure 1.0) across the province, located mostly within the lower mainland of Vancouver. Together, these five genetic-testing labs comprise a group of nearly 60 individuals (including 11 physicians and scientists) assigned the mandate of providing timely, reliable testing for all British Columbians.

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1.3.1 The B.C. Molecular Genetics Laboratory

The MGL has the explicit mandate of testing for inherited genetic abnormalities with the exception of predispositions to cancers. The MGL is supported through capital payments that are dispersed by the Ministry of Health Services through the PHSA and then through the Children’s and Women’s Hospital. The funds are distributed to the hospital and then released as part of a ‘global funding’ program. The so-called global funding came into effect in 2004 and has effectively capped the MGL’s budget at 2002 levels.

1.3.2 The B.C. Cancer Agency

The B.C. Cancer Agency (B.C.CA), located adjacent to the Vancouver General Hospital is a research-focused facility with the goal of providing testing services for acquired genetic abnormalities and some testing for cancer predispositions.

1.3.3 The Academic Laboratory Genetics Program

The Academic Laboratory Genetics Program at the B.C.CH houses two laboratories incorporating biochemical, cytogenetic genetic testing facilities. All genetic tests performed by
the Academic Laboratory Genetics Program are reimbursable by the Medical Services Plan (MSP).

1.4 The Molecular Genetics Laboratory

Our client, the B.C. Molecular Genetics Laboratory ("MGL") is located at the Children’s and Women’s Health Centre of B.C., and falls under the control of the Laboratory Genetics division of The Department of Pathology and Laboratory Medicine (Provincial Health Services Authority, 2007). The MGL is "committed to providing high quality genetic health care to residents of B.C., while participating in and contributing actively to research and education in the field of Medical Genetics" (B.C. Children’s and Women’s Hospital, 2007). In order to meet these commitments, the Provincial Medical Genetics Program and the MGL offer a variety of services including:

- The evaluation and diagnosis of congenital anomalies and genetic diseases in fetuses, children, and adults;

- Genetic counseling regarding the risks of occurrence or recurrence of congenital anomalies, mental retardation and genetic disease;

- Inpatient, outpatient and outreach consultations about congenital anomalies, genetic diseases, and teratogen exposures; and

- Education about medical genetics for the public, for undergraduate, graduate and post-graduate students, as well as for health professionals in B.C.
1.4.1 History of the MGL

Genetic testing services in B.C. have been subject to several challenges ranging from ethical debates about the morality of the testing to funding inadequacies. In 1987, the PHSA instituted a five-year contract for the provision of genetic testing in the province. During this period, some tests were completed on a fee-per-service basis and billed through the Medical Services Plan (MSP), whereas others were remunerated on a lump sum basis. When the contract expired, a new payment system was initiated that saw payments for services-performed sent to the hospital as a pool of aggregate funds. The goal of this funding structure was to control what many believed would be exponential increases in the costs of performing genetic testing. As a result of the new funding policies, the MGL was forced to try to fulfill its mandate of providing rapid, reliable, state-of-the-art testing while operating with a severely limited budget. At the same time, the number of samples tested in the province was increasing, new and more complex tests were becoming available, patient expectations were growing, and operating costs were spiraling upwards.

1.4.2 Reorganization and Finance Restructuring

In June 2002, the Government of B.C. commissioned the Ministries of Health Planning and Health services to [sic] "...develop and implement efficiency mechanisms for the Medical Services Plan, Pharmacare, laboratory services, ambulances and regional services". In 2003, the Ministry completed a comprehensive review of laboratory services in B.C., which concluded that the system as it was organized and coordinated was not sustainable (B.C. PLCO, 2007). The key findings of the report were summarized as follows:

- The lab sector was highly disorganized and fragmented
- There was limited capacity to control escalating costs and demand
Expenditures in B.C. labs, among the highest per capita in Canada, were increasing at rates that exceed those of population growth.

Payment structure drives up utilization and costs upwards.

Perhaps the most significant fact the study uncovered was that lab expenditures in B.C. were significantly higher than the Canadian average, $115 and $77, respectively. This resulted in the taxpayers of B.C. paying an additional $100 million to $150 million for lab services relative to the rest of Canada (B.C. PLCO, 2007). The report also acknowledged that innovation was paramount to services such as genetic testing, where new technologies were constantly emerging and required large investments on the parts of the labs.

Later in 2003, the B.C. government established the Provincial Laboratory Coordinating Office (PLCO) with the responsibility and mandate for recommending reforms to improve the organization and delivery of laboratory services in B.C. The laboratory services reform had four strategic priorities:

1. A Renewed Model for B.C.'s Laboratory System
2. Quality, Performance & Utilization Management
3. Addressing Human Resources & Lab Academic Issues
4. Improving Information Technology & Information Management

The recommendations of the PLCO resulted in the reorganization of the Provincial Health Services Authority Laboratory Services Authority (PHSA). This process was initiated with the strategic goal of unifying the diverse individual PHSA laboratories into one single entity in order to better coordinate the specialized services of the disparate laboratories (PHSA, 2007). As
a result, the Children's and Women's Hospital's Department of Pathology and Laboratory Services, along with the B.C. Cancer Agency, the B.C. Centre for Disease Control, the B.C. Mental Health and Addiction Services (Provincial Toxicology) were amalgamated into the new PHSA. The PHSA's ascribed mandate was to increase the cost-effectiveness of its lab components in order to redirect those savings to patient care (PHSA, 2007).

The reorganization of the PHSA laboratories brought with it a new funding policy for the MGL. Although the MGL operates independently of the C & W hospital, the funding was (and continues to be) dispersed through the hospital in an aggregate pool. The MGL then performs the testing and bills the ministry through this pool of funds. The funding levels have been capped since 2002 and are inadequate to support the mission of the genetic testing centers to provide rapid, reliable tests for all British Columbians. This limited funding prevents the B.C. genetic centers from testing more than 32 of the possible 1131 genetic disease loci. The staff at these genetic centers has worked within these limitations through careful management, resulting in optimized productivity. However, thousands of tests are sent to other jurisdictions across North America because B.C.'s genetic centers are unable to meet demand or do not have the resources to complete the tests. As a result, the province and the testing centers have lost hundreds of thousands of dollars in potential revenues to other regions, dollars that could be redirected back into the B.C. genetic testing centers.

1.5 The Aim

The goal of this paper is to present a sound business case to be used to inform the B.C. Health Ministry with the aim of increasing the MGL's funding, enhance neonatal testing and to provide new genetic tests for the residents of B.C. By securing a reliable source of funds the genetic testing centers will no longer need to outsource services from other areas of North
America, rather the B.C. genetic centers could become a model for other jurisdictions with a public health care system: how to provide state-of-the-art, responsive, and marketable genetic services both within and outside the province while relying on capital supplied by a universal health care system.

1.6 Scope

For the purposes of this business plan, the scope has been limited to focus on the activities, funding and organization of the MGL. This limited scope has allowed for a more comprehensive and focused analysis of the operations and future prospects of the MGL. In the sections that follow, we will perform several tasks including:

- Outline proposed changes to the funding mechanism for the MGL
- Propose the addition of a subset of new tests for the MGL to offer
- Describe the costs and benefits associated with increasing funding (to expand testing) or keeping the status quo (no increase in funding)
- Identify the key stakeholders who have a vested interest in the success of this project
- Provide recommendations for the MGL regarding how to enhance its ability to respond to the demands of its disparate clients (patients and the B.C. Ministry of Health)
2 SOCIAL AND FISCAL CASE FOR INCREASED FUNDING

The implementation of an increased portfolio of genetic services at the MGL would result in 3 types of realized benefits. The three principle benefits are:

Social benefits; which are increased benefits for the B.C. community,

Fiscal benefits; which are increased monetary benefits, to be realized by the MGL and, as a corollary, the Ministry of Health and the taxpayers of B.C.

Internal benefits; which are specific benefits for the MGL

This section will evaluate the social and fiscal implications of an increased test portfolio at the MGL.

2.1 Growth in Genetic Testing

Genetic testing began in earnest in the 1950's when scientists developed genetic techniques that made it possible to detect chromosomal abnormalities that could be attributed to medical problems such as structural malformations, retardation and other diseases caused by genetic abnormalities. This technique allowed individuals with potentially devastating medical problems to be identified long before physical signs or symptoms of the disease appeared. Advancements in molecular biology, including the discovery of recombinant DNA techniques during the 1970s further spurred the popularity and growth of genetic testing.

The Human Genome Project (HGP) which was considered pragmatically 'complete' at 92% in 2005 has further boosted the growth and popularity of genetic research. The HGP
represented an international effort to map and sequence the entire human genome, premised on the hope that this genetic map would further research efforts, leading to treatments and preventative strategies for common and rare genetic disorders.

2.2 Social Benefits for Enhanced Genetic Testing

Predictive testing is successfully used in newborn screening programs to identify children that require immediate prophylactic care to prevent the manifestation of the disease phenotype. Such is the case with the aforementioned Phenylketonuria, a genetic disorder that will result in mental retardation of the child unless a strict diet with limited amounts of phenylalanine is adhered to. Testing for very specific DNA changes in the ret proto-oncogene in high-risk patients for the development of medullary thyroid carcinoma can circumvent the need for frequent monitoring. In the cases where the mutation is detected, pre-emptive action can be taken to remove the thyroid and prevent the onset of thyroid cancer, which can be fatal (Holtzman et al., 1997).

The benefits of predictive genetic testing can be quite substantial. If a carrier is of a Mendelian disorder is identified, he or she may opt not to mate with another known carrier of the disease. This would represent a significant reduction in the chances of a child being born with a crippling congenital defect. Since these children often require substantial medical intervention and hospitalization, it is a net social benefit if these births are reduced. This scenario has played out quite successfully in the Ashkenazic Jewish population, where the incidence of Tay Sachs disease, a fatal disease, has been reduced by over 90% (Buckles, 2001). Although this is an extreme example, it illustrates that there are social benefits stemming from genetic testing that can measured in one way or another. In this case, the decision to not mate has resulted in a net savings to the publicly-funded healthcare system. Similarly, if predictive
testing confirms that a patient is not a carrier of a disease gene, and the patient then opts to mate with a carrier of recessive trait, their decision to have a child has resulted in a net gain to society in the form of a future productive person.

2.2.1 An Example of Social Benefits from Genetic Testing

In 1991, researchers from Stanford University determined the costs and benefits of prenatal screening for cystic fibrosis (CF), a debilitating recessive disorder that is the most common lethal genetic disorder in Caucasians in the U.S (Garber & Fenerty, 1991). The direct costs of the disease were determined to be a combination of testing for CF, abortion or birthing costs, health care, and all other costs associated with treating or preventing the disease. Indirect costs were determined to be those costs that result from disability or early death, including lost wages and opportunities. Using this information, they were able to determine that the difference between lost wages under a testing-regime and those under a no-testing paradigm were over $175,000 per high risk pregnancy tested (in 1985 USD). Since that time, many provinces and states across North America have adopted screening programs for all live births, not just for high risk pregnancies. Although there has been debate about the cost-effectiveness of this approach, there is evidence that early identification of CF can help affected children live longer (Centers for Disease Control and Prevention, 2004). This highlights the fact that genetic testing is an important service that offers not only social benefits in the form of knowledge of one's probability of having a genetic disorder, but also fiscal benefits in the form of healthcare dollar savings.

