

**A MEDICAL SUB-SPECIALTY SPECIFIC ANALYSIS
OF THE
BRITISH COLUMBIAN MEDICAL DIAGNOSTIC LABORATORY INDUSTRY**

by

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Abstract

The client, LifeLabs, invests millions of dollars annually in capital equipment purchases, with the majority of this spend being directed at replacement, upgrades and introductions of new test instruments. Despite the strategic nature of these decisions, the current decision making process employed by LifeLabs does not include evaluation of external environmental factors that may influence long-run profitability and risk. LifeLabs has commissioned this study to deliver an external analysis of the medical diagnostic laboratory industry in British Columbia, further requesting that the study focus on delivering recommendations for the industry segments of allergy, autoimmune and coagulation. The results of the analysis conducted herein are as follows:

To maximize future allergy segment attractiveness, it is recommended that med-lab providers collaborate with allergy specialists to install point of care technology (POCT) allergen testing capability at locations close to the specialists' places of practice.

To maximise future autoimmune segment attractiveness, it is recommended that med-lab providers educate family physicians and rheumatology specialists regarding the benefits and best uses of complementary test methods (such as IFA and Bio-Plex), as well as how to interpret results from those methods.

To maximise future coagulation segment attractiveness, it is recommended that med-lab providers collaborate with regional health authorities to install POCT coagulation testing (Prothrombin Time (PT) / International Normalized Ratio (INR)) capability at locations close to or within community acute care clinics, as well as nominated patient service centres, and throughout the long term care facility network.

Although it was the clients' explicit request not to tackle internal analysis as part of this study, it is also recommended that a follow-up internal analysis, and subsequent scenario analysis, be conducted to assure that the unique competitive advantages of the client firm are considered as part of the strategy formulation process.

Dedication

This paper is dedicated to my amazing wife, Debra, to whom I owe a huge debt of gratitude for the unwavering support and encouragement that she has provided me with throughout my EMBA program, and in particular, in the final months of the production of this paper. It is further dedicated to my wonderful children, Anthony and Aaryanna, who have involuntarily sacrificed so much time with their dad to make completion of this program a reality for me. Thank you!

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Glossary

Inpatient	A patient that is hospitalized for a period of 24 hours or more.
Outpatient	A patient that is treated without hospitalization.
Allergy	An immune system hyper-sensitivity that results in immune system responses to otherwise harmless substances.
Autoimmune Diseases	Diseases related to the immune system attacking the host's body, e.g. rheumatoid arthritis
Coagulation Related Diseases	Conditions that interfere with the normal clotting of blood, including excessive bleeding (haemorrhaging) or clotting (thrombosis), e.g. Stroke.
Screening Tests	Tests that are intended to detect the presence, or predisposition to, a disease in an individual.
Confirmation Tests	Tests that are intended to confirm the presence, or predisposition to, a disease in an individual, as well as to provide a more specific classification of the disease.
Sensitivity	A measure of the proportion of actual positives which are correctly identified as such (e.g. the percentage of sick people who are correctly identified as having the condition).
Specificity	A measure of the proportion of actual negatives which are correctly identified as such (e.g. the percentage of healthy people who are correctly identified as not having the condition).
PT	Prothrombin Time (PT) is a test used to evaluate the ability of blood to clot properly by evaluating the function of coagulation factors, and has numerous applications including pre-surgery screening of patients for any previously undetected bleeding disorders.
INR	International Normalized Ratio (INR) is a test used to monitor the effectiveness of blood thinning drugs such as warfarin (Coumadin).
CBC	Complete Blood Counts (CBC's) are amongst the most commonly performed tests in medicine. Abnormally high or low counts may indicate the presence of many forms of disease, hence blood counts can provide an overview of a patient's general health status.
ANA	Antinuclear antibody (ANA) testing is used in the detection of lupus and mixed connective tissues disease.

POCT	Point of care technology. Small scale test equipment capable of delivering fast convenient test results.
BCMA	British Columbia Medical Association
CPSBC	College of Physicians and Surgeons of British Columbia
BCALP	British Columbia Association of Laboratory Physicians
DAP	Diagnostic Accreditation Program (Administered by the CPSBC)
TAT	Turn-around-time for a test; a measure of service delivery.

1: Introduction

1.1 Client Overview

LifeLabs is a medical diagnostic laboratory (med-lab) services company that annually provides more than 50 million laboratory tests to over 10 million patients and nearly 20,000 physicians across British Columbia, Ontario and Quebec. LifeLabs services the diagnostic needs of outpatients (patients that are not hospitalized) by providing province-wide access to a full range of laboratory testing and information services.

LifeLabs is privately owned by Borealis Infrastructure. Borealis acts as the infrastructure investment arm of Ontario Municipal Employees Retirement System (OMERS), a Canadian pension plan with approximately C\$50 billion in net investment assets (Borealis, 2011). LifeLabs operates in a multi-goal environment with ultimate goals of long-run profitability and social responsibility. The latter is defined as the intent to contribute to the improvement of healthcare delivery in any market that it serves.

1.2 The Problem

LifeLabs invests millions of dollars annually in capital equipment purchases, with the majority of this spend being directed at replacement, upgrades or introductions of new test instruments. Equipment selection decisions that underlie investments in test instruments are strategic in nature as the investments involve large sums of money, are long lived and highly specific in nature, and affect the type of services that can be offered to clients. Despite the strategic nature of these decisions, the current decision making process employed by LifeLabs does not include evaluation of external and environmental factors that may influence long-run profitability and risk.

1.3 The Approach

LifeLabs has acknowledged this gap in the understanding of external factors, and has requested this study to deliver an external analysis of the medical diagnostic laboratory industry in British

Columbia (BC). To exploit the earliest possible opportunity for integration of this analysis into its test instrument investment decision making process, LifeLabs has requested that this study focus on the industry segments of allergy, autoimmune and coagulation. Instruments in each of these three areas are approaching the limits of their usable life.

To address the client's needs, Chapter Two will describe the medical diagnostic laboratory industry in BC, including: the services and customers, industry boundaries, industry segments, strategic groups, industry supply chain and market structure. Chapter Three will then analyse the external forces (specific to the segments of allergy, autoimmune and coagulation) that affect industry profitability now and in the future, using various tools including a Porter's Five Forces framework. Finally, Chapter Four will assess the implications of the findings of the external forces analysis for the client's strategy, and make recommendations regarding threat mitigation and opportunity exploitation.

2: Description of the Medical Diagnostic Laboratory Industry

The following section provides a detailed description of the medical diagnostic laboratory industry in BC in terms of services and customers, segmentation, strategic groups, industry boundaries, market structure, and supply chain.

2.1 Overview of Services and Customers

The medical diagnostic laboratory (med-lab) industry provides an extensive menu of tests that physicians and surgeons can order as a complement to their clinical investigation (direct consultation with patients), to assist in the diagnosis and treatment of disease. Med-lab testing results are a key input in about 70 % of decisions that physicians make (D. King, 2010).

Patients of physicians and surgeons are the main customer group of the (med-lab) industry in BC. “Patients” include inpatients, defined as patients who are hospitalized, and outpatients, defined as patients who are not hospitalized but who visit a hospital, clinic, or associated facility, or are visited by a health service provider, for diagnosis and treatment (Wikipedia, 2011). In addition to services offered at community clinics and doctor’s offices, outpatient med-lab services also include mobile collection from patient’s homes, long term care facilities, assisted living facilities, and remote communities. Although patients are the end customer, they do not choose or directly pay for most tests. Physicians choose the appropriate tests and the government pays for them via the provincial medical insurance plan (MSP).

In addition to patients, the industry also services the following customers: government organizations such as BC Cancer; pharmaceutical companies (enabling clinical trials); and corporate clients (enabling executive health programs, screening for illegal drugs, etc.).

2.2 Industry Segmentation

Industry segmentation is important in a number of ways. It identifies distinct groups of customers, and by extension, opportunities to effectively and efficiently service their distinct needs. It also provides insight into strategic groups operating in the industry and provides an opportunity to identify a mode of segmentation that is the most relevant to the client's issue - capital investment in test instruments.

The following discussion will present four different ways to segment the med-lab industry in BC: segmentation by customer type, by geography, by funding type, and by medical discipline.

2.2.1 Segmentation by Customer and Product Type

The first and largest customer segment, representing more than 90% of the market, is that of patients (LifeLabs, 2011). Further segmentation of this group, into inpatients and out-patients, reveals a distinct focus for each sub-group. Services provided to inpatients who are hospitalized fall into the *acute care* category. These acute care tests support emergency medicine and surgeries and are provided exclusively by public hospitals, which specialize in services for inpatients. Services provided to outpatients include the categories of *screening*, e.g. cancers, trace metals; *chronic disease management*, e.g. diabetes, kidney disease, heart and stroke; and *infectious disease*, e.g. hepatitis, HIV. Although outpatient services are provided by both public hospitals and private community labs, the latter group delivers the vast majority, approximately two-thirds of services to outpatients in BC (Medical Services Commission, 2009).

Services provided to the second customer group, government or private research organizations such as pharmaceutical companies, fall into the category of *studies*, and include: clinical trials, e.g. drug trials; and population studies, e.g. aboriginal health studies.

Services provided to the final customer group, corporate clients, fall into the category of *screening*, and include: executive health testing, generally composed of a panel (group) of tests; screening for occupational exposure, e.g. heavy metals; and screening for drugs of abuse, e.g. cocaine, methamphetamine.

2.2.2 Segmentation by Geography

BC can be divided into five regions: Vancouver Coastal (Lower Mainland), Fraser Valley, Vancouver Island, Interior BC and Northern BC, consistent with the organization of public health authorities as depicted in Appendix A. Each of these regions has a number of hub hospitals and a network of outpatient services.

Service providers focus their operations geography. Specifically, BC Biomedical provides access to lab services primarily in the Fraser Valley and Vancouver Coastal, Valley Medical Labs provides access to lab services exclusively in the BC Interior, and LifeLabs provides lab services across BC. However, LifeLabs has a much smaller presence in the Fraser Valley and the BC Interior than it does elsewhere. Public hospitals are managed by regional public health authorities and thus inherently geographically focused.

Table 2.2 Industry Segmentation Matrix – LifeLabs Participation

Diagnostic Services	Customers				
	British Columbia Residents				
	Vancouver	Fraser Valley	Island	Northern	Interior
Studies - includes clinical trials, population studies (e.g. aboriginal health), BC Cancer or BC Centre of Disease Control (CDC) funded studies					
Predictive Medicine (Genomics) - currently negligible					
Screening - includes preventative health, cancer screening, drugs of abuse, trace metals, executive health					
Chronic Disease Management - includes monitoring of therapeutic drugs levels e.g. stroke medication / blood thinners					
Infectious Disease - includes screening and confirmation (e.g. Hepatitis B), and may include strain identification.					
Acute Care - includes urgent tests (e.g. blood cultures) that need to be carried out rapidly to prevent possible death from illness.					