2.2.2 Realizing Social Benefits for B.C.

There are several social benefits that the province and the MGL would realize as a result of expanding the genetic services in B.C. These include, but are not limited to, the following:
1. The increased portfolio of tests performed at the MGL will augment the laboratory personnel’s ‘hands on’ expertise in a wide variety of genetic testing methods and methodologies. This will enhance the MGL’s overall knowledge base providing them with a deeper understanding of genetic testing, and the ability to provide enhanced services through an increase in knowledge and experience.

2. The increased testing ability at the MGL will increase their ability to better serve the local British Columbia community. This increase in test variety incorporates an increase in knowledge enabling the MGL to better provide both counseling and support services. The ability to process the tests in-house will result in faster turn-around times for patient samples since there will be no transportation time required. In most instances, the MGL can process a sample internally within two weeks (Brett Casey, personal communication). Since the listed turn-around time for most out-sourcing labs is longer than two weeks, there will be an observed increase in patient throughput, allowing the patient to pursue prophylactic treatment faster.

3. With the increase of their testing portfolio, the size and reputation of the MGL is guaranteed to grow. This growth has the potential to attract highly skilled and talented individuals wanting to work in a large and prestigious genetic laboratory. This in turn, brings skilled labor to Canada and British Columbia increasing social benefit.

4. The planned additions to the MGL’s testing portfolio incorporate a number of tests designed to facilitate and support the local British Columbian academic research community. By incorporating genetic tests that are required by these academic groups, the MGL hopes to better serve the academic community. This has the potential to
generate a clustering effect in the province, highlighting both the MGL and local research community's genetic capabilities.

### 2.2.3 Shadow Metrics for Social Benefits

In most cases, when analysts assess the benefits that a given product or service will have on a population they use market prices of the good to measure it. Genetic testing services offered through a publicly-funded healthcare system do not have a market value. As a result, a proxy metric (a 'shadow metric') must be used in order to fully describe the social benefits that the province would realize from enhanced genetic testing services (Boardman et al., 1997).

Several types of impacts (costs & benefits) require valuations. These valuations can be based on market values of real goods and services or, if no market exists or no monetary values are assigned, they require shadow prices. In the case of adding new services, the MGL must consider both types of valuations as there will be both social benefits and fiscal benefits as a result of the expanded services offering.
We will discuss shadow values first in detail to describe the social benefits that the province could realize as a result of expanding genetic testing services. The benefits that we believe are most important to this decision are shown in table 2.0. We have selected the items under the heading 'Physical Infrastructure, Equipment, Supplies' for the following reasons:

- A calculation of the shadow costs can only be accomplished by assessing the cost savings resulting from the elimination the antonymous function (i.e. the shadow price of 'reduced health burden' would be the cost savings realized by the public health system resulting from a reduction in chronic care) (Boardman et al., 1997)

- Genetic diseases constitute some portion of the total social costs of caring for short and long-term disabilities

- A more responsive system that delivers fast, accurate results will contribute to both increased usage of the system and increased wellbeing of the patients that use it

The shadow metrics listed in the 'human resources' section of the table were selected for the following reasons:

### Table 2.0 Social and Economic Benefit Shadow Metrics

<table>
<thead>
<tr>
<th>Valuations based on market prices</th>
<th>Valuations that require shadow metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Infrastructure, Equipment, Supplies</td>
<td>Human resources</td>
</tr>
<tr>
<td>Testing Resources; Materials, Labor, Equipment</td>
<td></td>
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<tr>
<td>Reduced outsourcing</td>
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<tr>
<td>Product outputs</td>
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<tr>
<td>Reduced morbidity from long-term disability</td>
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<tr>
<td>Enhanced personal wellbeing</td>
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<tr>
<td>Reduced healthcare burden</td>
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<td>More responsive system</td>
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<td>Staff</td>
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<td>Facilities</td>
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<tr>
<td>Equipment</td>
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<tr>
<td>Increased productivity</td>
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<tr>
<td>Increased knowledge</td>
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</table>

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- A calculation of the shadow costs can only be accomplished by assessing the cost savings resulting from the elimination the antonymous function (i.e. the shadow price of 'reduced health burden' would be the cost savings realized by the public health system resulting from a reduction in chronic care) (Boardman et al., 1997)

- Genetic diseases constitute some portion of the total social costs of caring for short and long-term disabilities

- A more responsive system that delivers fast, accurate results will contribute to both increased usage of the system and increased wellbeing of the patients that use it

The shadow metrics listed in the 'human resources' section of the table were selected for the following reasons:
• By increasing their service offerings, the MGL will increase their knowledge of genetic disorders and the technologies used to detect them. This will allow the lab and its technicians to remain competitive and current on DNA testing procedures.

• Expansion of testing services to include a selection of rare disorders that are otherwise under-serviced by most labs. This will allow the MGL to function as a ‘boutique’ tester of services to meet domestic (within B.C.), inter-provincial and international demand. This will lead to increased fiscal benefits for the MGL that can be used or redirected as desired.

2.2.4 Social Costs of Heritable Genetic Defects in Canada and B.C.

A 1993 report published by the Public Health Agency of Canada calculated several costs associated with long-term disability in Canada. Using ‘productivity lost’ as a proxy metric for long-term disability costs they found that Canada loses an estimated $38.3 billion a year (Public Health Agency of Canada, 1993) in productivity to disease. The value of that loss in 2005 dollars is $53.1 billion (using the consumer price index as the discount rate). If preventable or manageable genetic disorders represent just 1% of that figure (which is likely a conservative estimate) then the total cost would be $531 million to Canada, of which B.C. would lose over $70 million. If the percentage of preventable or manageable cases were 10% of all long-term disability cases, the net social cost would rise to $5.31 billion for Canada and $700 million for B.C. Early identification of these cases using predictive genetic testing would allow for the use of prophylactic treatments to reduce or eliminate the disability. As a result, the social benefit of predictive genetic testing is equal to the cost of not identifying the disease before its onset.
Assumptions for this test:

- Genetic disorders account for a significant proportion of the lost productivity resulting from long-term disability in the 1993 statistics.

- At least some portion of the lost productivity can be attributed to preventable or manageable genetic disorders that were left untreated.

Calculations for social benefits arising from enhanced 'personal wellbeing' are more difficult to arise at, but they are likely to have effects on productivity as well. Knowledge of one's health is important because it can affect your desire and ability to perform in society. The social cost associated with a decrease in net productivity is equal to the social benefits that could be realized from improving personal wellness through knowledge and understanding of one's genetic background.

Measurements for the social benefits arising from 'a more responsive system' are similar to those for reductions in long-term disabilities. If the system is more responsive to the needs of its patients then more at-risk people will be tested and this will result in a decreased burden on the healthcare system. The actual value for the social benefits will be smaller than the value for reductions in long-term disabilities, but still significant.

Earning 'recognition as a leader' in the area of genetic testing services would create a net social benefit by attracting highly skilled researchers and technicians to laboratories within the province. In addition, it would provide fiscal benefits to the MGL in the form of increased demand for its services. The people of the province and the MGL would both benefit from value-added testing services (one as a consumer of the service and the other as a provider of higher quality testing) and from reduced costs to taxpayers as a result of the MGL becoming more self-
sufficient in terms of funding. On the other hand, maintaining the status quo, limited funding for a limited number of tests, will allow labs in other regions to benefit from increased knowledge and recognition which can be used to attract highly skilled researchers. These talented and educated scientists can then contribute to developing innovative technologies for more rapid, reliable genetic testing, placing the MGL at a disadvantage.

The status quo approach puts the MGL in a position where it runs the risk of falling behind its peers in terms of overall capabilities. This would create a situation where British Columbians receive services that are below the standards of many other regions in the world. This would result in a large relative social loss for the people of B.C. because the efficacy of the tests would fall below other regions and result in inaccuracies that create false-negatives and false-positives. These inaccuracies would result in a subset of patients receiving incorrect diagnoses, which in turn would prevent prophylactic treatment to delay or prevent onset of the disease.

Calculating the accuracy of available tests is difficult due to the variety of factors which contribute to the ability to correctly detect a disease gene. As a result, we can only extrapolate relative gains against other labs in relation to the MGL if they were to make investments that attracted skilled workers and new technologies. For example, If the MGL developed higher accuracy testing platforms that resulted in an average increase in accuracy of 5% then they would save the province between $3.5 million and $35 million in lost productivity annually (*using the calculations for lost productivity from above).
Assumptions for this calculation:

- Tests range in accuracy depending on the equipment, technical staff and conditions used.

- Increased services will result in improved recognition for the MGL.

'Increased knowledge' for technicians resulting from increased testing will enhance the ability of the lab to provide accurate and reliable results to the patients of the province. This will contribute to the ability of the lab to correctly detect mutations and protect against false-positives. The net social benefit of this will be similar to the calculations for the 'recognition as a leader' shadow value.

2.3 Fiscal Benefits for Enhanced Genetic Testing

The fiscal benefits for the MGL can be directly derived by examining market prices for similar services offered elsewhere. The reduction in the number of tests outsourced will have several fiscal impacts on the MGL and the province:

1. Genetic testing facilities have rigid requirements for sample processing that can create additional cost overheads. Moreover, shipping costs are incurred by the MGL when they are required to ship samples to another region for processing. These costs can be quite substantial due to the need to transport hazardous materials rapidly in a cooled state. The increase in in-house testing services at the MGL will decrease these additional cost overheads creating a fiscal benefit.

2. A primary fiscal benefit resulting from this venture is the realization of new revenues by reducing the number of genetic tests outsourced to other provinces and internationally.
Between 2002 and 2007 the MGL outsourced approximately $240,000 worth of testing services which could have generated a revenue of $480,000 with the inclusion of lost opportunity costs had the tests been performed internally (see ‘Financial Analysis’ section). As the number of tests performed is expected to grow with population increases, the fiscal benefits of this venture are quickly realized.

3. The increase in the MGL’s testing portfolio will bring the lab closer to its goal of becoming a ’one-stop-shop’ for genetic testing services. Rather than relying on external labs to provide processing capabilities, the MGL could move further along the value chain for more tests. This will make the MGL a popular destination for research facilities and smaller genetic testing laboratories requiring testing services. The enhanced ability to respond to external and internal demand should lead to a significant increase in demand and a decrease in marginal costs through the achievement of economies of scope.

4. The implementation of additional testing services into the MGL’s portfolio is expected to contribute to increased revenues from out-of-province testing sources. The ability to function as a one-stop-shop will help the MGL lower its expenditures and become more self-sufficient.

5. A strategic selection of new tests, those that are typically the most demanded tests that cannot be performed in-house, will significantly reduce the number of tests outsourced to other regions. As the Ministry of Health has a social obligation to perform any genetic test requested by a healthcare professional, it must find a laboratory that performs the service. This leads to outsourcing of services which can increase costs markedly (especially if the contracted lab charges a premium for the service). By targeting those
tests that are most often outsourced, as well as others that are not offered by many other labs, the overall costs of outsourcing will decrease substantially.