2.2.3 Segmentation by Funding Type

Med-lab testing is funded using a number of mechanisms, including block and global public funding, lump sum annual funding allocated to hospitals by the BC Ministry of Health Services; BC medical services plan (MSP); out-of-province funding, covered by another province's provincial medical plan; federal government funding, e.g. immigration, armed forces, veteran affairs; private insurance; and patient pay.

For simplicity, the market will be segmented based on the categories of public funding (global), public funding (fee schedule, assumed to include the middle three categories discussed above), and private funding. Public funding (global) is only available to public hospital med-labs, while private funding is only available to private med-labs. Public funding (fee schedule) is available to both public and private med-labs.

2.2.4 Segmentation by Medical Discipline

Med-lab testing can also be segmented by medical discipline, according to the specialities of the medical and scientific doctors who are employed by med-labs to assure test integrity and interpret results. These disciplines included clinical chemistry, hematology, microbiology, molecular diagnostics, histology, and cytology.

Even finer segmentation, by medical sub-discipline (or sub-specialty) is of particular relevance to the client, as it most closely corresponds to test instrument product groupings. The medical disciplines of chemistry and hematology will thus be described in greater detail to provide the sub-speciality (allergy, autoimmune, and coagulation) level descriptions necessary to support the sub-specialty level analysis that takes place in Chapter 3.

The following section provides an overview of each discipline:

2.2.4.1 Chemistry

Chemistry is a branch of clinical medicine concerned with the testing of bodily fluids. The discipline originated in the late 19th century with the use of simple chemical tests for various components of blood and urine. More sophisticated techniques were subsequently added and clinical chemistry now has a very broad array of tests, which can be grouped into the sub-

specialties of: routine chemistry; endocrinology, the study of hormones; immunology, the study of the immune system and antibodies; and pharmacology and toxicology, the study of drugs.

Most tests (assays) are carried out on serum or plasma. Serum is the yellow watery part of blood that is left after blood has been allowed to clot and all blood cells have been removed. This is most easily done by centrifugation which packs the denser blood cells and platelets to the bottom of the centrifuge tube, leaving the liquid serum fraction resting above the packed cells. Plasma is essentially the same as serum, but is obtained by centrifuging the blood without clotting. Plasma therefore contains all of the clotting factors, including fibrinogen. (Wikipedia, 2011)

Most laboratories are highly automated and use assays that are strictly quality controlled. Large med-labs will accept samples for up to about 500 different kinds of tests (LifeLabs, 2011). A portion of these tests is usually referred to other labs, as few labs maintain the capability to do the full array of tests.

The Sub-specialty of Immunology

Clinical immunology is the study of diseases caused by disorders of the immune system (failure, aberrant action, and malignant growth of the cellular elements of the system), as well as diseases of other systems, where immune reactions play a part in the pathology and clinical features. Immunology also studies ways to prevent transplant rejection. (Wikipedia, 2011)

The diseases caused by disorders of the immune system fall into two broad categories: immunodeficiency, in which parts of the immune system fail to provide an adequate response, examples include chronic granulomatous disease; and autoimmunity, in which the immune system attacks its own host's body, examples include systemic lupus erythematosus and rheumatoid arthritis. Other immune system disorders include different hypersensitivities, in which the system responds inappropriately to harmless compounds, e.g. asthma and other allergies, or responds too intensely [Wikipedia, 2011].

The client's specific interests fall in the areas of autoimmunity and allergy. Both classifications of disease are very significant. Autoimmune diseases, specifically rheumatoid arthritis, are the leading cause of disability in the population, and are increasing as the population ages. Allergies now affect a large and increasing portion of the population.

Diagnostic laboratory testing is a vital complement to clinical expression (patient symptoms) in autoimmune cases, as it helps to produce a conclusive diagnosis even when clinical expression is vague. This enables early detection and treatment, which is vital to improving the quality of life (rheumatoid arthritis and lupus) and survivability outcomes (lupus) for patients.

In the case of allergies, diagnostic testing is also very important as it not only provides an alternative to allergy specialist delivered skin testing and oral challenge, but can also reduce or eliminate incorrect identification of allergens as a result of cross-reactivity, and predicts reaction severity to specific allergens. The latter enables a greatly improved quality of life, for example, by opening up a much broader range of food menu choices for people that were erroneously identified as allergic to peanuts due to cross reactivity but were actually allergic to birch pollen.

2.2.4.2 Hematology

Hematology (or hematopathology) is a branch of clinical medicine concerned with the analysis of blood, the blood forming organs and blood diseases. Blood diseases affect the production of blood and its components which include red blood cells, white blood cells, platelets and blood proteins. Blood diseases also affect the mechanism of coagulation.

Complete blood counts (CBC's) are amongst the most commonly performed med-lab tests in medicine. Abnormally high or low counts may indicate the presence of many forms of disease, hence blood counts can provide an overview of a patient's general health status.

Med-lab tests under the discipline of hematology can be grouped into sub-specialities of haematology and hemostasis (coagulation).

The Sub-specialty of Coagulation

Coagulation is the complex process by which blood forms clots. Coagulation begins almost instantly after an injury causes damage to the endothelium (lining of the blood vessel). Exposure of the blood to proteins, such as tissue factor, initiates changes to blood platelets and the plasma protein fibrinogen, a clotting factor. Platelets immediately form a plug at the site of injury; this is called primary hemostasis. Secondary hemostasis occurs simultaneously – proteins in the blood plasma called coagulation factors or clotting factors respond in a complex cascade to form fibrin strands which strengthen the platelet plug. [Wikipedia, 2011]

Disorders of coagulation can lead to an increased risk of bleeding (hemorrhage) or obstructive clotting (thrombosis). Diagnostic tests are vital in detecting disorders as well as in managing treatment.

One example of an important diagnostic test is Prothrombin Time (PT). It is used to evaluate the ability of blood to clot properly by evaluating the function of coagulation factors, and has numerous applications including pre-surgery screening of patients for any previously undetected bleeding disorders.

An example of a test employed in management of chronic disease is the International Normalized Ratio (INR). INR is used to monitor the effectiveness of blood thinning drugs such as warfarin (Coumadin). These anti-coagulant drugs help inhibit the formation of blood clots. They are prescribed on a long-term basis to patients who have experienced recurrent inappropriate blood clotting. This includes those who have had heart attacks, strokes, and deep vein thrombosis (DVT). Anti-coagulant therapy may also be given as a preventative measure to patients who have artificial heart valves, and on a short-term basis to patients who have had surgeries, such as knee replacements. The anti-coagulant drugs must be carefully monitored to maintain a balance between preventing clots and causing excessive bleeding. (Lab Tests Online, 2011)

2.2.4.3 Microbiology

Microbiology is a branch of clinical medicine that studies microorganisms, including bacteria, viruses, fungi and parasites, which are of medical importance and are capable of causing diseases in human beings.

Consistent with the above definition, med-lab tests under the discipline of microbiology can be grouped into the sub specialities of: bacteriology, the study of bacteria; virology, the study of viruses; mycology, the study of fungi; and parasitology, the study of parasites.

2.2.4.4 Molecular Diagnostics

Molecular diagnostics is an emerging field of laboratory medicine that can be applied to various sub-specialities, often as a complement or substitute for techniques applied in clinical

microbiology, including: oncology, the study of cancers; virology; bacteriology; and blood screening tests (Roche, 2011).

Molecular diagnostics employs a number of technologies including DNA sequencing and genotyping, and polymerase chain reaction (PCR) technology. The latter is used to rapidly replicate a single specific strand of DNA, or RNA, to quantities sufficient for accurate laboratory analysis. Two examples of the applications and utility of genotyping and PCR, respectively, follow:

Detection of human papillomavirus (HPV): in addition to detecting the virus, genotyping can identify high risk HPV types known to be associated with progression to cervical cancer. This provides a far more specific test (one that produces less false positives) than traditional methods.

Rapid detection of disease causing pathogens: PCR can detect pathogens, such as tuberculosis, fungi, and bacteria that can lead to life-threatening sepsis, much faster than traditional microbiology methods that have much longer incubation times.

2.2.4.5 Histology

Histology (or Histopathology) is a branch of clinical medicine that employs microscopic examination of tissue in order to study the manifestations of disease. Specifically, it involves the examination of a biopsy or surgical specimen by a pathologist, after the specimen has been processed and histological sections have been placed on glass slides. (Wikipedia, 2011)

Histology is a vital tool used in the confirmation of the presence of cancer in specific tissues. It is also used to define surgical margins (where to cut) for the removal of cancers, and in the study of heart attacks. The two main sub-specialities of Histology can thus be classified as Oncology and Myocardial Infarctions (heart attacks).

2.2.4.6 Cytology

Cytology (or Cytopathology) is a branch of clinical medicine that studies and diagnoses diseases at the cellular level. Cytology is generally used on samples of free cells or tissue fragments, in contrast to histopathology, which studies whole tissues. Cytology samples are often smeared

across a glass microscope slide for subsequent staining and microscopic examination by a pathologist.

A common application of Cytology is the Pap Smear, which is used as a screening tool to detect precancerous cervical lesions. Cytology is also commonly used to investigate: thyroid lesions; diseases involving sterile body cavities, such as that which surrounds the lungs; and a wide range of other body sites (Wikipedia, 2011). The two main sub-specialities of Cytology can be classified as Oncology and Other.

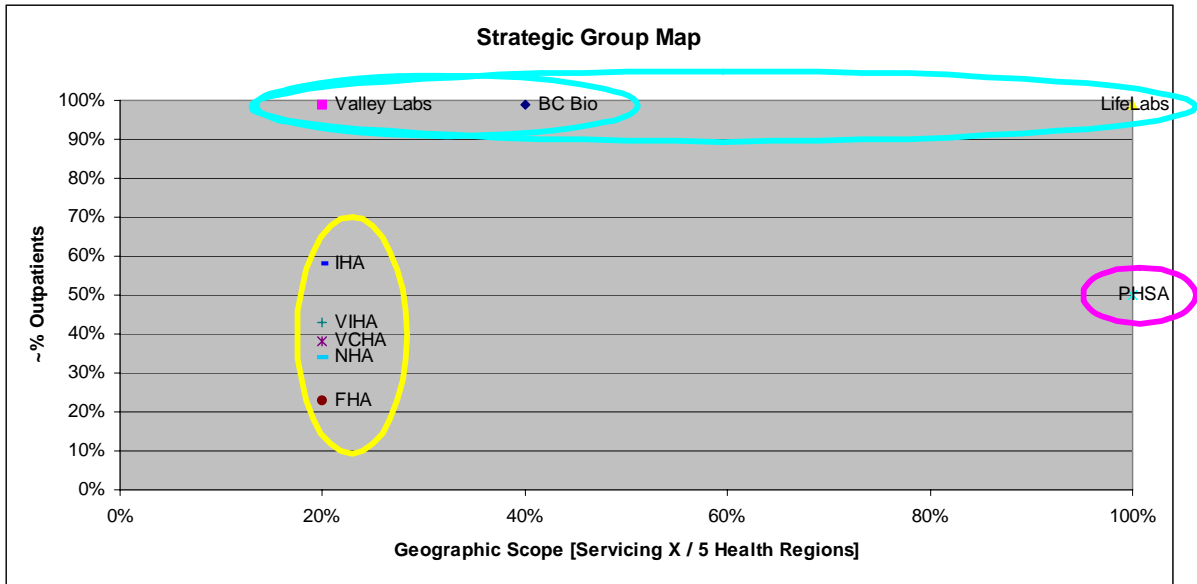
2.3 Strategic Groups

The intent of this section is to identify groups of rival organizations that have similar competitive strategies and positions in the industry. Identification of such strategic groups is important because it identifies which organizations are in direct competition, identifies groups whose competitive positions may be tenuous, and helps to identify barriers that inhibit movement from one strategic group to another (mobility barriers). (Shapiro, 2010).