The combination of the identified social and fiscal benefits coupled with an increase in local testing capabilities has created a solid case for the implementation of this venture. The remainder of this paper will be dedicated to making a business case for the expansion of the MGL's services.
3 SERVICE EXPANSION PLAN

The goal of the MGL is to progressively add more value through the addition of new services, more staff and additional equipment. The objective of this venture is to enhance the MGL's competitive advantage, provide more genetic testing services for British Columbian's, limit the number of tests that are performed outside of the province, and contribute to the innovation of new genetic testing by supporting the local academic community.

The need for such a strategy is obvious: The MGL has performed extremely well despite chronic underfunding, as evidenced by the lab's productivity per dollar of funding, but as technologies continue to expand and become more complex they will inevitably become more expensive. Procuring the necessary supplies will be more costly, putting added pressure on an already limited budget. Similarly, labor costs will continue to rise as the need for highly technical, specialized workers increases.

We have examined a comprehensive list of possible tests that the MGL could offer that would enhance the lab's value chain. From this list, we have selected a subset that the MGL should offer that are consistent with the lab's outlined mission which is to provide "high quality genetic health care to residents of the province, while participating in and contributing actively to research and education in the field of Medical Genetics". The selection criteria are described below.

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1. The seven ‘most demanded’ tests: The seven tests that are most frequently outsourced to other labs

2. Three rare gene disorders (8 test loci): The MGL should become specialists in delivering services for three rare disorders which constitute 8 tests (known as ‘Boutique’ tests)

We have selected the subset of tests based on several criteria. The criteria we chose for the ‘most demanded’ tests selection are:

- Meets a significant local (provincial) demand
- Addresses a significant clinical issue

The criteria for the selection of ‘boutique’ tests are:

- The MGL has the core capabilities to provide the services
- There should be a limited number of labs that provide the tests, and none should be in Canada

The next section examines the ‘market’ for the new tests by reviewing the effects of the disease that the test identifies, the clinical need for the test, the need to meet the demand, and the expected health and business gains.
3.1 Synergies of Additional Testing

Increasing the range of tests offered by the MGL makes sense for the following reasons:

- The MGL already exists and is the only site in British Columbia dedicated to DNA testing for predictive inherited genetic disorders

- The new tests identified in this paper will utilize existing technology platforms available at the MGL. This allows the MGL to achieve economies of scope, decreasing the marginal cost of individual tests

- By utilizing existing equipment at the MGL, the initial outlay to increase the range of tests available will be minimal

- The increased test portfolio will bring the MGL closer to its goal of becoming a one-stop-shop for genetic testing services, increasing its attractiveness to other labs and research institutions

- The MGL has a pre-existing set of skilled labor that is difficult to replicate. Their knowledge will spill-over to new staff as they are hired and trained, leading to increased efficiencies

- Expanding the MGL’s testing portfolio will allow the MGL to better cater to the domestic and market demand for the ever-increasing supply of genetic tests
As represented in Figure 2.0, The MGL will achieve economies of scope by utilizing testing synergies, enabling them to achieve a lower marginal cost per individual test.

### 3.2 Service Identification Checklist

As stated above, the new services were selected based on certain criteria. In addition to the conditions previously listed, there are other considerations that must be taken into account. The following questions should be addressed:

- **Market demand**: Does sufficient demand for this service exist?
- **Competitive forces**: Are there a number of public or private labs offering the test that could act as competitors for the test?
- **Supply**: Does inexpensive access to the supplies of this product exist?
- **Number of jobs created**: How many jobs will be created by this opportunity?
• **Implications to the genetic testing community**: Do the additional tests have a positive impact on the research community?

• **Amount of financing required**: Are the overall capital requirements justified from a publicly-funded system perspective?

• **Project risk**: Are there significant risks that could make this venture very costly if the projected benefits are not realized?

• **Community support**: Is there community and stakeholder support for the initiative?

• **Timing of the project**: Will implementation of the new tests and hiring of new labor and equipment be accomplished in a reasonable time-frame as to maximize potential fiscal and social benefits?

• **Infrastructure and resources**: Is there sufficient available infrastructure and resources in the lab to accommodate new capacity?

Checklists for the two proposed types of tests are presented following section 3.4.
3.3 Most Demanded Tests

1. Neurofibromatosis Type-1/Type-2

Neurofibromatoses are a group of disorders that are characterized by abnormal growth of neural cell tissues. These disorders result in neuronal tumors and produce bone and skin anomalies (NINDS, 2007). Most affected individuals inherit the disease, but up to 50% of new cases arise spontaneously as a result of mutation. The disorders have been classified as type 1 (NF1) and type 2 (NF2). NF1 is more prevalent and less severe than NF2, but both can be debilitating and fatal in some instances. NF1 symptoms include headaches, seizures, bone malformations, and skin disorders. Symptoms are normally first apparent within the first 10 years of life. NF2, characterized by bilateral tumors on Cranial Nerve VIII, is far more difficult to diagnose and is often not detected until the tumors have caused significant damage. Both NF1 and NF2 require significant monitoring and care to ensure that tumors are treated early before they cause significant damage (NINDS, 2007).

Genetic testing for high-risk individuals can help identify the disease long before the onset of symptoms. Identification of diseased-individuals allows for prophylactic treatment to reduce the impact of the disease on the patient. Currently, physicians and clinicians must outsource tests for Neurofibromatoses to labs in other regions. The only other Canadian lab that performs the test is the London Health Sciences Centre (LHSC) in London, Ontario (Genetests, 2007). The turnaround time for this test is listed as approximately 6 weeks (LLSG, 2006) and requires that samples conform to rigid requirements in order to be processed. No prices are available for this test through the LHSC, but a private lab in Belgium, Gendia, has listed the service at €850 (approx. $1200 Canadian dollars) for NF2.
Social Benefits of testing:
- Improved life expectancy from identification of early stage tumors to prevent nerve damage (Reduced morbidity)
- MGL can provide faster results to patients and direct guidance
- Improved patient well-being

Fiscal Benefits:
- MGL would be able to achieve fiscal savings as their COGS is quite low on average (see Financials section)

MGL Benefits:
- Increased capabilities
- A more diversified portfolio of offerings
- Achieve economies of scope and scale through synergies

2. Marfan Syndrome (FBN):

This disorder has a highly variable clinical manifestation. Symptoms can vary in terms of severity and in terms of the organ systems that are affected. Most patients suffer from vision and eye-related issues including retinal detachment and early-onset glaucoma. The cardiovascular system is also often impacted, with issues ranging from dilation and swelling of portions of the heart to predispositions to tears in cardiac tissue (Dietz, 2005).

Molecular genetic testing of the FBN1 gene, the only gene known to be associated with the disease, can detect 70-93% of mutations (Dietz, 2005). As an autosomal dominant disorder, 50% of the children of an affected individual will exhibit symptoms of the disease. Early detection of the disease is critical since it affects both vision and the cardiovascular system. Left undiagnosed, patients can incur permanent damage to their vision or, worse, fatal heart-failure.

The MGL offers linkage testing for FBN, but this requires prior identification of genetic markers that are associated with the disease gene (i.e. DNA sequences that are close to the
disease gene that would be expected to be inherited along with the FBN1 gene). If this information is unavailable, molecular analysis of the DNA sequence would be required and this would necessitate outsourcing to other labs with the capabilities to perform the test. No other lab in Canada offers sequence analysis; therefore outsourcing must involve an international lab.

Gendia offers the test for €1300 (approximately $1850 Canadian dollars) (Gendia, 2007). The Harvard Medical School also offers full bidirectional sequencing of the FBN1 gene for $1599 USD (approximately $1675 Canadian dollars) with a turnaround time of about 6 weeks.

Social Benefits of testing:
- Improved well-being for patients if vision or cardiovascular damage is prevented
- MGL can provide faster results to patients and direct guidance

Fiscal Benefits:
- The costs of outsourcing are prohibitively expensive
- The MGL would be able to provide pecuniary savings because their average COGS is quite low (see Financials section)

MGL Benefits:
- Increased capabilities
- A more diversified portfolio of offerings
- Achieve economies of scope and scale through synergies
- Reduce dependence on providers of the testing

3. Malignant hyperthermia susceptibility (MHS):

MHS is a pharmacogenetic disorder, meaning that the manifestation of the disease state is dependent upon administration of a triggering compound. In the case of MHS, anesthetics trigger stores of calcium in muscle to be released, leading to muscle contraction and increased cellular metabolism, resulting in production of heat. This process can cause cardiac arrhythmias (irregular heartbeats) or even heart failure (Rosenberg and Dirksen, 2006).
To date, 3 genes have been shown to confer MH susceptibility. MHS1 is associated with mutations in RYR1 and a molecular test is available to detect these mutations. The disease is inherited in an autosomal dominant fashion, implying that 50% of the children of an affected parent would carry the disease gene. If MHS is detected then prophylactic measures can be taken to minimize exposure to anesthetics and, in some extreme instances, limit physical activities.

Testing for MHS is available through the Molecular Diagnostics Laboratory in Toronto (no price or turnaround time provided). Gendia, the for-profit Dutch company, offers testing for €700 (approximately $1000 Canadian dollars) (Gendia, 2007).

**Social Benefits of testing:**
- Prevention of possible complications arising from the use of anesthetics
- Reduce chance of death (increased productivity)

**Fiscal Benefits:**
- The MGL would be able to provide pecuniary savings because their average COGS is quite low (see Financials section)

**MGL Benefits:**
- Increased capabilities
- A more diversified portfolio of offerings
- Achieve economies of scope and scale through synergies

4. Rett Syndrome:

This sex-linked (the mutation is carried on the X chromosome as opposed to one of the other 22 chromosomes, or autosomes) dominant disorder manifests in a range of learning disabilities from mild impairment in females to mental retardation syndromes in males. Diagnosis of the disease can be through clinical diagnostic criteria after the onset of symptoms,
or it can be accomplished through genetic testing (prenatally or post-natally). Since it is a dominant disorder 50% of the children of carriers can expect to have inherited a defective chromosome (Christodoulou, 2001) There is no effective way to prevent the onset of symptoms or to minimize their effects, so afflicted children and their families can only expect psychosocial support from the healthcare system. If the tests are conducted prenatally, then the family has the option of terminating the pregnancy.

Three labs in Canada offer testing for Rett syndrome, which includes full sequencing of the gene. No prices for the test are available, but the LHSC in London, Ontario has listed the turnaround time for the test at 3 months (LLSG, 2006). A similar test offered by the City of Hope's Clinical Molecular Diagnostic Laboratory in California offers the test for a negotiated price (not available) within 5 weeks (City of Hope: CMDL, n.d).

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### Social Benefits of testing:
- Offers patients the choice of whether or not to pursue a pregnancy or to abort a pregnancy (proxy benefit: reduced burden on the healthcare system)
- Faster turnaround time for diagnosis increases patient well-being

### Fiscal Benefits:
- The MGL should be able to provide pecuniary savings because their average COGS is quite low (see Financials section)

### MGL Benefits:
- Increased capabilities
- A more diversified portfolio of offerings
- Achieve economies of scope and scale through synergies
- Reduce dependence on providers of the test
5. Myotonic Dystrophy Type 2:

A neuromuscular disease characterized by slow relaxation of skeletal muscle tissue following contraction as well as general muscle dysfunction. Onset is normally in the third decade of life and diagnosed by standard PCR techniques. The disease state is caused by an unusual expansion of nucleotides (the letting of the DNA alphabet) within a gene region for the CNBP gene, the only gene known to affect this disorder. Children of an affected parent will receive a disease chromosome 50% of the time. Prenatal testing of at-risk individuals can be done using targeted mutation analysis (a molecular biology technique that involves looking at a very specific, small region of DNA for a known defect).

Early diagnosis is critical for congenital myotonic dystrophy to ensure that the patient receives intervention that will influence the ability of the child to succeed later in life. Surgeries for uncoordinated eye muscles and/or special education are some of the potential prophylactic steps that can be taken to aid with the progression of the disease (Muscular Dystrophy Association, n.d.). This prophylactic step can improve the future well-being of an affected child and reduce the overall burden to the healthcare system.

Genesis Genetics Institute in the U.S. offers the test as part of its preimplantation genetic screening program for patients undergoing in vitro fertilization (Genesis Genetics Institute, 2007). No cost information or turnaround time is provided. Athena Diagnostics Laboratory in Massachusetts reports a 4 week turnaround time for testing, but does not report the nominal fee of the test (Athena, 2007).
Social Benefits of testing:
- Early diagnosis can offset some of the negative symptoms later in life (increased well-being; decreased morbidity)
- Prenatal tests allow the parents to make an informed choice about options to terminate a pregnancy (reduced healthcare burden)

Fiscal Benefits:
- The MGL should be able to provide pecuniary savings because their average COGS is quite low (see Financials section)

MGL Benefits:
- Increased capabilities
- A more diversified portfolio of offerings
- Achieve economies of scope and scale through synergies
- Reduce dependence on providers of the test

6. Fasioscapulohumeral Muscular Dystrophy (FSHD):

FSHD is a neuromuscular disorder that manifests itself in affected individuals normally before the patient reaches the age of 20. The disease is characterized by the slow, progressive asymmetric wasting of the muscles of the face, shoulder and upper arms. The severity of the disease is variable, but about 20% of affected patients require a wheelchair at some point in their life.

The disease is inherited in an Autosomal dominant manner, meaning that 50% of the progeny of a parent carrying a disease gene would also harbor the defective allele. Testing for the disease is accomplished using targeted mutation analysis to detect the presence or absence of a large deletion in the gene.

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Prospective parents worried about being carriers can submit to testing prior to trying to attempting to conceive a child, or submit to prenatal testing (Chorionic Villus Sampling or amniocentesis). This allows for the parents to make an informed decision about the potential that their child would have of inheriting the disease.

There are two labs in Canada that offer the test for FSHD, the Alberta Children’s Hospital and the Children’s Hospital of Eastern Ontario, but neither lab reports the nominal fee or turn-around time of the tests. Leiden University Medical Center in the Netherlands offers to provide the test for €720 for prenatal testing or €682 for postnatal testing (LUMC, 2007). The turnaround time is not listed, but the Athena Diagnostics Laboratory reports a 3-4 week turnaround for the test (Athena, 2007).

**Social Benefits of testing:**
- Offers patients the choice of whether or not to pursue a pregnancy or to abort a pregnancy (proxy benefit: reduced burden on the healthcare system)

**Fiscal Benefits:**
- The MGL should be able to provide pecuniary savings because their average COGS is quite low (see Financials section)

**MGL Benefits:**
- Increased capabilities
- A more diversified portfolio of offerings
- Achieve economies of scope and scale through synergies
- Reduce dependence on providers of the test

7. **Familial Periodic (Hibernarian) Fever (TRAPS):**

TRAPS are a collection of inherited inflammatory disorders caused by a series of genetic mutations on chromosome 12 that each result in a set of stereotypical symptoms. The most
Salient features of the disease are dramatic episodes of high fever, severe pain in the abdomen, chest or joints, and inflammation of the eyes or conjunctiva. Although not normally fatal, some patients can accumulate blood proteins in vital organs leading to amyloidosis, a potentially deadly condition (NAIMS, 1999). Early detection is important as a protection against this condition.

There is evidence that the disease is inherited in an Autosomal dominant manner, indicating that 50% of the children of a carrier would receive the defective copy of the chromosome. Testing for the mutations involves bi-directional PCR of genomic DNA, which can be done either prenatally or post-natally. The reasons to procure a test include confirmation of a physician diagnosis, to differentiate the condition from other TRAPS disorders and to aid in the selection of an appropriate treatment.

There are only 5 labs listed on GeneTests.com, a repository of genetic testing materials, services and laboratories, which perform DNA testing for TRAPS. GeneDX Inc., a Maryland-based company, offers the test to consumers for a price of $1500 for prenatal sampling, or $350-$650 for postnatal testing (GeneDx, 2007). The listed turnaround time is approximately 2-4 weeks.
Social Benefits of testing:
- Confirmation of a physician’s diagnosis (increased well-being)
- Differentiate disease from other TRAPS disorders allows for a more proactive treatment (increased well-being)
- Faster turnaround time for diagnosis increases patient well-being

Fiscal Benefits:
- The extremely costly prenatal test for the disorder could be reduced if in-house testing is employed. (see Financials section)

MGL Benefits:
- Increased capabilities
- A more diversified portfolio of offerings
- Achieve economies of scope and scale through synergies
- Reduce dependence on providers of the test

3.4 Boutique Test Selection

The MGL, through Brett Casey, has indicated a desire to pursue a strategy that would see the MGL become a leader in the testing of several rare diseases ('boutique testing'). The addition of these tests would not only increase the labs portfolio of services, but it would also increase awareness about the MGL amongst other genetic testing labs and research centers. Moreover, the tests would allow the MGL to better support the local academic community by positioning itself as a provider of these unique tests. This would essentially change the strategic position of the lab within the genetic testing services industry, making it a servicer of niche market demand.

We have selected 8 tests that should be priority additions to the MGL’s portfolio. These tests were selected based on their relative uniqueness within the market. The social benefits, fiscal impact and MGL-specific profits will not be discussed in great detail (as previous reports...
have concluded that the need for these tests is necessary and warranted⁴). Briefly, the tests that have been selected are:

- **Infantile Epilepsy**
  
  o **Test loci**: SCN1A
  
  o **Description**: characterized by convulsions brought on by a fever in infants or small children. During a febrile seizure, a child often loses consciousness and shakes, moving limbs on both sides of the body.

- **Long QT Syndrome**
  
  o **Test loci**: KCNQ1, KCNH2, SCN5A
  
  o **Description**: characterized by QT prolongation and T-wave abnormalities on the ECG; can lead to arrhythmia’s or cardiac infarctions.

- **Periodic Fever Syndromes**
  
  o **Test loci**: TNFRSF1A, CIAS1, MEFV, MVK
  
  o **Description**: characterized by long, dramatic, episodes of high fever, severe pain in the abdomen, chest, or joints; skin rash; and inflammation in or around the eyes.

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⁴ A previous report by F. Bell and M. Patrick (2007) concluded that the MGL has the capabilities to implement testing for Long QT syndrome.
Social Benefits of Boutique Testing:
- Increased patient well-being
- Decreased morbidity
- Increased productivity
- Decreased Healthcare burden

Fiscal Benefits:
- In most cases, the MGL can provide cheaper servicing in-house than through outsourcing (see Financials section)
- Increased Revenues
- Decreased Expenditures
- Realizing economies of scale and scope

MGL Benefits:
- Increased capabilities
- A more diversified portfolio of offerings
- Achieve economies of scope and scale through synergies
- Reduce dependence on providers of the test
- Recognition as a leader in the testing of certain diseases
- Enhanced exposure amongst the testing community
- More control over the genetic testing value-chain

Checklists for the selection criteria for both the ‘most demanded’ tests and the ‘boutique’ tests are shown in Tables 3.0 and 4.0, respectively. Table 5.0 shows the frequency of outsourcing the specific tests. Together, these tables demonstrate that both sets of tests (‘most demanded’ and ‘boutique’) conform tidily to our selection criteria and, as a consequence, would be a good fit with the MGL’s existing capabilities.
### Table 3.0 Checklist for Most Demanded Tests

<table>
<thead>
<tr>
<th>Selection Criteria</th>
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</tr>
</thead>
<tbody>
<tr>
<td>High Market Demand</td>
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</tr>
<tr>
<td>High Competitive Forces</td>
<td>✓</td>
</tr>
<tr>
<td>Inexpensive Access to Supplies</td>
<td>✓</td>
</tr>
<tr>
<td>Number of Jobs Created</td>
<td>3</td>
</tr>
<tr>
<td>Positive Effect on Research Community</td>
<td>✗</td>
</tr>
<tr>
<td>Sufficient Benefit from Costs</td>
<td>✓</td>
</tr>
<tr>
<td>High/Costly Risk</td>
<td>✗</td>
</tr>
<tr>
<td>Community &amp; Stakeholder Support</td>
<td>✓</td>
</tr>
<tr>
<td>Sufficient Timing to Realize Benefits</td>
<td>✓</td>
</tr>
<tr>
<td>Sufficient Infrastructure</td>
<td>✓</td>
</tr>
</tbody>
</table>

### Table 4.0 Checklist for Boutique Tests

<table>
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</thead>
<tbody>
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</tr>
<tr>
<td>High Competitive Forces</td>
<td>✗</td>
</tr>
<tr>
<td>Inexpensive Access to Supplies</td>
<td>✓</td>
</tr>
<tr>
<td>Number of Jobs Created</td>
<td>3</td>
</tr>
<tr>
<td>Positive Effect on Research Community</td>
<td>✓</td>
</tr>
<tr>
<td>Sufficient Benefit from Costs</td>
<td>✓</td>
</tr>
<tr>
<td>High/Costly Risk</td>
<td>✗</td>
</tr>
<tr>
<td>Community &amp; Stakeholder Support</td>
<td>✓</td>
</tr>
<tr>
<td>Sufficient Timing to Realize Benefits</td>
<td>✓</td>
</tr>
<tr>
<td>Sufficient Infrastructure</td>
<td>✓</td>
</tr>
</tbody>
</table>
Table 5.0 Average Annual Referral Frequency