As noted above, public hospitals primarily service the inpatient customer group, while private community labs service the majority of outpatients. This suggests that industry rivals can be divided into public and private service providers. To explore this inference further, the organizations servicing the med-lab industry in BC are mapped against two strategic dimensions: inpatient versus outpatient balance, and geographical scope. Geographical scope is calculated based on the proportion of regions serviced, out of a total of five.

Figure 2.3 reinforces the inference that there are two main strategic groups, *public* (yellow grouping) and *private* (cyan grouping), in the med-lab industry in BC. Figure 2.3 also shows that there is a major gap in positioning between the public and private groups, on the axis of “percentage of outpatients”. There is also a significant gap between the more geographically-focused providers (BC Bio and Valley Labs), and LifeLabs on the geographic scope axis, suggesting a differentiated position for LifeLabs. Finally, the figure clearly demonstrates that PHSA has a highly differentiated service offering, and as such does not fit into either strategic group, although it has a closer association with the public group, based on its ownership.

Figure 2.3: Strategic Group Map



- PHSA Provincial Health Services Authority (includes BC CDC and BC Cancer)
- VCHA Vancouver Coastal Health Authority
- FHA Fraser Health Authority
- VIHA Vancouver Island Health Authority
- NHA Northern Health Authority
- IHA Interior Health Authority

[Source: Bayne 2003, Author]

Figure 2.3 reinforces the inference that there are two main strategic groups, *public* (yellow grouping) and *private* (cyan grouping), in the med-lab industry in BC. Figure 2.3 also shows that there is a major gap in positioning between the public and private groups, on the axis of “percentage of outpatients”. There is also a significant gap between the more geographically-focused providers (BC Bio and Valley Labs), and LifeLabs on the geographic scope axis, suggesting a differentiated position for LifeLabs. Finally, the figure clearly demonstrates that PHSa has a highly differentiated service offering, and as such does not fit into either strategic group, although it has a closer association with the public group, based on its ownership.

To better understand the public and private groups, Table 2.3 describes the strengths and weaknesses of the players within the groups. The public group is characterized by inpatient focus, high political influence, low-medium scale, and low flexibility (the ability to scale operations up or down). The private group is almost the opposite, characterized by outpatient focus, low-medium political influence, high scale and high flexibility.

Table 2.3: *Strengths and Weaknesses of Competitors in British Columbia*

Competitor	Strengths	Weaknesses
Public Hospital Laboratories (in each of the health authorities)	<ul style="list-style-type: none"> ✓ Political Strength ✓ Public backing and sympathy ✓ Preferential access to new licenses ✓ Breadth of testing 	<ul style="list-style-type: none"> × Lack scale × Difficult to scale up and down × Strong union influence × Inpatient focus × Long wait times for outpatients × Slow decision making × Lack of fiscal accountability
BC Biomedical Laboratories	<ul style="list-style-type: none"> ✓ Strong incentive alignment; owned by a group of physicians ✓ Strong ties to other physicians in Fraser Health Authority ✓ Strong presence in BCALP* ✓ Small business feel ✓ Breadth of testing 	<ul style="list-style-type: none"> × Lack scale × Limited capability to support broad collection network × Slow decision making × Limited business expertise × Exclusively outpatient focused
LifeLabs	<ul style="list-style-type: none"> ✓ Largest scale and most cost efficient ✓ National infrastructure ✓ Fast (relatively) decision making ✓ Access to capital (via Borealis) ✓ Breadth of testing 	<ul style="list-style-type: none"> × Big business image × Lacking influence in BC physician community × Viewed as a threat by the public sector × Exclusively outpatient focused
Valley Medical Laboratories	<ul style="list-style-type: none"> ✓ Very strong incentive alignment; owned by small group of physicians, directly engaged in the business ✓ Nimble and fast decisions 	<ul style="list-style-type: none"> × Mom & pop shop × Small scale × Outdated IT systems × Low automation × Low business expertise × Exclusively outpatient focused

Note “*”: BC Association of Laboratory Physicians (BCALP)

[Source: Author]

2.4 Industry Supply Chain

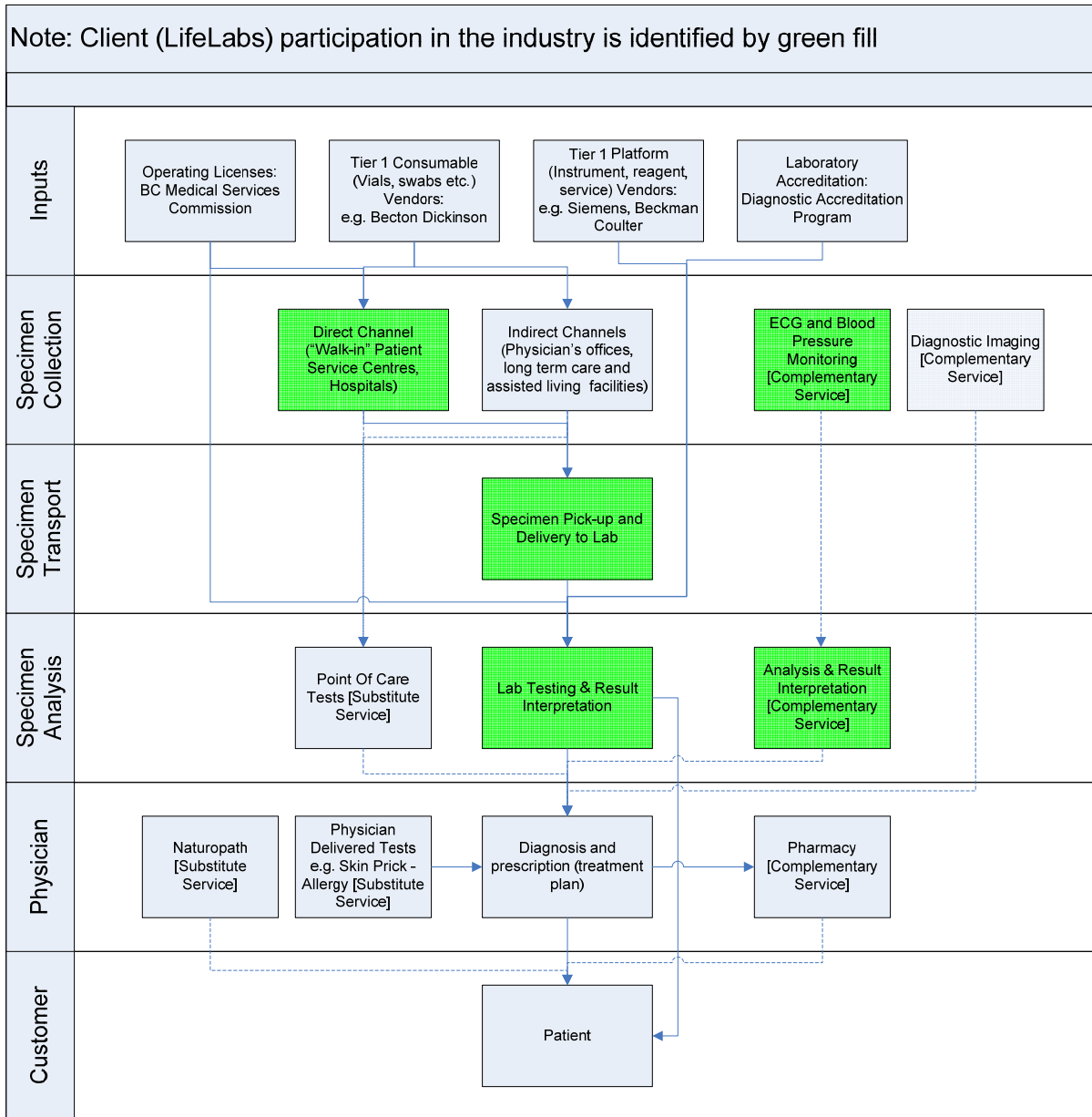
The following discussion describes the flow of goods and services for the med-lab industry in BC, from raw inputs through to final customers. This section will explain how the industry is organized, how market power and profits are distributed along the supply chain, the degree of vertical integration of the industry, and how the vertical structure of the industry may be changing (Shapiro, 2010).

2.4.1 Overview

In simple terms, the key steps in the med-lab supply chain are specimen (blood, urine, other) collection, specimen transport, specimen analysis, result interpretation, result communication, and diagnosis and treatment of the patient's illness. Hence, the ultimate benefactor or final customer of the service is the patient. As previously discussed, although patients are the end customer, doctors choose the appropriate test(s), and the government pays for most tests via MSP.

The inputs that enable the above described flow of service delivery are: procurement of instruments and consumables that enable collection and testing of specimens; attainment of government licences to open transfer or expand collection centres and testing laboratories; and attainment of ongoing quality accreditation through the Diagnostic Accreditation Program (mandatory) and ISO (optional).

Figure 2.4: Supply Chain for the Medical Diagnostic Laboratory Industry in BC



[Source: Author]

2.4.2 Key Groups of Participants

There are four key groups that make up the above described supply chain: government and non-government organizations that are responsible for licensing and accreditation; platform suppliers that supply instruments, reagents and service; integrated laboratories; and physicians and surgeons.

2.4.2.1 Licensing and Accreditation Granting Bodies

Licenses for med-lab collection or testing in BC are granted by the Medical Services Commission (MSC), which is part of the BC Ministry of Health Services. The MSC not only screens new licence applications and licence transfer applications (location change), but also screens applications for changes in operating hours and number of phlebotomists (medical technicians that collect blood) at a collection site.