<table>
<thead>
<tr>
<th>Service (Genetic Screen)</th>
<th>Average Annual Referral (Outsource) Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurofibromatosis Type-1/Type-2</td>
<td>4.5</td>
</tr>
<tr>
<td>Marfan Syndrome</td>
<td>2.25</td>
</tr>
<tr>
<td>Malignant Hyperthermia</td>
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</tr>
<tr>
<td>Familial Periodic Fever</td>
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</tr>
<tr>
<td>Rett Syndrome</td>
<td>6.0</td>
</tr>
<tr>
<td>Myotonic Dystrophy</td>
<td>0.5</td>
</tr>
<tr>
<td>Fascioscapular Humeral Dystrophy</td>
<td>24.5</td>
</tr>
<tr>
<td>Infantile Epilepsy (SCN1A)</td>
<td>N/A</td>
</tr>
<tr>
<td>Long QT Syndrome (KCNQ1)</td>
<td>N/A</td>
</tr>
<tr>
<td>Long QT Syndrome (KCNH2)</td>
<td>N/A</td>
</tr>
<tr>
<td>Long QT Syndrome (SCN5A)</td>
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</tr>
<tr>
<td>Periodic Fever Syndromes (TNFRSF1A)</td>
<td>N/A</td>
</tr>
<tr>
<td>Periodic Fever Syndromes (CIAS1)</td>
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</tr>
<tr>
<td>Periodic Fever Syndromes (MEFV)</td>
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<tr>
<td>Periodic Fever Syndromes (MVK)</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Total Average</strong></td>
<td><strong>6.1</strong></td>
</tr>
</tbody>
</table>
4 INDUSTRY ANALYSIS

The viability and growth rate of the MGL relies heavily on the state of its environmental conditions. In order to examine the MGL’s strategic position within the external environment, we have employed a ‘forces’ analysis that identifies key strictures that shape the genetic services industry. The most predominant of these forces controlling opportunities and threats have been identified below:

Extent of Rivalry

Within the local environment, the MGL essentially functions as a monopoly. The B.C. Ministry of Health has charged the MGL with the responsibility of providing DNA testing for heritable diseases. Internationally, the MGL competes on a per-test basis with as few as one other lab, or as many as 1000 genetic testing facilities. These facilities typically service their own domestic markets; however, when their services are externalized they compete globally on price, quality, turnaround time, and one-stop-shopping functionality. The MGL will predominantly attract Canadian and North American customers due to the reduced transaction costs associated with transport and collaboration. The purchasing power of the U.S. dollar may spur additional interest from American facilities looking to externalize some testing services.

The extent to which the MGL can currently compete is severely limited by their insufficient staffing levels and their limited portfolio of in-house testing services. An increased staffing level and higher levels of productivity would enable the MGL to achieve economies of scope, lowering their marginal cost per test. Likewise, the additional in-house testing services
would reduce MGL’s reliance on external genetic testing facilities which currently leaves them susceptible to many externalities which could in turn negatively affect the B.C. community.

Additionally, the MGL’s current excess capacity in both physical space and, to some extent, their equipment, provides the MGL with an opportunity to add additional tests to their current portfolio, increasing throughput with minimal additional funding. In fact, we have shown that the MGL could increase output to 1132 samples/FTE from its current 906/FTE see ‘Financial Analysis’ section). These solutions combined will enhance the MGL’s ability gain a competitive advantage within the genetic testing industry.

**The Threat of New Entrants**

The B.C. Ministry of Health’s current restrictions guarding against the privatization of domestic genetic testing services creates significant barriers to entry, granting the MGL natural monopoly powers within the province. This is coupled with the MGL’s ability to achieve economies of scale and scope through its product offerings. The threat of entrants into the global market however remains constant, forcing the MGL to compete for externalized services. The biggest threat to the MGL would be the privatization of testing services. This threat is currently guarded against because of provisions contained in the Canada Health Act, which guarantees access to health care services. If this barrier were removed, the threat of new entrants would be real and would lead to increased competition for the MGL and loss of their monopoly status.

**The Bargaining Power of Suppliers**

The suppliers to the genetic testing industry provide raw materials used in the genetic diagnostics. The suppliers of di-deoxy sequencing supplies, reagents and enzymes aggressively
compete in a Bertrand (price) system. This robust competition between suppliers allows the MGL to achieve cost savings through reduced prices. The MGL’s increased productivity levels will require higher levels of supplies to be sourced, enabling the MGL to achieve further cost savings from bulk purchases. If the threat of supplier power was to increase, the MGL could collaborate with the PHSA’s other testing facilities, effectively cartelizing the purchasing of genetic supplies domestically or internationally.

**The Bargaining Power of Domestic and International Customers**

The MGL, operating within the public sector has a primary objective of catering to the B.C. community. The MGL’s domestic customers consist primarily of physician-referred patients and the local academic research community. Neither group has significant bargaining power to influence the MGL because neither group is responsible for payments because the MGL’s services are paid-for in full by the Ministry of Health.

Pay-per-service tests fees for out-of-province customers could be influenced by the power of the buyer, but this is unlikely given that no one buyer accounts for a disproportional share of the MGL’s service demand.

Switching costs for out-of-province customers will be low, so there will be some potential for bargaining; however, the boutique tests are offered by only a select few labs, so there are limited labs to switch to.

**The Threat of Substitute Services**

Currently there is no substitute in B.C. for the genetic analysis services provided by the MGL. With the advent of the sequenced human genome, and the observed demand increases, it
is expected that genetic testing will experience continued growth for years to come. It is unlikely that a substitute could appear in the short-term, ensuring the MGL will remain at the forefront of the identification of genetic abnormalities and disorders. In the long-term, the threat of substitutes will grow as new technologies and innovations, including direct-to-consumer testing, come on-line. It is therefore imperative that the MGL invest in R&D to stay attuned to new business models and new technology platforms.

However, due to the extensive list of competitors in this industry, the MGL faces the constant challenge of competing for pay-for-services from external entities. The creation of a one-stop-shop image with the incorporation of additional tests into the MGL’s portfolio will increase their attractiveness when compared to competing genetic testing facilities.

The Role of Government

The Canada Health Act, passed by the federal government in 1984, is the legislation for publicly funded health care insurance. The function of the Canada Health Act is:

"to protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers." (Health Canada, 2005)

Genetic testing services fall within the definition of an insured health service and therefore the tests are guaranteed free access to all patients. Moreover, there are provisions within the act that place limits on private clinics, and their ability to receive payments from the publicly-funded system. The B.C. Ministry of Health does not currently control service pricing or acceptable standards. Rather, they have elected to disperse funds to the MGL through a global funding program. The funds are budgeted based on historical projections, and these projections
are lower than the actual costs of providing the tests. As a consequence, even if a private lab were to enter the local industry, there would be no room for profitability.

**The Role of Collaborators**

Domestically, the MGL is connected to its customers through physician-referrals; thus, the physicians are acting as collaborators with the MGL to ensure that there is a demand for their services. Collaborative efforts between the MGL and physicians will create a ‘front-end’ advocacy and support group (the physicians) for the MGL. In addition, the MGL should aim to develop strong relationships with the local academic research community, with the dual purpose of aiding the local research community and increasing the MGL’s awareness and visibility. Advancements in this relationship may offer additional economies scale and knowledge as well as the possibility of jointly sharing the risks involved with the implementation of the proposed boutique tests. Currently, the MGL has begun to develop linkages with local research, but more efforts should be made to enhance collaboration with the referring physicians.

It is important to point out that there is currently a lack of collaboration between the MGL and other Canadian genetic testing facilities. This is mostly the result of difficulties in coordinating activities in a federal state such as Canada. Each province has exclusive jurisdiction over the administration of healthcare services, making it difficult to articulate a national vision for genetic testing services in Canada. This negatively affects the MGL and other Canadian genetic testing centers because there is a lack of coordination and collaboration that could help with making the delivery of genetic testing more affordable, rapid and reliable.
Life-cycle of Services

The analysis of the proposed additional services for the MGL has taken into account the lifecycle of the existing and new tests. The additional services will provide synergies exploitable with existing supplies and equipment, increasing the productivity levels of the MGL. The identification and diagnosis of genetic disorders does not mature or expire as in many traditional markets, enabling the MGL to maximize output without pruning existing services. However, The MGL’s current lack of research and development in the development of new genetic testing methods and techniques may leave them in the wake of genetic labs on the forefront of new innovations in this field.
5 MOLECULAR GENETIC LABORATORY CURRENT SITUATION
ANALYSIS

This section will perform an analysis of the MGL’s current situation. A comprehensive internal analysis will provide a clear picture of the MGL’s current strengths, weaknesses and resource levels. Critiques of the MGL’s strategic positioning will identify the advantages and disadvantages of strategic alternatives.

5.1 Internal Analysis

Identifying the MGL’s internal (S)trengths and (W)eaknesses, provides objective information that matches resources and capabilities to the competitive environment. The internal analysis therefore identifies problems that require addressing and attributes requiring nurturing.

Strengths; The MGL’s strengths are its resources and capabilities that can be used as a basis for developing a competitive advantage and include:

- The MGL’s current output per person (FTE) is very high. Their current productivity levels outperform many other genetic labs.\(^5\)

- The MGL’s current management is driven, committed and focused. This strong management team assures a well-informed strategic direction for the MGL

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\(^5\) Identified in “Analysis of the Provision of Molecular Genetic Testing for Long QT Syndrome by the Molecular Genetics Laboratory” (Bell, F. Patrick, M. 200)
• The MGL’s leadership is consistently looking to improve their level of quality and the range of services provided by the MGL.

• The MGL’s current workforce consists of invested, dedicated, intelligent and experienced staff that are eager and willing to expand their knowledge and technical skills.

• The MGL currently maintain the core equipment and facilities necessary to undertake a broad range of additional services and ensure they are available in a timely manner and to a degree of quality necessary to compliment their current services.

• The MGL have a small organizational structure allowing for effective organizational communication and planning. This facilitates rapid responses to changes in market demand, as there is little bureaucratic red tape to cross.

**Weaknesses:** The absence of certain strengths may be viewed as a weakness, for the MGL these are:

• The MGL currently performs a limited set of genetic testing internally making them reliant on external genetic labs. This makes the MGL susceptible to market fluctuations, changing demand and enforced time restraints.

• The MGL’s limited set of in-house genetic testing makes them a less favorable choice for external entities when selecting a genetic lab to perform tests as one-stop-shopping is preferable.
• The MGL is currently understaffed, resulting in a processing bottleneck that decreases the labs throughput

• The MGL's externally sourced genetic tests reduce the lab's annual revenues that could be acquired by offering in-house services. This results in significant pecuniary costs to the B.C. Ministry of Health and B.C. taxpayers. It also results in a sample processing bottleneck, decreasing the lab's throughput capabilities

• The MGL's current range of genetic service is limited by their current technological equipment. Although labor is the primary bottleneck, equipment utilization is approaching maximum capacity. The MGL should examine the feasibility of incorporating additional equipment such as a robotic liquid handling station, PCR instruments and an upgraded sequencer into their current infrastructure

• MGL's employees lack experience with new techniques and technologies associated with additional genetic testing

• The MGL has inadequate funding which currently prohibits them from attracting or maintaining appropriate human resources and technology

• The MGL is currently incapable of meeting the increasing demand of genetic testing without appropriate resources
Internal Analysis Summary

The internal analysis has illustrated the current state of MGL and molecular genetic testing in B.C. which can be seen as both discouraging yet hopeful. The MGL is at a critical stage in its development where key strategic decisions and alternatives must be evaluated ensuring the success and ongoing prosperity of genetic testing in B.C. The MGL’s capacity and vision for growth must be utilized in an effort to keep pace with advancements in genetic testing and the global community.