Licences can only be granted to med-lab testing facilities that have been accredited by the Diagnostic Accreditation Program (DAP). The DAP is governed by the DAP Committee, which is appointed by the College of Physicians and Surgeons of British Columbia (CPSBC). DAP has a Laboratory Medicine specific accreditation program which is comprised of audits (DAP term: surveys) and independent external quality assurance testing (DAP term: proficiency), and includes specific requirements for each of the following areas: sample collection, transport, and order entry (accessioning); chemistry; hematology; transfusion medicine; microbiology; anatomic pathology (histology and cytology); and point of care technology (POCT).

This group provides value to the community by assuring that the laboratory services provided to the public meet stringent medical quality standards.

2.4.2.2 Platform (Instrument, Consumable and Service) Suppliers

Platform suppliers provide test instruments, associated service, and a wide array of consumables from needles and vials, used in collection, to media and chemicals (reagents), consumed during testing. Platform suppliers provide extensive value in the form of test and product innovation, as well as process automation. They deliver improved medical utility, which often translates to improved patient outcomes, as well as lower operating cost. Since they have a global customer base, platform suppliers can also be a valuable source of information on global health trends and the success of new tests and technologies in other jurisdictions.

Most platform suppliers have speciality areas, and as such the composition of the supplier groups varies significantly from one medical sub-specialty to another. For Coagulation, the lion's share of product is supplied by two, multi-billion dollar organizations: Siemens, partnered with Sysmex, and Beckman Coulter, partnered with Instrumentation Laboratories and recently acquired by Danaher. For allergy, there are also few suppliers, primarily Phadia and Euroimmun.

However, these latter organizations are far smaller, operating in the hundreds of millions of dollars revenue range (at least one order of magnitude smaller than their coagulation cousins). This smaller size places them much closer to the magnitude of their customers' (integrated laboratories) operations. For autoimmunity the range of suppliers is once again small: Phadia, Euroimmun, Biorad, and Diasorin, and their scale is similar to that of allergy (with some supplier overlap). (Links to the websites of each of the suppliers discussed in this paper can be found in the References.)

2.4.2.3 Integrated Laboratories

Integrated laboratories, public or private, have the greatest span of vertically integrated activities in the med-lab supply chain. They provide a full array of services, including: specimen collection, via a network of patient service centres (PSC's), at which patients can visit to drop off their samples or have them collected, and via mobile collection services; transport, pick up from PSC's, mobile collection service hubs, physician offices, and other care facilities; testing, across a broad range of subspecialties; interpretation of results by lab physicians; communication of results to the requesting physician; and on-demand consultation to aid in result interpretation by the requesting family physician or specialist.

Private providers, such as LifeLabs and BC BioMedical Laboratories offer the full array of services described above, as does Valley Medical Laboratories on a much smaller scale. Public hospitals also offer a large portion of the services described above, although their focus depends on geography, or more specifically on population density. Hospitals in more remote health regions such as the Interior Health Region or the Northern Health Region carry out a broad array of the services described above, including many outpatient oriented services. Hospitals in urban settings tend to focus more on inpatients, as outpatients are comprehensively serviced by private labs.

Integrated labs provide value to the patient by providing them with a convenient, reliable, high quality health service. They also provide utility to physicians by informing their diagnostic decisions with reliable test results and providing them with additional consultation to interpret results should they need it.

Inpatient and outpatient services have not been strongly distinguished above, as the supply chain for inpatients is made up of very similar components to those of the supply chain for outpatients. The only major difference is that an inpatient environment, such as a hospital, has all of the above described elements as well as additional substitute (e.g. point of care testing) and complementary services (e.g. diagnostic imaging, electrocardiogram (ECG), pharmacy, etc.) which are fully integrated into its service offering.

2.4.2.4 Family Physicians and Specialists

There are approximately 5,000 Specialists and 5,500 General Practitioners practicing in BC (CPSBC, 2010). Physicians compare and contrast test results and lab physician interpretation against patient symptoms (clinical presentation) in order to effectively diagnose disease and prescribe treatment.

Physicians also play a very strong role as agents for the buyer (patient), advising or dictating the type of tests to be ordered and signalling their preference for service provider through the use of preferred service provider requisition forms.

2.4.3 Market Power and Rent Capture

The scarcest resources, and thus areas of greatest rent capture potential, are: the physicians themselves; the government licences to operate specimen collection centres and test analysis laboratories; and the platform technologies and associated intellectual property that enable testing. This will be elaborated on in Section 2.6: Market Structure.

2.4.4 Changes in the Vertical Structure

The emergence of point of care technology (POCT), which enables remote or decentralized testing, could signal the beginning of the disintermediation of the med-lab supply chain. POCT is an emerging technology that enables laboratory testing to be performed effectively on a small scale. Although the cost per test is still high, it offers great utility by providing rapid test results directly at the point of care. POCT has the potential to enable the replacement of the large, high volume, and very expensive analysers used by centralized integrated laboratories by small, far less expensive, desk-top test units that would be deployed as a large decentralized network.

2.5 Industry Boundaries

The previous discussion implicitly assumed that the relevant boundary for the med-lab Industry is the province of British Columbia. The following section tests the validity of this assumption.

To assess the boundaries of the industry it is useful to start with the customer perspective. Outpatients value convenience and thus prefer to have services within their communities as it minimizes inconvenience to them. Patients requiring acute care (inpatients) primarily value quality of care and speed of service delivery. Convenience is not a significant consideration. Despite convenience not being highly valued by inpatients, most acute care services are available within the boundaries of their home health authority. Thus, from a patient perspective, the market appears very local in nature.

Looking beyond the customer perspective, however, reveals a different picture. Funding providers, regulators and service providers all operate at the health region or provincial level. In the case of service providers, aggregation of smaller local markets into larger markets is critical to achieving the scale economies required to provide cost efficient health service to the public. Private labs in particular employ large centralized laboratories to achieve the volumes required to operate at minimum efficient scale. Government control of access to services, via licensing, and cost, via fee schedules under MSP, is also administered by the provincial government at a provincial level.

Hence, given the large minimum efficient scale and provincial regulation of the industry, it is reasonable to continue to assume a provincial boundary for the medical diagnostic laboratory industry. Expanding the boundary to include multiple provinces, or to a national level is not considered reasonable as market structures vary considerably from province to province.

2.6 Market Structure

2.6.1 Market Size and Market Share

The medical diagnostic laboratory services industry has been in existence for more than fifty years in British Columbia, far more if inpatient only services are considered.¹ Steady consolidation has been occurring in the industry throughout the last three decades, including an accelerated burst in the 1990's, and has now resulted in the survival of only three labs of any significant scale (excluding public labs),– LifeLabs, BC Biomedical Labs, and Valley Medical Labs. These private labs together service approximately 67% of the outpatient market (approximately \$200 million per year), with LifeLabs, BC Bio and Valley holding 39%, 24%, and 4% of the outpatient market respectively (Medical Services Commission, 2009). Public labs service the remaining 33% share (approximately \$100 million per year).

New tests are made available to the public every year. However, the proportion of the overall test menu which changes is very small. Test demand continues to grow at a slow but steady pace of approximately 2 to 3% per year (LifeLabs, 2011). This growth can be attributed to test demand increasing as the demographic mix shifts towards the elderly, as well as the increasing medical focus on early detection and effective treatment of both acute and chronic diseases, which is assisted by diagnostic testing and therapeutic drug monitoring.

2.6.2 Market Structure

As previously described, the medical diagnostic laboratory industry in BC is made up of three major private laboratories and six public health authorities. Despite the existence of a total of nine major entities providing med-lab service, the number of major players in a region rarely exceeds three or four because service providers focus geographically, as described in Table 2.2. At a local level the number of players servicing a specific community, e.g. Central Surrey, is even smaller,

¹ Research conducted in support of this paper was unable to determine the total level of funding for inpatient and outpatient laboratories in BC. However, Ontario data suggests that total inpatient hospital laboratory funding is approximately 50% greater than total outpatient funding (Ontario Association of Medical Laboratories, 2007). If the same factor was applied to the BC numbers, it would mean an inpatient funding level of approximately \$450 million per year, taking the total public share of the combined, in-patient and outpatient, market up to about 73% of total spending on lab services, with 27% spending from private sources. Although this percentage may be grossly over or under-stated, it demonstrates that the inpatient market is substantial and needs to be considered to arrive at true expressions of market share for the combined market.

rarely exceeding two. This is because of the licensing restrictions placed by government (through the MSC) on the density of specimen collection centres.

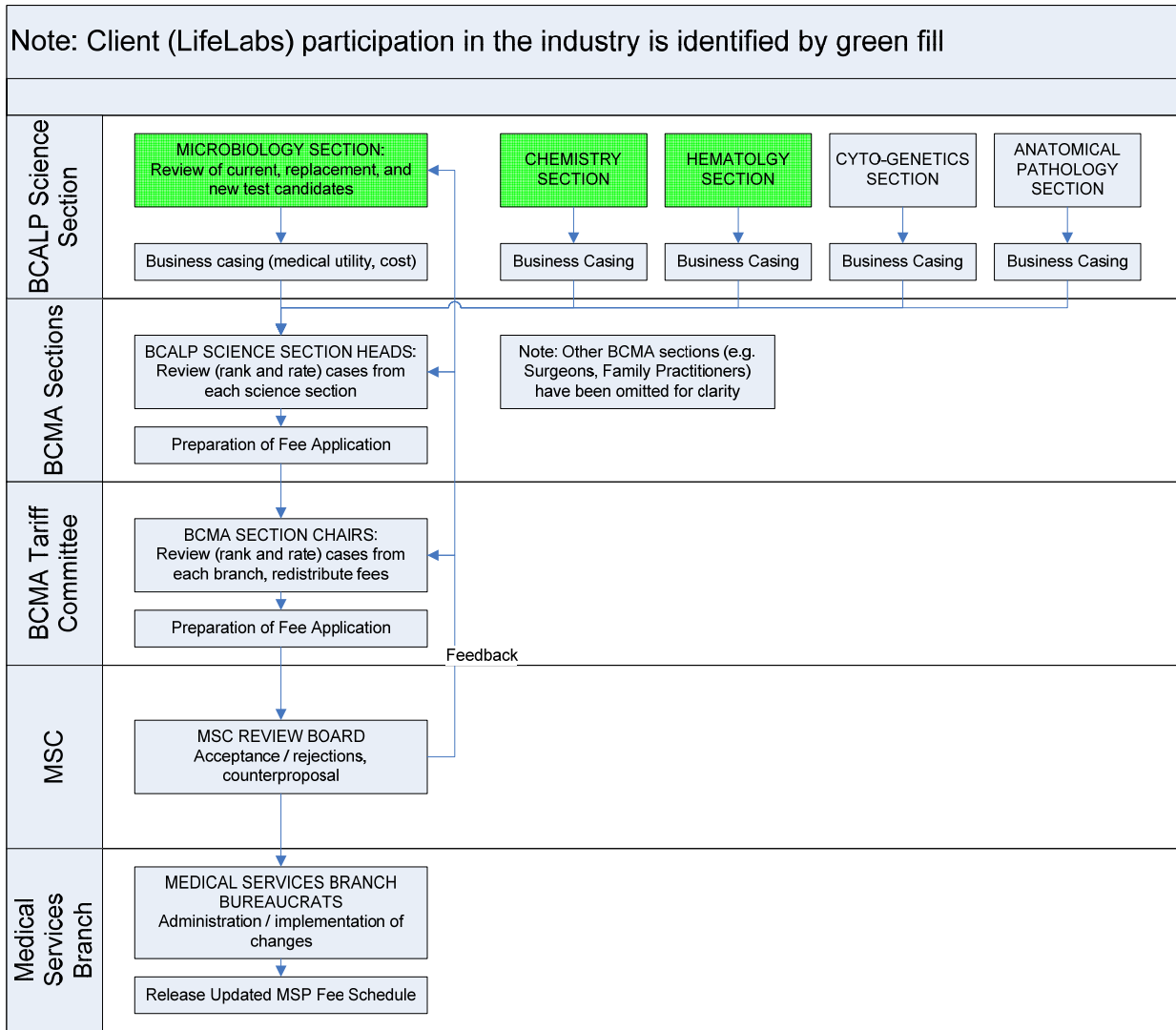
According to current MSC guidelines, the following conditions must be met to gain approval to open a new specimen collection centre: the application has to be supported by five physicians; each phlebotomy (blood collection) chair provisioned for the site needs to be assumed to handle thirty-five patients per day; and the distance between the proposed site and any other collection site, public or private, cannot be less than thirty minutes on public transit. If two applications are simultaneously placed by two providers for the same area, they are generally considered on their merits. However, as a rule of thumb, public trump private applications, usually because public applications are associated with hospitals or acute care centres. Once an application is approved, the applicant is effectively granted an eighteen month option to exercise the licence. During this eighteen month period, other applications for the same area will not be considered by the government. MSC application rules do change periodically, and currently require stronger expressions of community need to justify additional capacity than in the past. (LifeLabs, 2011)