The positive opportunities outlined in this analysis have a limited time span; thus should the PHSA and the Ministry of Health delay their decision to adequately address the MGL’s funding and staffing levels, then the quality and reliability of genetic testing services in B.C. may decrease relative to other jurisdictions.

To succeed, the MGL must look to utilizing and nurturing its strengths while overcoming its weaknesses through the implementation of the paper’s identified recommendations.

5.2 Organizational Structure

This section is designed to deconstruct the MGL’s organizational structure, making commentary on identified problems and suggesting recommendations for changes to better fit the MGL’s proposed expansion. An analysis of the larger organization, PHSA is beyond the scope of this paper.

Current Organizational Structure

The MGL’s current organizational structure is shown in Fig. 3.0. This depicts a typical simple organizational structure in which various levels of authority govern subordinates actions.
This organizational structure has formed naturally at the MGL allowing for efficient synergies and performance levels to be achieved at the MGL. This current structure allows for optimal performance utilizing the MGL’s current resources.

![The MGL's Current Organizational Structure](image)

**Figure 3.0** The MGL’s Current Organizational Structure

**Proposed Organizational Structure**

The MGL’s proposed organizational is the structure that best ‘fits’ the MGL’s business model and current strategy. Fig. 4.0 graphically illustrates the proposed structure that would be best suited to match the needs, goals and visions of the MGL. This new structure is designed on the premise that there will be new funding to hire additional staff. This organizational structure is presented as a slightly modified ‘simple structure’, which verges on a divisional structure. The levels of authority have been set to streamline operations by facilitating communication within the organization while allowing for better reporting and performance measurement. By maintaining a simple structure organization, the MGL will ensure that the strategic apex (Brett Casey) has maximum control over day-to-day operations and the strategic directions of the lab.
This recommended organizational structure may vary from the implemented structure given budgetary and logistical constraints.

![Organizational Structure Diagram]

**Figure 4.0 The MGL’s Proposed Organizational Structure**

### 5.3 Resource Analysis

The MGL has seen a 10-15% rise in the demand for genetic services in recent years making it a necessity to identify inadequacies in their resources. The MGL’s resources have been previously identified as insufficient to remain competitive and offer the flexibility of growth to their operations. This section will individualize the MGL’s resources offering suggestions to reduce or negate the imposed constraints.

**Labor Constraints**

**Constraint:** Limited labor, the MGL’s primary productivity constraint stems from their lack of physical man power. Their current infrastructure is underutilized due to the lack of labor to operate machinery
**Solution:** Employ additional staff, using the additional funding acquired from the Ministry of Health, the MGL should employ an additional three full time staff.

**Result:** The increased staffing levels at the MGL will concurrently increase the lab's productivity levels while reducing the marginal costs of testing services due to the optimized machinery throughput.

**Equipment Constraints**

**Constraint:** Laboratory Equipment, the MGL’s current laboratory equipment offers excessive capacity for their current operations. The inclusion of the identified tests into the MGL’s portfolio however, will require the addition of equipment in order to support productivity levels.

**Solution:** Additional laboratory equipment, The MGL has identified the need for:

1. An upgrade to one of the MGL’s 4-capillary Applied Biosystems Instruments to a 16-capillary capacity at an estimated cost of $110,000

2. A robotic liquid-handling station at an estimated cost of $150,000

3. Four PCR instruments at an estimated combined cost of $40,000

**Result:** The addition of this equipment into the MGL would enable an optimal level of productivity to be reached while maintaining synergies between existing and newly implemented tests.
Budgetary Constraint

**Constraint:** Funding, The MGL’s current budget limitations do not sufficiently cater for the economic requirements of the MGL. The MGL is currently operating at 1.5 times their operating budget.

**Solution:** Increased funding, a revised budget and a change to the funding scheme should be implemented immediately by the Ministry of Health.

**Results:** This increased in budget would allow the MGL to function efficiently, and appropriately cater for the British Columbian community. The funds would be distributed enabling the MGL to effectively remove the afore mentioned constraints.

5.4 Position Analysis

The MGL currently operates in an environment that requires constant vigilance and rapid response. New technologies and test loci are constantly being introduced, so there is a need to be aware of the potential consequences that these new developments could have on the MGL. In order to sustain the MGL’s current position as well as compete in the global industry, the MGL will focus on their core competencies when expanding their services. This will include the selection of test that best fulfill synergies with existing testing services providing a cost based advantage, as well as selecting boutique tests that cater for a niche market. Figure 5.0 and figure 6.0 represent positioning diagrams illustrating the MGL’s strategic positioning where they current are (1), and where they will aim to compete (2).
Table 6.0 represents an options based analysis illustrating the foreseeable implications from a selection of strategic alternatives. These alternatives have been evaluated using the financial analysis discussed later.
<table>
<thead>
<tr>
<th>Goals</th>
<th>Implement Boutique Testing</th>
<th>Implement High Demand Testing</th>
<th>Implement Boutique and High Demand Testing</th>
<th>Maintain Status Quo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Run Profitability</td>
<td>Low/Med</td>
<td>Low/Med</td>
<td>Low</td>
<td>Med/High</td>
</tr>
<tr>
<td>Long Run Profitability</td>
<td>Low/Med</td>
<td>Low/Med</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Synergies</td>
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<td>High</td>
<td>None</td>
</tr>
<tr>
<td>Productivity</td>
<td>Small Increase</td>
<td>Medium Increase</td>
<td>High Increase</td>
<td>Level</td>
</tr>
<tr>
<td>Number of Employees</td>
<td>Small Increase</td>
<td>Small Increase</td>
<td>Medium Increase</td>
<td>Level</td>
</tr>
</tbody>
</table>

Legend:

- **Best Option**
- **Average Option**
- **Good Option**
- **Worst Option**
6 STAKEHOLDER ANALYSIS

The goal of this section is to provide a stakeholder analysis, identifying and evaluating the characteristics of individuals, firms, and government agencies that have a vested interest in the conclusions of this business plan. For the purposes of this report, this analysis will focus on information relating to the introduction of an enhanced variety of genetic tests at the MGL. To do this we have focused on the characteristics of interest, influence, resources and the support of the goal of this paper’s aim. While minimal uncertainty with regards to this analysis is preferable, scope and time constraints have made it impossible to fully gauge the interest of all parties. In order to correctly orient the MGL, the MGL’s reporting chain leads them to the Site Director at the B.C. Children’s and Women’s Hospital, then to the Executive Medical Director of PHSA Laboratories and ultimately to the CEO of the PHSA.

6.1 B.C. Ministry of Health / PHSA

The implementation of the proposed expansion of services at the MGL will increase funding from the B.C. Ministry of Health to the MGL, potentially decreasing funding from another service. These proposed changes will decrease the funds sent to external sources, actually allowing the B.C. Ministry of Health substantial cost savings in the long run. This redirection of funds will potentially make genetic testing services cheaper at the MGL enabling the B.C. Ministry of Health further cost savings.
6.2 B.C. Molecular Genetics Laboratory

The execution of this business plan will increase funding to the MGL, allowing for increased staffing levels to be attained which will enable the MGL to operate with both higher efficiencies and productivity levels. The increased portfolio of testing services available at the MGL will increase employees’ knowledge and skill sets. Additionally, this expansion of services has the ability to increase the attractiveness of the MGL to higher education facilities and personnel, potentially attracting additional talent into the MGL.

6.3 B.C. Physicians

The MGL’s primary customer base is a large body of physicians that reside within the British Columbian province. These physicians act as the MGL’s frontline of operations, handling queries and requests for genetic testing from the British Columbian community. The implementation of this business plan has the ability to provide these physicians with a quicker turnaround time for testing services, as well as a better level of support for both physicians and their patients due to the MGL’s enhanced knowledge and counseling ability.
7 FINANCIALS

The social and clinical case for adding new services to the MGL’s portfolio has been made throughout this document. This section addresses the ‘fiscal impact’ that new services and resources would have on the MGL’s overall ability to meet growing demand for testing services, to control increasing expenditures, and to provide pay-for-service tests to out-of-province clients. We first examine the current fiscal position of the lab by comparing the MGL’s actual expenditures with the budget allocations from the current global funding program. This is followed with a comprehensive ‘pro forma’ analysis to project new cash flows five years into the future. The results of this analysis will provide the MGL with guidance on how to proceed into the future.

7.1 Current Financial Situation

The MGL has experienced rapid growth in testing demand since 2002. The number of samples received by the lab has increased 40.6% in the last five years (Figure 7.0). Concurrent with the increase in samples received, there has been a 23.8% increase in referred out spending (Figure 8.0), which erodes the labs ability to meet its objectives and obligations.
Notwithstanding the increase in domestic and external demand for genetic services, the MGL’s actual allotment of funds to provide the services had decreased by a compound annual growth rate (CAGR) of 1.61% since the inception of the global funding program in 2004 (Figure 9.0), although the projected budget in 2007 is expected to be slightly higher than previous years. This has created a paradox for the MGL:

- How does the lab operate in a fiscally-constrained environment while maintaining the level of service demanded by patients and physicians?

- How to provide rapid, reliable and state-of-the-art services to patients while minimizing costs incurred to a publicly-funded healthcare system?
The advent of the global funding program led to annual decreases in overall budget for the MGL up to 2006 (CAGR=-1.61%)
The global funding policy introduced in 2004 has effectively capped the MGL's budget at an insufficient level and fails to account for inflation. Comparing the actual spending by the MGL to the budget and the Canadian Consumer Price Index shows the dramatic effects that the global funding has on the operating budget of the lab (Figure 10.0, 11.0, 12.0).

**Figure 10.0 Total Budget vs. Actual vs. CPI Adjusted Budget**

The actual spending by the MGL and the CPI have both exceeded the budget for most of the last 5 years.
Figure 11.0 Non-Labor Funding

The current global funding program has capped the funding for most of the MGL's activities. The non-labor funding budget has decreased by a CAGR of 2.3%, whereas actual spending is up by a CAGR of 1.66%

MGL Budget vs Actual

![MGL Budget vs Actual](image)

Figure 12.0 Budgeted Expenditures vs. Actual Expenditures

The rate of growth of expenditures has outpaced the growth in the budget since 2002. Actual expenditures have exceeded budget allotments since 2002 by a combined total of $530,126

As Figure 12.0 shows, the gap between expenditures and the budget is projected to close somewhat during the fiscal year of 2007. This is partially the result of increasing productivity and economies of learning, but it is also an effect of rising revenues for the lab. The MGL receives samples from labs outside the province, processes them for a fee, and returns the processed samples within a specific time frame.
The lab collects a nominal fee for each processed sample that includes, in most instances, a mark-up above the actual costs of processing the sample (see Appendix A for price schedule and turn-around times). These out-of-province samples represent revenues for the MGL and have begun to become quite substantial in recent years. In fact, revenues have increased by almost 7000% since 2002 (Figure 13.0). These revenues now more than offset the expenditures incurred from outsourcing, helping to lower the lab's overall spending per annum.