In addition to controlling access to services via licensing of specimen collection centres, the government controls med-lab test prices by setting MSP fee schedules. The process for setting fees is shown in Figure 2.6 below. The first step in the process is the drafting of recommendations for changes, additions or de-listings of tests by the respective science sections of the BC Association of Laboratory Physicians (BCALP). The recommendations from the science sections describe the clinical value and cost per test to demonstrate value to the government. Those recommendations are then screened by the BCMA, in competition with other, non-laboratory medicine recommendations, and successful recommendations are taken forward as fee applications.

Thus, although fee schedules (prices) for med-lab testing are ultimately determined by the government, via MSC, the British Columbia Medical Association (BCMA) has a significant influence on the portion of total medical funding that is appropriated by laboratory medicine.²

² Why is the government so involved in the med-lab industry? A likely explanation follows: First, it is running an insurance plan, MSP, covers 100% of the test costs for the patient. Second, it appreciates that economies of scale and scope are very significant in the industry and as such a small number of service providers makes sense. The first issue drives it towards limiting supply so that the service is not over-consumed. After limiting volume it places itself in danger of oligopoly or duopoly pricing, by virtue of the second issue, and thus attempts to regulate price down to a more socially efficient level.

Figure 2.6: Application Process for Changes to Laboratory Testing Fees



[Source: Kelly, 2011]

In summary, the market structure of the industry can be described as consisting of local oligopolies with government price (test level) and volume controls (patient service centre licensing). As a result, the competition in the industry is mainly based on service delivery (turn-around-time (TAT)) and quality via the Diagnostic Accreditation Program. TAT is a critical characteristic as it has implications for test integrity, patient outcomes, and patient and physician convenience.

3: Analysis of the Medical Diagnostic Laboratory Industry

The preceding chapter has described the medical diagnostic laboratory industry in BC in detail, including services and customers, industry segmentation, strategic groups, industry boundaries, supply chain and market structure.

To provide the client with insight into the external environmental factors that are most likely to influence long-run profitability and risk, this chapter will analyse those forces that affect industry profitability now and in the future. The analysis will isolate forces specific to the medical sub-specialties of allergy, autoimmune, and coagulation, so as to enable the development of specific recommendations for the client's most urgent decisions.

The following analysis is composed of a life-cycle analysis, demand and cost analysis, Porter's Five Forces analysis (Porter, 1980), and a political landscape analysis. Life-cycle and demand and cost analyses are used to include considerations that may be deficient in a stand-alone Porter's Five Forces analysis. A political landscape analysis concludes the section to ensure that any important political climate factors that were omitted by the preceding analyses are addressed.

3.1 Life Cycle Analysis

Assessing lifecycle is useful for confirming the current state of the industry and roughly predicting what is likely to happen next.

The long history, slow growth, slow test schedule turnover, and provider consolidation described in Section 2.6 are all characteristics that are consistent with the mature phase of the industry lifecycle. Thus, the industry as a whole can be described as mature. Life cycle theory suggests that in a mature industry revenue is likely to be flat or declining, and that cash flow is likely to be

flat, assuming an increased emphasis on cost control. It also suggests that there is a high degree of standardization in the industry.

Since the label of mature is not true for all industry segments (the clearest example being Molecular Diagnostics which is in the embryonic phase), it is prudent to assess lifecycle specifically for the segments (sub-specialities) being studied. These include allergy, autoimmune, and coagulation. The brief analysis presented in Table 3.1 demonstrates that autoimmune and coagulation segments are consistent with the maturity phase, while allergy has growth phase characteristics.

Table 3.1: Life-cycle Phase Analysis by Industry Segment (Medical sub-specialty)

Segment	Current Characteristics	Current Phase	Implied Future State
Allergy	<ul style="list-style-type: none"> • Increasing prevalence amongst, and awareness from the population • Alternatives to traditional (Skin Prick) tests gaining increasing acceptance 	Growth	<ul style="list-style-type: none"> • Continued growth in demand and revenue • Entry of new instrument and technology providers is likely
Autoimmune	<ul style="list-style-type: none"> • Slowly increasing test demand 	Maturity	<ul style="list-style-type: none"> • Continued slow growth in demand • Small, stable supply base
Coagulation	<ul style="list-style-type: none"> • Slowly Increasing test demand 	Maturity	<ul style="list-style-type: none"> • Continued slow growth in demand • Small, stable supply base

3.2 Demand and Cost Analysis

Demand and cost analysis provides insight into the factors that determine the value created by med-lab services (the difference between the willingness to pay for, and the costs of providing the services), as well as into the effects of price and supply regulation.

The following analysis is split into two sections. The first examining factors that influence demand (willingness to pay) and the second examining factors that influence cost.

3.2.1 Demand Analysis

3.2.1.1 Income

Incomes affect demand. A good or service can be either classified as normal, if its consumption increases as income rises, or inferior, if its consumption increase as income falls.

As discussed in section 2.2.3 the funding for the Medical Laboratory industry can be split into three major sources: Public Funding (Global), Public Funding (Fee Schedule MSP), and Private Funding. For the consumer (patient) this translates respectively to three scenarios: emergency treatment; non-emergency screening, diagnosis or management of disease; and higher value add screening or diagnosis of disease.

Since the first two funding sources, global hospital funding and MSP, are public insurance the patient's income has no material effect on consumption. However, government income does. The greater the government's tax revenues, the greater their willingness to spend more on med-lab services. Under private funding, med-lab testing again behaves like a normal service. However, in this instance demand increases as patient income rises. Thus, in aggregate, diagnostic med-lab service in BC exhibits the characteristics of a normal service.

Since tax revenues are currently flat and are likely to remain flat or decline due a shrinking labour force, incumbents in the med-lab industry are likely to experience a reduction in willingness to pay from their largest buyer, the BC government (BC Stats, 2011).

3.2.1.2 Prices of Related Goods

The next determinant of demand is the price of related goods and services, specifically substitutes, for which an increase in the price of one good or service results in the increase of demand for the other, and complements, for which the increase in price of one good or service results in a decrease of demand for the other.

Demand for med-lab services is influenced by the price of complementary services such as physician consultations, electrocardiogram (ECG), blood pressure monitoring, diagnostic imaging, e.g. magnetic resonance imaging (MRI), X-Ray, and pharmacy. Urgent and basic physician consultations, ECG, blood pressure and diagnostic imaging services are publicly or

privately insured, as are some pharmaceuticals. As a result, they have a negligible effect on consumer demand but can have a significant effect on government demand. Publicly funded med-lab services are affected by price changes in the suite of complementary medical services managed by the BCMA, as previously described in Figure 2.6. Elective screening services, such as MRI scans are often privately funded and can be very costly, and thus have a noticeable affect on consumer demand. For example, increases in elective MRI price can have an adverse impact on demand for private pay med-lab screening services and vice-versa, as they impact the consumer's willingness and ability to pay.

In summary, demand for both publicly funded and privately funded med-lab services is susceptible to price changes in complements. However, incumbents are unlikely to be dramatically affected by complements as the prices of the various services are relatively stable.

Demand for med-lab services is also influenced by the price of substitute services. Publicly funded med-lab services are strongly, potentially dramatically affected by price changes in substitutes. Some examples follow.

Screening: If genomic screening technology made cost effective and accurate predictive screening possible, the government would likely shift substantial budget funding from current med-lab screening technology to genomics. The lower the price of such testing, the more dramatic the shift.

Chronic disease management: If the price of POCT became low enough and the reduced load on the hospital system as a result of more effective disease management were appreciated and monetized, the government would likely agree to increased MSP fees for med-lab tests that were offered on distributed basis throughout the community via POCT.

Infectious diseases: If the price of molecular diagnostic identification of pathogens drops enough, the government is likely to increase MSP funding of the technique, which is faster and more specific than traditional methods, leading to more effective disease monitoring and treatment.

Privately funded services are also affected by price changes in substitute services. These include naturopaths who may have a different usage rate and mix of med-lab tests compared to physicians, physician administered tests such as the skin prick test conducted in house by allergy

specialists, and POCT tests. If naturopaths were to reduce their fees, an additional portion of consumers of physician service would shift to naturopaths, thus changing test demand and mix. If private pay allergy tests that are more specific and less onerous (one finger prick for the med-lab test versus multiple skin pricks for physician administered test), were to be offered at a low enough price, consumers would pressure allergy specialists to provide access to the test, thus increasing demand for med-lab testing. If POCT based testing (using numerous small test instruments widely distributed throughout the health network or patients' homes) was provided to consumers for chronic disease management, then this would reduce time to results and would require smaller blood samples, increasing willingness to pay.

In summary, demand for both publicly funded and privately funded med-lab services will be affected by changes in the price of substitutes. Changes in the prices of two substitutes are likely to have a dramatic affect on demand: it is likely that incumbents will need to face the threat of broad adoption of POCT and molecular diagnostics during the 5-10 year planning horizon.

3.2.1.3 Advertising and Consumer Tastes

Demand for med-lab services increases with increased advertising, however its effect is usually limited to a very narrow set of tests. For example, increased discussion of Vitamin D deficiency in the media recently has significantly increased the demand for Vitamin D testing. Also, LifeLabs education of doctors raised the awareness of the value of screening for colorectal cancer using the FIT method, and has increased the general awareness of colorectal cancer in the patient population, resulting in increased demand.

Although the media does affect med-lab demand, the med-lab industry itself does not advertise in the media. Its advertising consists of the education of physicians regarding the existence and quality of a test (informative advertising) through seminars at conferences, visits to physician's offices and newsletters. Med-lab patient service centres and some physicians' offices also make test flyers available to patients.

Since advertising is primarily delivered in the form of physician education, it is important for incumbents to stay active in physician forums, to stay connected to physician (customer agent) needs and to effectively communicate the value of new, superior tests and the rationale for retirement of old, inferior tests.

3.2.1.4 Population

General Provincial Trends

As of October 1, 2010, the population of BC had reached 4,551,853 people. Over the previous year the provincial population grew at a rate of 1.5%, second only Saskatchewan at 1.53% (BC Stats, 2010). According to BC Stats, the population in BC is likely to expand by approximately 1.6 million people by the year 2036, at an average growth rate of 1.2% (compared with 1.6% for the last 27 year period).

Some highlights from the BC Stats 2036 projection are: Growth will be driven by immigration with half the population 45 or older, an approximately 4 year increase from the current median age. There will be a reduction in the relative size of the under 18 age group, from about 20% to about 17%, more seniors than children and a continued increase in female to male ratio, from 100:98.5 now to 100:97. There will be a relatively smaller labour force, about 65% of the working age population compared with current 70%; and the strongest growth will be in the Lower Mainland but the youngest population will be in the North East, driven by jobs in energy sector. The Okanagan population will still be older than the provincial average, however by a smaller amount, about 2 years compared to the current 4 years, and senior migration to Vancouver Island will continue.

Although BC is the second fastest growing population in Canada, the rate of growth is quite modest and unlikely to have a significant impact on demand. However, shifts in demographics are likely to increase demand for tests associated with chronic disease monitoring due to an increased proportion of seniors, as well as for risk factors and lifestyle factors due to an increased proportion of those of middle age in the population. Demographic changes are also likely to decrease microbiology test demand due to a decrease in youth population. These shifts are likely to be especially pronounced on Vancouver Island.

Sub-specialty Specific Trends – Autoimmune and Coagulation

Since the population is ageing, the segments of autoimmune and coagulation are likely to grow in the range of 3-5% per annum. Growth in autoimmune and coagulation will be driven by the increase in rheumatoid arthritis and heart and stroke disease respectively.

Sub-specialty Specific Trends – Allergy

The American Academy of Allergy, Asthma and Immunology estimates that from 2 to 4% of children and 1 to 2% of adults have allergic reactions to food (AAAAI, 2011). In a 2003 study of the prevalence of peanut allergy in 4339 primary-school children in Montréal, the prevalence of peanut allergy was found to be 1.50%. (Kagen, 2003)

In England, there has been a more than two fold increase in the prevalence of peanut allergies between 2001 and 2005, an almost 50% increase in the presence of hayfever, asthma and eczema together between 2001 and 2005, and a three fold increase in anaphylaxis requiring hospital treatment between 1994 and 2004 [Wikipedia, 2011].

Although allergy is currently a very small portion of the med-lab market, the above mentioned trends suggest that annual growth rate of about 10% is not an unreasonable estimate. Thus, incumbents should invest in the development of broader allergy test capability.

3.2.1.5 Other Factors

Other events that have historically proven to have an impact on med-lab test demand include infectious disease scares, such as the 2009/2010 H1N1 flu pandemic, and major sporting events such as the 2010 Vancouver Winter Olympic Games.

In the H1N1 case, people did not want to visit their physicians for fear of contracting the flu and thus withdrew from the market, thus reducing total test demand in the impacted months by about 10% compared to the prior year (LifeLabs, 2011). Similar, but much more localized demand reducing effects have also been seen with Norwalk virus, mumps, and whooping cough. In the case of the Vancouver Winter Olympic Games, the negative effects of the games on access to medical facilities reduced demand for med-lab services by about 10% for the same period the prior year (LifeLabs, 2011).

Incumbents need to recognize that exceptional events will continue to disrupt operations and consider the disruption mitigating benefits of a highly distributed system (such as POCT) in people's homes or long term care facilities. This is especially relevant to chronic disease monitoring and the coagulation segment by extension.

3.2.2 Cost Analysis

3.2.2.1 Input Prices

The main input costs for med-lab industry service providers are: materials costs, including reagents (chemicals), media such as tissue cultures, and collection vessels such as vials consumed in the process of testing; labour costs; transportation costs; test instrument costs; facilities costs; and licensing and accreditation costs.

For incumbents, labour and materials costs are expected to remain flat, with increases offset by productivity gains. Transport costs are likely to increase in the long run as the price of oil continues to climb. Licensing costs are also expected to increase as adjacent sectors, such as diagnostic imaging, have recently had competency scandals, increasing the likelihood of even stricter accreditation guidelines. Thus, in aggregate, costs are expected to rise.

Incumbents are thus advised to assess if they have sufficient expertise in cost control and cost reduction as these competencies will be critical to defending profits.

3.2.2.2 Technology

International health crises such as H1N1 and SARS have highlighted how disintegrated provincial and national health infrastructure is in Canada. As a result, the government is now very invested, both federally and provincially in developing a fully integrated system that allows for effective, nationally coordinated responses to crises, including pandemics and natural disasters. In non-crisis times, such a system is expected to provide significantly improved productivity and quality of care by providing physicians with rapid access to patient history. Patient history would include med-lab test results, diagnostic imaging test results, consultation notes, and pharmaceutical history. This initiative is broadly termed Electronic Medical Records (EMR) and is a formally documented goal of the BC Provincial government (Ministry of Health Services, 2011). It is thus clear that centralized diagnostic databases will soon become an integral component of healthcare delivery.

Since the government is unlikely to mandate a single proprietary EMR software solution, because it would make it susceptible to hold-up, it is important that incumbents become involved in the definition of interface specifications so that they do not end up with unworkable or extremely

high cost interface requirements. Incumbents already involved in development of interface software should consider leveraging their competencies to build the middleware required to effectively interface with the government's systems. One example of an existing interface product is Excelleris, an electronic med-lab results reporting software co-developed by LifeLabs and BC Biomedical, which is now used by approximately 6,000 of the 12,000 doctors in British Columbia and provides patients with direct access to their results through a service called my e-Health (LifeLabs, 2011). Excelleris has the potential to lead to further interface development, possibly enabling connection between incumbent lab information systems (LIS, med-lab provider databases) and the provincial (PLIS, a centralized database for all public med-lab provider data in BC) or health authority lab information systems.

EMR is likely to increase costs for incumbents. Although EMR-based test ordering is likely to improve ordering efficiency by reducing or eliminating problems associated with unclear or incomplete data on hard-copy requisitions, this will not be enough to offset the costs of developing interfaces and sharing information.

3.2.3 Demand and Cost Analysis Summary

Stable or declining government revenues combined with an increase in the availability of substitute services are likely to place downward pressure on the demand for med-lab services. Continued population growth and aging is expected to offset this downward pressure in the segments of allergy and autoimmune. However, this is not the case in the segment of coagulation.

Although materials and labour costs are likely to stay relatively constant, transportation and licensing costs are likely to drive an increase in input costs. Additional new input costs such as EMR interfacing are also likely to be imposed on incumbents by government.

Therefore, although value created by the health system is likely to grow because of incremental advancements in the utility of med-lab services and improvements in the quality of physicians decision making (enabled by integrated data), the value added by med-lab incumbents is likely to go down because of a constant or reduced government willingness and ability-to-pay and an increase in input costs.

Despite the predicted downward pressure on incumbent profitability, opportunities to capitalize on changes and create new value exist. For example, willingness to pay for POCT for chronic disease management is likely to be high, which will enable incumbent providers to diversify into POCT under MSP billing or to charge consumers for a premium mode of service delivery (private providers only), even if the government does not support funding POCT above the current conventional med-lab level.

Table 3.2: Med-lab Demand and Cost Analysis by Industry Segment

Segment	Key Demand Shifters	Key Cost Shifters	Key Price Factors
Allergy	<p>↓ <u>Falling prices and increasing value of substitute services:</u> e.g. skin prick test vs. allergy component testing; blood draw vs. finger prick (POCT).</p> <p>↑ <u>Population:</u> increasing allergy prevalence.</p>	<p>↑ <u>Prices of inputs:</u> Transport, licensing, and proprietary reagent kits costs increasing in this segment.</p> <p>↑ <u>EMR interface development</u></p>	<ul style="list-style-type: none"> • Regulators (BCMA / MSC) ↑ New and Better Assays (Tests) ↓ Emerging Technology
Autoimmune	<p>↓ <u>Falling prices and increasing value of substitute services:</u> e.g. blood draw at clinic vs. finger prick at home (POCT).</p> <p>↑ <u>Population:</u> e.g. Ageing population drives increase in rheumatoid arthritis.</p>	<p>↑ <u>Prices of inputs:</u> Transport, licensing, and proprietary reagent kits costs increasing in this segment.</p> <p>↑ <u>EMR interface development</u></p>	<ul style="list-style-type: none"> • Regulators (BCMA / MSC) ↓ Emerging Technology
Coagulation	<p>↓ <u>Falling prices and increasing value of substitute services:</u> e.g. blood draw at clinic vs. finger prick at home (POCT).</p> <p>↑ <u>Population:</u> e.g. ageing population drives increase in blood clot management for heart and stroke.</p>	<p>↑ <u>Prices of inputs:</u> Transport and licensing cost increasing in this segment.</p> <p>↑ <u>EMR interface development</u></p>	<ul style="list-style-type: none"> ↓ Regulators (BCMA/MSD) ↓ Emerging Technology

3.3 Porter's Forces Analysis of Industry Attractiveness

The preceding demand and cost analysis provides insight into factors affecting value created and prices in the industry. However, to develop a more comprehensive understanding of the business landscape it is necessary to analyse how the structure of the industry affects average profits today and in the future. The structure of the industry will be examined using the Porter's Forces (threat of substitutes, threat of entry, buyer power, supplier power and rivalry). Each of the Five Forces will be assessed qualitatively for its threats to rents of the current incumbent firms, both now and in the most likely future. A qualitative conclusion will be drawn regarding the overall level of attractiveness of the industry and the most likely future state.

Aspects of the Porter's Five Forces that are common to all segments will be discussed first, followed by discussion of the unique characteristics of the sub-specialty segments: allergy, autoimmune and coagulation.