**Figure 13.0 Actual Referred Out vs. Actual Revenue**

Growth in revenues has now offset the growth in referred out costs. Revenues are generated through out-of-province pay-per-service samples.

### 7.2 Pro Forma Analysis

The pro forma analysis section examines two possible scenarios for the MGL and its stakeholders (i.e. the Ministry of Health Services and the PHSA):
✓ Maintain the status quo situation and test portfolio and attempt to negotiate additional funding or a change to the global funding system with the PHSA

✓ Expand the current service offerings by 50% (15 tests) to generate more revenues to address budget shortfalls, better respond to local demand, and achieve economies of scale, scope and learning

The calculations for all projections were accomplished using compounded annual growth rates (CAGRs), calculated by extrapolating growth during 2004-2006 (with some exceptions) into the future. Additionally, the financial calculations projected by this analysis used the following assumptions:

**Key Assumptions:**
- Historical growth rates will accurately reflect future growth
- Increased offerings will lead to increased out-of-province demand
- New capital equipment purchases will increase efficiency (samples/FTE) by 25%
- A larger portfolio of tests will allow for more buyer-power for the MGI, which will result in a reduction in the cost of supplies by 25%

Demand for genetic testing services is increasing steadily each year (40% since 2002, or 4.35% CAGR), yet budget allocations to meet the increasing demand are inadequate and shrinking (Figure 14.0). Within the budget, each component budget (labor, supplies, miscellaneous, referrals) is also decreasing.
The budget allotted for the MGL is insufficient and decreasing annually under the current global funding program. Calculations were based on a CAGR of -1.61%. Decomposing the budget into its component parts reveals that the budget for labor, supplies and non-labor, non-supplies funding are all decreasing (-1.95%, -1.34% and -0.10%, respectively)

In order to address the budget shortfalls, the MGL needs to either receive an injection of new funds or increase its own revenues by increasing the number of pay-per-service out-of-province tests that are processed each year. Previously, we have recommended a battery of tests (see Sections 3.3, 3.4) that the MGL could offer that would increase revenues from out-of-province clients and decrease the number of tests that are outsourced each year (Figure 15.0). These tests represent some of the most frequently demanded tests that the MGL cannot service in-house, as well as a subset of very rare disorders. The demand for these tests is expected to grow at the same rate as the existing tests offered in-house (Figure 16.0, 17.0).
Figure 15.0 Projected Outsourcing Demand

The projected actual outsourcing is calculated using a CAGR of 4.37% whereas the actual budget (although actually decreasing) was assumed to have 0% growth.

Figure 16.0 Historical Demand for Proposed New Services (2004-2007)

The demand for the 15 new tests were increasing over the period of 2004-2007. Note: Boutique tests have been lumped into the same group because they are quite rare.
Projected demand for the new services that the MGL will offer is based on a CAGR of 54.87%.

### 7.2.1 Conclusions of the Pro Forma Analysis

If the MGL were to add the proposed tests to its portfolio it would observe an increase in overall revenues (Figure 18.0) and a decrease in outsourcing to other labs (Figure 19.0). Looking at Figure 18.0, it becomes apparent that the status quo funding/services policy will prevent future growth in revenues because the lab will have hit full labor capacity in 2007. This means the lab will generate approximately $380,000 over the period of 2008-2012.
Figure 18.0 Projected Revenues

The status quo projected revenues plateaus at $76,000 because the lab is currently operating at full-capacity. In contrast, the new services portfolio, which includes new capacity (labor and equipment), is expected to grow annually at a rate of 25% (CAGR) until 2012 when the lab will again reach full-capacity.

Figure 19.0 Referral (Outsourcing) Projections

The need to outsource tests is expected to grow in the next 5 years at a rate of 4.37% (CAGR). By taking on the new services, the MGL will decrease its expenditures on outsourcing quite substantially.
7.2.1.1 New labor and Equipment Capacity

In contrast to the static revenues foreseeable under the status quo program, an increased service offerings package, coupled with an increase in labor and equipment capacity, will generate approximately $821,000 in revenues over the next five years. The new capacity generated through the addition of new technologists (tech level III) and new equipment will allow the lab to process a larger number of samples (slightly more than projected demand) until 2012 when the lab will again reach maximum capacity. These gains will be realized while there will be a concurrent decrease in the number of tests that are outsourced to foreign labs (Figure 20.0), again leading to a decrease in overall expenditures.

Figure 20.0 Projected Outsourcing of Samples
The number of samples outsourced to other labs will be cut by 67.7% by 2012

New labor and Services= Increased Productivity & Buyer Power
The projected cost increases resulting from taking on three new technicians will result in higher expenditures (Figure 21.0), but will be offset by an increase in revenues. New capital equipment purchases will contribute to increased revenues by increasing overall labor efficiencies. This will also contribute to a reduction in the cost of supplies. Moreover, the increase in the MGL’s portfolio will allow for synergies with its existing offerings, enabling the MGL to negotiate for bulk buyer discounts from suppliers.

![Projected Labor Expenses](image)

**Figure 21.0 Projected Labor Expenses**

Existing labor costs are increasing at a CAGR of 5.04%. The new labor, initially to cost $45000/technician, is assumed to increase at the same rate.

### 7.2.1.2 Pricing Schedule

The MGL’s current pricing schedule (Appendix A) should be adjusted to ensure that revenues can offset the new costs that will be incurred from the additional labor, capital equipment purchases, and supplies. The MGL’s current low cost-of-goods-sold (COGS) will
facilitate this price flexibility. The MGL can, on average, provide a test for $102, although this price will increase to $138 by 2012. The current mark-up for tests is about 250% (based on an average price of $257). In order to offset new costs, the mark-up should be increased to 300% (Figure 22.0).

![Billable Price for Services](image)

**Figure 22.0 Billable Price for Services**

The MGL’s cost-of-goods-sold (COGS), which was calculated by taking the quotient of expenditures over samples processed, is quite low. The MGL should apply at least a 300% margin to out-of-province tests to ensure that revenues offset the costs of taking on new capacity and testing.

### 7.2.1.3 Opportunity Costs

Because the MGL has a binary decision, maintain the status quo or invest in new capacities and new services, there must be a consideration of what would be lost if either approach is taken at the expense of the other. This can be shown by measuring the opportunity costs: The costs of an opportunity that are foregone to pursue another course of action.

In the current study, the course of action that has been selected is to make a capital investment in new labor and equipment to expand the MGL’s portfolio. To pursue this action, an
initial injection of $230,371.79 to reconcile the actual spending and the budget, plus an additional $791,737.88 spread over the following four years to ensure that spending stays in line with the budget (see Table 7.0). The opportunity costs of this investment are equal to the potential interest that could have been earned if the money was invested in an alternate risk-free endeavor.

On the other hand, the opportunity costs that are foregone by maintaining the status quo are equal to the lost potential revenues that could have been generated by adding the new tests and new capacity. The other source of opportunity costs is the cost associated with outsourcing services to other labs. By taking on new tests the lab would reduce its dependencies on other centers to process samples and reduce its expenditures in that area. The status quo approach would forego the cost savings and incur an opportunity cost (Figure 23.0).

In total, the status quo program would incur $440,399 in opportunity costs over five years. In contrast, the opportunity costs of funding the new program are equal to $362,817 (*the difference between status quo expenditures and new services expenditures over the five year period 2008-2012). The difference favors the new services program over the status quo approach. It is therefore fiscally beneficial for the MGL to pursue this option. Table 7.0 shows the net expenditures (revenues are shown as negative inputs) resulting from each approach. It is clear that the new services program would lead to an enhanced financial position for the MGL as graphically depicted in Figure 24.0.
<table>
<thead>
<tr>
<th>Year</th>
<th>Projected Actual Spending with New Services &amp; Labor</th>
<th>Plus Lost Potential Revenues (Opportunity Costs)</th>
<th>Total # of Expenditures (not including Opportunity Costs)</th>
<th>Suppliers</th>
<th>R&amp;D Allocations (Supplies)</th>
<th>Actuarial $ Budget</th>
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</thead>
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<tr>
<td>2008</td>
<td>$59,586,000</td>
<td>$60,000,000</td>
<td>$1,414,000</td>
<td>$1,000,000</td>
<td>$2,500,000</td>
<td>$1,500,000</td>
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<tr>
<td>2009</td>
<td>$60,000,000</td>
<td>$60,000,000</td>
<td>$1,414,000</td>
<td>$1,000,000</td>
<td>$2,500,000</td>
<td>$1,500,000</td>
</tr>
<tr>
<td>2010</td>
<td>$60,000,000</td>
<td>$60,000,000</td>
<td>$1,414,000</td>
<td>$1,000,000</td>
<td>$2,500,000</td>
<td>$1,500,000</td>
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<tr>
<td>2011</td>
<td>$60,000,000</td>
<td>$60,000,000</td>
<td>$1,414,000</td>
<td>$1,000,000</td>
<td>$2,500,000</td>
<td>$1,500,000</td>
</tr>
</tbody>
</table>

Notes:
- Projected spending with new services and labor
- Plus lost potential revenues (opportunity costs)
- Total # of expenditures (not including opportunity costs)
- Suppliers
- R&D allocations (supplies)
- Actuarial $ budget
7.2.1.4 Sensitivity Analysis

Because of the fact that our pro forma analysis results are highly dependent upon subjective assumptions regarding improved efficiencies, it is necessary to conduct a what-if, or 'sensitivity', analysis. This allows us to analyze the net changes in projected expenditures resulting from deviations between our projected efficiencies and other less favorable conditions.

The sensitivity table (table 8.0) shows the effects on the MGL's total expenditures between 2008 and 2012. The variable savings and efficiencies identified in this table stem from the change to the MGL's testing portfolio. We have chosen to use 0%, 12.5%, 25%, and 37.5% as the variables in this study.

As indicated by a green shaded cell, we have concluded that the MGL must achieve at least a 25% savings in the purchase of supplies, and a 12.5% increase in labor efficiencies in order to make the financial rationale for additional testing true.

Notwithstanding the actual savings in lab expenditures resulting from the expanded testing portfolio, the social case for additional testing has been made, and clearly demonstrates a social need for a strong molecular testing facility within B.C.; one capable of responding rapidly to change, of providing reliable and timely results for patients, and providing state-of-the-art services to the patients of B.C.
<table>
<thead>
<tr>
<th>Bulk Buying Savings</th>
<th>0%</th>
<th>12.5%</th>
<th>25%</th>
<th>37.5%</th>
</tr>
</thead>
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<tr>
<td>0%</td>
<td>$1,763,285</td>
<td>$1,838,830</td>
<td>$1,878,129</td>
<td>$1,894,809</td>
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<tr>
<td>12.5%</td>
<td>$1,306,904</td>
<td>$1,348,307</td>
<td>$1,368,464</td>
<td>$1,377,020</td>
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<tr>
<td>25%</td>
<td>$991,989</td>
<td>$1,102,783</td>
<td>$1,022,109</td>
<td>$1,026,068</td>
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<tr>
<td>37.5%</td>
<td>$779,109</td>
<td>$778,388</td>
<td>$792,136</td>
<td>$793,726</td>
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</table>

Table 8.0 Sensitivity Analysis

<table>
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<tr>
<th>Labor Efficiencies Increase</th>
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<th>25%</th>
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<tr>
<td>Acceptable Option</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Non-Acceptable Option</td>
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8 FINDINGS

This paper presented a comprehensive analysis of the MGL’s current situation and examined the potential for expanding genetic testing services in B.C. We have identified a set of key findings which have enabled us to formulate recommendations for the MGL. Below is a list of our key findings:

- **Costs are rising;** Costs incurred by the MGL both internally (performing genetics testing services) and externally (fees associated with outsourcing) are rising.