3.3.1 Common Forces

3.3.1.1 The Threat of Entry (low and stable)

The threat that potential new entrants pose to an industry's profitability depends primarily on entry barriers. The lower the barriers to entry, the greater the potential for new players to enter the industry if incumbents are earning above average rates of profit. "Entry barriers exist whenever it is difficult or not economically feasible for an outsider to replicate the incumbents' positions, and usually rest on irreversible resource commitments." (p.25, Ghemawat, 2010).

There are extensive barriers to entry for the med-lab industry. First, government regulation (licensing) precludes new players from entering markets that are adequately served (under-served markets are generally very geographically dispersed and difficult to serve profitably). Scale economies require that an entrant attain significant scale in order to generate positive economic profits (rents). Incumbents have extensive sunk costs in property, plant and equipment, including everything from patient service centres and transport fleets, through to laboratory facilities and test equipment. Scope economies require that an entrant offer a broad range of test services to amass enough total volume to effectively utilize the capacity of test equipment. Other incumbent advantages including a reputation for service quality, technological know-how and learning

effects, priority access to raw material inputs, and existing ownership of some high traffic business locations. There are also high exit barriers associated with limited ability to liquidate highly specific assets and extensive severance costs due to a largely unionized workforce.

Threat of entry can thus be summarized as low and stable across all segments, including allergy, autoimmune and coagulation.

3.3.1.2 The Degree of Rivalry (low and stable)

The degree of rivalry in an industry refers to the degree and nature of competition. It is affected by the number and relative size of competitors, the industry's basic conditions, including how capital intensive it is, and behavioural determinants, such as high exit barriers, or association of high strategic value to market position. (Ghemawat, 2010)

As described in section 2.6.2, the market structure of the industry can be described as consisting of local oligopolies with government price (test level) and volume controls (patient service centre licensing). Government price and volume controls on the publicly insured portion (more than 95%) of the industry's output mitigate price competition (LifeLabs, 2011). As a result, competition in the industry is primarily based on turn-around-time and quality, via the Diagnostic Accreditation Program. Even in the approximately 5% private pay portion, price competition is limited because value-added services are often differentiated.

The non-price competition described above suggests that industry rivalry is low and likely to stay low, unless substantial reductions in regulation occur. Even in such an instance, rivalry is unlikely to escalate dramatically as capacity cannot be adjusted easily or quickly and incumbents have significant advantages. Thus, even a less regulated market would be unlikely result in significant price competition.

Rivalry can thus be summarized as low and stable across all segments.

3.3.2 Introduction to Segment-Specific Forces

3.3.2.1 The Threat of Substitutes

The threat that substitutes pose to an industry's profitability depends on the price-to-performance ratios of the different types of products or services to which customers can turn to satisfy the same basic need. It is also affected by switching costs (Ghemawat, 2010).

As prices of new, substitute technologies drop and capabilities improve, improving price-to-performance ratios, the substitute threat will increase.

Switching costs for the consumer (patient) differ substantially depending on whether new substitute tests become MSP funded or not. If all tests are MSP funded then shifts to more convenient and higher specificity tests will be demanded by most, if not all, patients. If new tests become privately funded then the value will need to be very clear and the shift is likely to affect a smaller portion of patients. Since physicians act as agents for patients, lower switching costs for physicians will directly translate to faster adoption of substitutes and indirectly improve the likelihood of MSP funding by way of physician endorsement through the BCMA.

Since the price-to-performance ratios of substitutes vary by segment, threat of substitutes will be addressed segment by segment.

3.3.2.2 Buyer Power

Buyer power increases with the bargaining power of buyers and the price-sensitivity of buyers. Bargaining power is high when buyers are large and concentrated relative to rivals (med-lab service providers), few buyers purchase a large proportion of the industry volume, buyers can threaten backward integration, and when buyers have good information on rival pricing. Price sensitivity of buyers is high when the product is a high proportion of buyer's costs, there are many similar products available from rivals in the industry, there are substitutes with good price-to-performance ratio, and switching costs (relationship specific investments) are low (Shapiro, 2010).

As previously discussed, despite the patient being the end user of services, they are only assumed to be the buyer for private pay services. The BC provincial government is the buyer of all services delivered under MSP and other global funding mechanisms, and will thus be considered the main buyer.

Since the government's bargaining power and price sensitivity varies by segment, buyer power will be addressed segment by segment.

3.3.2.3 Supplier Power

Supplier power increases with the bargaining power of suppliers as well as the price insensitivity of rivals in the industry. Bargaining power is high when suppliers are large and concentrated relative to rivals (med-lab service providers), rivals in the industry purchase a small percentage of suppliers' product; and suppliers can threaten credibly forward integration. Price insensitivity of buyers is high when there are few alternate suppliers or when product is differentiated, when there are few substitute inputs for the industry, and switching costs (relationship specific investments) are high (Shapiro, 2010).

Since the supplier's bargaining power and price insensitivity of rivals varies by segment, supplier power will be addressed segment by segment.

The above notwithstanding, there is one universal issue that affects all suppliers across segments, that is, the increasing requirements to achieve US Food and Drug Administration (FDA) and Health Canada approval. Increased requirements for FDA and Health Canada approval of new med-lab equipment and tests will result in a reduced rate of innovation and diversity of available technology, as regulatory barriers to entry for platform suppliers become prohibitive for smaller players. For larger players, increased FDA requirements and wait time will result in acceleration of plans to consolidate assays onto "super-platforms" (large laboratory equipment capable of servicing a diverse range of med-lab segment requirements). The above described changes will increase supplier concentration and reduce the availability of substitutes, thus increasing supplier power.

3.3.3 Allergy Segment Analysis

Med-lab testing in the allergy segment is designed to aid in the diagnosis of, and prediction of severity of reactions to allergens that are either inhaled, ingested or come into contact with the skin.

3.3.3.1 The Threat of Substitutes (low and increasing)

Price : Performance

The Allergy segment of med-lab testing has two significant, yet very different, substitute threats: physician delivered tests (Skin prick testing (SPT) and Oral Challenge) and point of care technology (POCT). The two physician delivered tests are currently in common use, and thus offer a medium level substitute threat to med-lab. As previously described, POCT refers to a technology and a related group of products currently under development, that would modify the mode of test delivery for a subset of the tests (screening) currently provided by med-lab testing and physician testing. Genomics is not considered to be a relevant substitute threat for med-lab screening for allergy, as the timeline required to achieve genomic allergy screening capability is likely to be well beyond the 5-10 year planning horizon of this paper.

Two examples of the large scale conventional instruments currently used by med-lab service providers are the Phadia ImmunoCap 250 and Euroimmun Analyser 1. Both analysers use Enzyme-Linked Immunosorbent Assay (ELISA) test methods and are relatively large units, suited to large, centralized laboratories. These platforms offer high sensitivity screening assays (tests) and in Phadia's case also offer secondary, high-specificity allergy components testing.

Phadia also has a point of care technology (POCT) product under development that has the ability to screen for allergens using a minute sample of whole blood that can be easily collected with a finger prick. Although this test will be less sensitive than those of full sized equipment in the laboratory, it has very low impact on the patient and offers almost instantaneous results, making it very compelling for physicians and patients alike. It is therefore likely that most allergen screen tests will move to POCT, with only higher specificity (confirmation type) tests remaining on the large scale laboratory test instruments that are currently used by the med-lab service providers.

Skin prick testing (SPT) involves the allergy specialist piercing the surface of the skin (forearm) with a lancet (type of needle) multiple times to create test sites and then applying different reagents, each with a cocktail of allergens, to distinct sites to identify allergic response. No test instruments are required to conduct the test. Although currently subject to lower specificity than advanced med-lab instruments due to cross-reactivity, SPT are very familiar to allergy specialists. For more allergy specialists to move away from SPT to med-lab they would need to see an economic payback (incremental revenue from being able to see more patients due to faster visits is greater than the loss of SPT revenue from MSP), as well as clinical value to the patient. It is also likely that future generations of SPT reagents will employ more sophisticated reagents that address cross-reactivity, narrowing the value gap between them and component level med-lab tests. Since the improvement in price-to-performance associated with switching from SPT to med-lab is insignificant, a switch to POCT is more likely. POCT offers the allergy specialist an opportunity to continue to provide in-house service (and billing), speed up service delivery, and improve the patient experience. In such an instance the real question becomes the cost of POCT equipment and assays. POCT costs are currently prohibitively high but they are likely to fall dramatically in the future.

To summarize this discussion and test conclusions drawn in the preceding section, Table 3.3.3 (below) maps price and performance attributes against each substitute service. The table reinforces the prior suggestion that the best future state combination of tests, based on price-to-performance ratio would be a POCT screen (preliminary test) to identify possible allergens, followed by a med-lab allergy components test to rule out cross-reactivity and predict reaction severity.

Table 3.3.3: Price and Performance Comparison for Substitutes (Allergy Segment)

Substitutes	Method	Instrument	Price	Convenience	Sensitivity	Specificity
Skin prick test	Multiple reagents applied directly to pricked forearm	n/a	Free - MSP (Cost Low)	<ul style="list-style-type: none"> × Painful × Irritating • Physician location ✓ Immediate results 	• Med	• Med
Oral Challenge	Allergen ingested orally under emergency medical supervision	n/a	Free-MSP (Cost Low)	<ul style="list-style-type: none"> × Stressful × Potentially harmful × Time consuming • Physician location 	✓ High	✓ High
Med Lab (Screen)	IV draw or Finder prick / stick	Phadia ImmunoCap 100/250; Euroimmun Analyser 1	Free - MSP (Cost Low)	<ul style="list-style-type: none"> × Painful × Separate location • Next day results 	✓ High	• Med
Med Lab (Component)	IV draw or Finder prick / stick	Phadia ImmunoCap 100/250	Paid – Med (Cost Med)	<ul style="list-style-type: none"> × Painful × Separate location • Next day results ✓ Predicts reaction severity 	✓ High	✓ High
POCT Test (Screen)	Finger prick / stick	Phadia Abbott?	Free – MSP? (Cost High)	<ul style="list-style-type: none"> ✓ Low pain ✓ Low irritation ✓ Same or separate location ✓ Near-immediate results 	• Med	• Med

[Source: Author]

Summary

From the above assessment, it is clear that there is currently a low threat to med-lab allergy testing from substitute methods such as SPT and POCT, and an increasing threat from POCT (to both med-lab and SPT) in the future, as the technology develops and costs drop.

3.3.3.2 Buyer Power (medium-high and stable)

The government can be considered to have significant bargaining power as it is very large and concentrated compared to med-lab service providers, purchasing more than 95% of allergy segment output, and has good information about public rival pricing (LifeLabs, 2011). Although the government could threaten further backward integration through the expansion of the public lab system, such a threat would not be considered to be credible as it would mean moving away from its core strength in acute care, and most likely result in an increase in the overall cost of service delivery.