- **Limited funding;** The MGL is critically underfunded and does not have a sufficient budget to realize its goals and mission statement. Even without the introduction of the newly identified testing services, the MGL is operating at capacity due to funding constraints.

- **Poor structure;** The MGL’s reliance on external sources for services unavailable in-house places the MGL in a poor position. This situation makes them highly susceptible to their environment and with little hope of maintaining economic stability.

- **Social case;** There is a clear case for increased funding due to the social benefits.

- **Fiscal case;** There is a clear case for increased funding due to the economic benefits.
• **Genetic testing is increasing**: The popularity and necessity of genetic screening is increasing in the global community. This ensures a sufficient demand and a solid future for the genetic testing industry.

• **Synergies**: The implementation of the proposed genetic tests incorporates several resource synergies exploitable by the MGL. These will aid implementation and allow the MGL to immediately experience the benefits.

• **Demanded tests**: This paper has identified and analyzed the genetic tests that most frequently outsourced. This analysis has concluded that there is a sufficient demand to incorporate these into the MGL's in-house ability.

• **Boutique tests**: This paper has identified and analyzed the genetic tests that would best aid the local academic research community. This portfolio of boutique tests will allow the MGL to best serve this niche community.

• **Monopoly**: The MGL has a natural monopoly position stemming from economies of scale and economy of scope which naturally inhibit entry. Moreover, the Canada Health Act contributes to limiting the ability of private clinics to compete and earn profits. This dominant stance in the industry will block new entrants into the genetic testing market.

• **Research and Development**: The MGL currently has no source of research and development. This is a weakness in their current organizational structure and has been addressed with a proposed organizational structure.
- **Capabilities:** The MGL has a strong, talented and dedicated group of employees. This high performance team is currently operating optimally despite being at capacity.

- **Organizational Structure:** The MGL’s current organizational structure requires a small amount of tweaking to optimize their productivity and allow for the proposed expansion.

- **Constraints:** There are numerous constraints currently limiting the MGL’s productivity. Labor, funding are the critical factors that this paper addresses to ease these constraints enabling the MGL to effectively compete in the global market.

- **Stakeholders:** There are multiple stakeholders that will be affected by the implementation of this business plan. Fortunately, all stakeholders will be positively affected increasing the likelihood of implementation of this business plan.
9 RECOMMENDATIONS

The MGL is in a position to ensure that it is able to meet the obligations laid out in their mission statement, “to provide(ing) high quality genetic health care to residents of B.C., while participating in and contributing actively to research and education in the field of Medical Genetics”, if the lab is provided with the necessary funding to take on additional testing capabilities and testing capacity.

This study has demonstrated that the clinical case for the new testing regime is strong, as it increases the social benefits for the population of B.C. through reductions in lost productivity and health care costs, increased well-being, and increased provincial employment. These benefits in combination with the solid business case, demonstrating the financial viability and fiscal benefits achievable with the increased testing portfolio amount to a sustainable future for the MGL.

This paper will be utilized by the MGL to provide the Ministry of Health with an informed business and social rationale for additional funding to meet both the MGL’s and the Ministry of Health’s missions and obligations.

Table 9.0 Financial Summary

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>Total '08-'12</th>
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<tr>
<td>Current Budgeted Expenditure</td>
<td>$383,084.42</td>
<td>$376,916.76</td>
<td>$370,848.40</td>
<td>$364,877.74</td>
<td>$359,003.21</td>
<td>$1,854,730.52</td>
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<td>Expenditure with Status Quo</td>
<td>$467,073.09</td>
<td>$519,453.59</td>
<td>$580,491.39</td>
<td>$652,473.19</td>
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<td>Expenditure with Additional Services</td>
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<td>$598,424.88</td>
<td>$581,008.69</td>
<td>$558,892.21</td>
<td>$525,058.20</td>
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<td>Additional Funding Required with Status Quo</td>
<td>$83,988.67</td>
<td>$142,536.83</td>
<td>$209,642.99</td>
<td>$287,599.45</td>
<td>$379,500.82</td>
<td>$1,103,264.77</td>
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<tr>
<td>Additional Funding Required with Additional Services</td>
<td>$230,371.79</td>
<td>$221,508.12</td>
<td>$210,160.29</td>
<td>$194,014.47</td>
<td>$166,034.99</td>
<td>$1,022,109.67</td>
</tr>
</tbody>
</table>
Ministry of Health Funding

As identified in table 9.0, the MGL requires an initial injection of $230,371.79 in 2008, totaling $1,022,109.67 by the end of 2012. As comprehensively analyzed by this paper’s business case, the advantages both socially and fiscally of the increased funding to the MGL represent a clear case of overall benefit. These funds will address the current discrepancies between the MGL’s budgeted allowance and their actual spending, while allowing for the execution of this business plan, creating a financially viable and sustainable future for the MGL.

Genetic Testing Portfolio

Repeatedly this paper has referenced the needs and benefits of an increased genetic testing portfolio for the MGL. Stemming for the comprehensive social benefit and business case analysis represented in this paper, a key element in the sustainability of the MGL is the inclusion of the identified most demanded tests as well as a selection of boutique tests. Upon receiving additional funding, the MGL should immediately incorporate the identified additional genetic testing into their current repertoire, enabling them to achieve all noted benefits.

Table 10.0 Additional Expenditures

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>Total '08-'12</th>
</tr>
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<tbody>
<tr>
<td>Additional Equipment Expenditure</td>
<td>$60,000.00</td>
<td>$60,000.00</td>
<td>$60,000.00</td>
<td>$60,000.00</td>
<td>$60,000.00</td>
<td>$300,000.00</td>
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<tr>
<td>Additional Labor Expenditure</td>
<td>$135,000.00</td>
<td>$135,000.00</td>
<td>$135,000.00</td>
<td>$135,000.00</td>
<td>$135,000.00</td>
<td>$675,000.00</td>
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<tr>
<td>R&amp;D Allowance (Supplies)</td>
<td>$14,041.41</td>
<td>$12,378.05</td>
<td>$10,977.26</td>
<td>$9,890.67</td>
<td>$8,478.04</td>
<td>$55,716.33</td>
</tr>
</tbody>
</table>

Laboratory Staff

Utilizing the increased funding available to the MGL, the MGL should immediately hire three additional technicians (at Tech III level) to address the labor bottlenecks identified throughout this report and graphically represented in figure 25.0. The increased number of
technicians employed by the MGL will alleviate capacity bottlenecks, allowing the MGL to concurrently increase capacity while reducing their marginal test costs through the achievement of economies of scale. As identified in table 10.0, the funding requirements of these additional staff proposed by this paper is $135,000 annually, representing 42% of the increased funding requirements.

Figure 25.0 Identified MGL Bottlenecks

Research and Development

The organizational structure at the MGL has a current lack of research and development (R&D) facilities. In order to align with, and remain on the forefront of genetic analysis technologies, the MGL should incorporate the suggested additional Tech III staff member mandated with a research and development focus. The role of the R&D arm of the MGL will be to examine potential innovations to the current technologies and processes employed by the lab.
and to monitor the MGL's environment ensuring they remain competitive in terms of genetic testing capabilities. For example, the R&D unit could study new sequencing platforms that offer enhanced resolution, cheaper reads or more rapid throughput. The goal being to avoid obsolescence or unnecessary costs resulting from out-dated technologies.

**Customer Analysis**

Further to this paper's findings, the MGL should complete a comprehensive analysis of their customers. The MGL's customer base consists of a dynamic collection of domestic entities (physician referred patients and the academic community) and external entities (research and genetic entities requiring externalized services) who create revenue for the MGL on a pay-for-service basis. This analysis should be targeted towards the identification of these customers willingness-to-pay (WTP) for the MGL's existing and proposed genetic testing services. The outcomes of this analysis will ensure the MGL is maximizing their potential revenues by optimizing their service portfolio for domestic and international customers.

**Collaboration**

The MGL should increase their current collaborations with domestic and inter-provincial entities. Domestic collaborations between the MGL and the academic community will increase efficiencies and support between the two, having the potential to share the risks associated with additional genetic services at the MGL. Inter-provincial collaborations will be utilized by the MGL to establish relationships with other genetic testing laboratories, offering advantages of reduced costs (enabling the cluster as a whole to achieve cost benefits from reduced transactional costs and profit margins) and the elimination of service redundancies. These
collaborations will aid the future sustainability of the MGL and increase Canada’s genetic analysis services.

**Future Genetic Services**

Noted by Brett Casey, North America currently lacks the facilities that provide toxicity testing services. The planned implementation of R&D facilities into the MGL would have the facilities, resources and ability to research such a venture. This innovative service would provide the MGL with a substantial competitive advantage, expanding their service offerings and ensuring a strong and sustainable future for the MGL.

**Laboratory Equipment**

From the pool of additional funds provided by the Ministry of Health, as identified in table 10.0, the MGL should allocate $60,000 over a five year period totaling $300,000. The proposed equipment purchases of:

1. An upgrade to one of the MGL’s 4-capillary Applied Biosystems Instruments to a 16-capillary;

2. A robotic liquid-handling station;

3. Four PCR instruments;

This will enable the MGL to implement the identified additional genetic services, address the MGL’s current capacity issues as well as offer increased productivity levels achievable through economies of knowledge and enhanced equipment efficiencies.
# APPENDICES

## Appendix A

<table>
<thead>
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<th>DISEASE</th>
<th>CODE</th>
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<td>ACROMIODEMIA</td>
<td>ACH</td>
<td>6</td>
</tr>
<tr>
<td>150</td>
<td>THALASSEMA - ALPHA</td>
<td>HA</td>
<td>8</td>
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<tr>
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<td>THALASSEMA - BETA</td>
<td>HB</td>
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<td>ANGELMAN SYNDROME</td>
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<td>6</td>
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<tr>
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<td>ASHIPLEX (TAY SACHS)</td>
<td>ASH</td>
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<td></td>
<td>BONE MARROW</td>
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<td>CYSTIC FIBROSIS</td>
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<td>DPPLA</td>
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<td>DUCHENNE/BECKER MUSCULAR DYSTROPHY</td>
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<td>150</td>
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<td>FRIEDREICH ATAXIA</td>
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<td>HEMOPHILIA A (FVIII)</td>
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256.5 AVERAGE: 6.911
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MMWR (No. RR-13): [inclusive page numbers]


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