The price sensitivity of government is considered to be moderate. Although med-lab spending is a significant cost, the allergy segment makes up a very small portion of the overall health budget. This is also reinforced by the fact that substitutes such as POCT do not yet have good price-to-performance ratios, nor strong reputations for quality.

Overall, for the allergy segment, the buyer power of government is considered to be medium-to-high and stable.

3.3.3.3 Supplier Power (medium-high and stable)

In Canada, Phadia is the largest supplier to the allergy segment, with testing for 650 allergens and 70 allergen components (Phadia, 2011). Another significant European supplier that has a comprehensive 200 allergen (Euroimmun,2011) line of tests is Euroimmun, however it is yet to attain Health Canada approval for its line of allergy products.

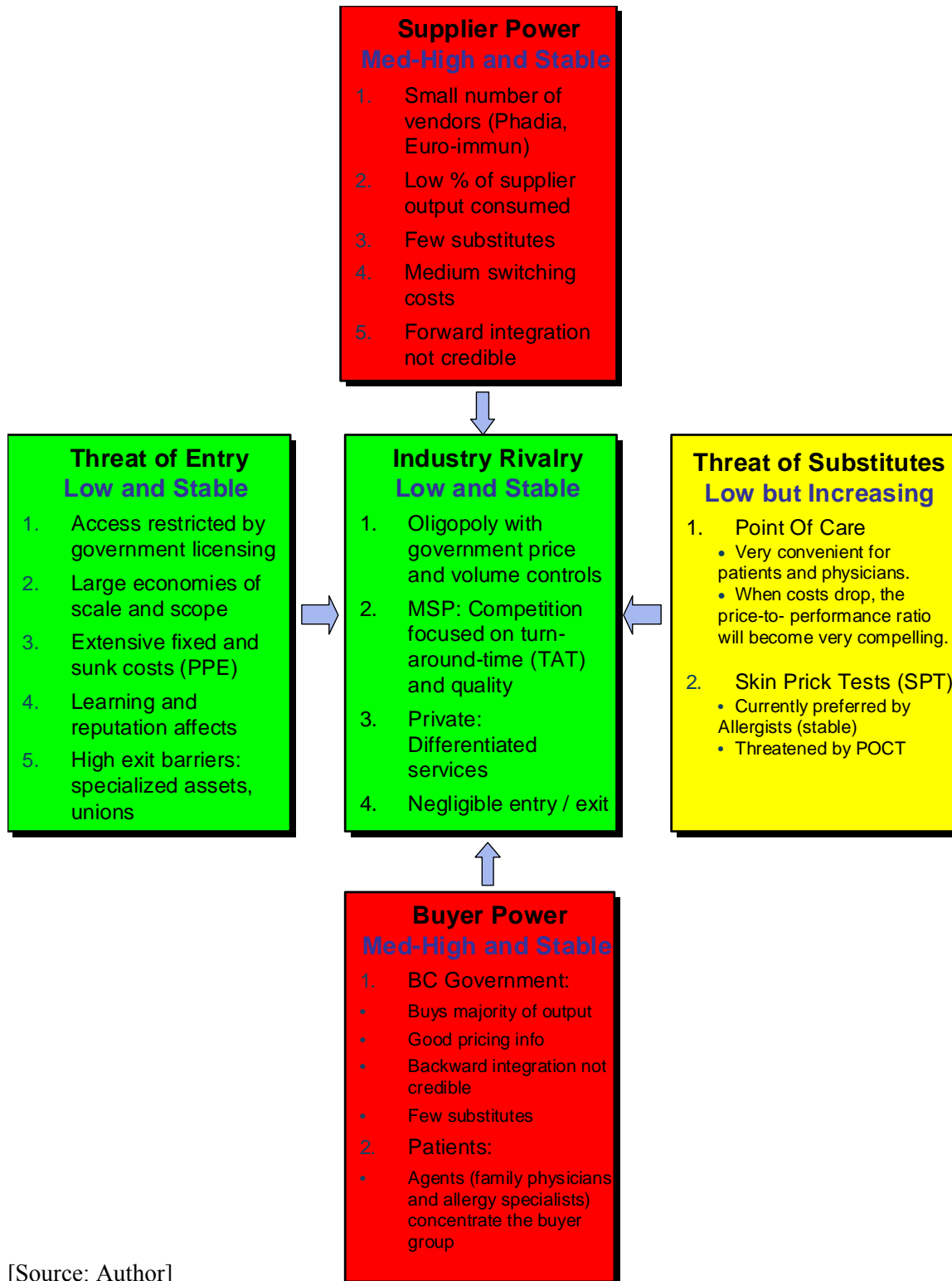
The very high concentration of suppliers capable of providing comprehensive test platforms for allergy and the relatively low percentage of total supplier output consumed by the BC med-lab industry, leads to high supplier bargaining power. This is moderated by the fact that suppliers are not significantly larger than rivals (med lab service providers) and cannot credibly threaten forward integration. As such supplier power in the allergy segment is medium to high.

Looking into the future, supplier power is likely to stay high as allergy is a specialized, relatively low volume segment that is unlikely to attract more suppliers. Thus, overall supplier power in the allergy segment is medium to high and stable.

3.3.3.4 Allergy Segment Summary

The figure below presents the conclusion of medium industry attractiveness (average profitability) for the allergy segment, based on the positive elements of low rivalry and low threat of entry, offset by the negative elements of significant buyer power and supplier power. The future industry attractiveness for the segment is decreasing primarily due to an increasing threat of significant disruption by substitute services delivered via POCT.

Figure 3.3.3: Porter's 5 Forces Analysis of the Allergy Segment



[Source: Author]

Overall Assessment: Average (and Decreasing) Segment Profitability

3.3.4 Autoimmune Segment Analysis

Med-lab testing in the autoimmune segment is designed to diagnose and monitor the progression of a variety of autoimmune diseases, including: lupus, rheumatoid arthritis, celiac disease and antiphospholipid syndrome (APS).

3.3.4.1 The Threat of Substitutes (very low and stable)

The autoimmune segment of med-lab testing is not currently threatened by substitution to a service from another industry. Unlike the tests conducted in the allergy segment, med-lab test for autoimmune diseases are much more complicated and have much longer cycle time, including long incubation periods, thus making them far less susceptible to displacement by POCT. Med-lab testing is also not likely to be affected by substitution for physicians by naturopaths, as med-lab testing is a vital diagnostic aid in either instance. Finally, genomics is not considered to be a relevant substitute threat for med-lab screening for autoimmune disease, as the time required to achieve genomic autoimmune disease screening capability is likely to be beyond the 5-10 year planning horizon of this paper.

From the above assessment, it is clear that there is currently a very low threat to med-lab autoimmune testing from any substitute services delivered by other industries, and no indication of the threat increasing in the next 5-10 years (unless unexpected advancements in genomics occur).

3.3.4.2 Buyer Power (medium and stable)

The government can be considered to have significant bargaining power as it is very large and concentrated compared to med-lab service providers. It purchases 100% of autoimmune segment output and has good information about public rival pricing. Although the government could threaten further backward integration, i.e. expansion of the public lab system, such a threat would not be considered to be credible as it would mean moving away from its core strength in acute care and most likely result in an increase in the overall cost of service delivery.

The price sensitivity of government is considered to be low-moderate as although med-lab spending is a significant cost, the autoimmune segment makes up a very small portion of its overall health budget. This is also reinforced by the fact that no viable substitutes currently exist.

Overall, for the autoimmune segment, the buyer power of government is considered to be medium and stable.

3.3.4.3 Supplier Power (medium-high and increasing)

In Canada, the autoimmune segment is serviced by a number of suppliers which include DiaSorin, Bio-Rad Laboratories, DAS, Inova Diagnostics, Immuno Concepts, Euroimmun, and Phadia (the latter two also service the allergy segment). Since this segment has a complicated array of suppliers and products, it is important to understand product differentiation before commencing analysis of supplier power.

Product Differentiation

Antinuclear antibody (ANA) testing, which is used in the detection of lupus and mixed connective tissues disease, is the most instructive example of differentiation by test method. It is the most extensively used category of test used in the segment and provides an opportunity to examine supplier-technology associations as well as the associated price-to-performance issues. The table below provides a summary of supplier product offerings for ANA testing.

Examination of Table 3.3.4 below reveals a number of important segment characteristics that impact supplier power including: wide variations in breadth of supplier offerings across and within technology categories (including open and proprietary consumables models), buyer agent (physician) power and preference for certain technologies, and the imperfect substitute nature of alternate technology offerings. Each of these characteristic will be incorporated into the supplier power analysis below.

Table 3.3.4: Product Offerings for ANA Testing (Autoimmune segment)

Technology	Supplier, Instrument, (Menu)	Price (Cost)	Convenience (Physician)	Sensitivity	Specificity
Immuno-Fluorescence Assay (IFA)	<ul style="list-style-type: none"> Immuno Concepts AFT2000 (Broad) / Image Navigator Innova Quanta-Lyser (Broad) / NOVA View DAS IF Prep / MLB Bion (Broad) <i>via Qualisys</i> Bio-Rad PhD / <i>Open</i> (Broad) DAS AP16/22 / Euroimmun 	Free MSP (High Cost)	<ul style="list-style-type: none"> × Semi-quantitative and subjective × Complex and difficult for family physician to interpret ✓ American College of Rheumatology endorsed 	✓ Very High	• Med
Enzyme-linked immunosorbent assay (ELISA /EIA)	<ul style="list-style-type: none"> ImmunoCAP100/250 (Broad) Innova DSX/DS2 (Broad) Innova Quanta-Lyser (Broad) DiaSorin Liaison (Narrow) Bio-Rad Evolis (Mid) Euroimmun Analyser 1 (Broad) 	Free MSP (Low Cost)	<ul style="list-style-type: none"> × Prone to missing some outlier conditions ✓ Quantitative and objective 	• Med-High	✓ High
MultiplexFlow Immunoassay	<ul style="list-style-type: none"> Bio-Rad BioPlex 2200 (Mid) 	Free MSP (Low Cost)	<ul style="list-style-type: none"> × Prone to missing outlier conditions ✓ Quantitative and objective ✓ Easy to interpret 	• Med-High	✓ Very High

[Source: Author]

Supplier Power Analysis

Supplier concentration is high in the autoimmune segment and the percentage of supplier output that the BC med-lab industry purchases is quite low, leading to high supplier bargaining power. This is further reinforced by a number of suppliers having closed systems, in which only proprietary consumables can be used, e.g. Euroimmun in IFA and BioRad in BioPlex. Although,

these characteristics are somewhat moderated by the suppliers not having the competence to credibly threaten forward integration, bargaining power is high. Med-lab service providers are also quite insensitive to price because most supplier offerings are differentiated based on technology which has different performance characteristics, or tests menu which affects operating decisions, thus significantly reducing the number of viable substitute products.

Switching costs in this segment are moderate to high, especially in instances where platforms can only run proprietary consumables (such as the Euroimmun IFA instrument which only accepts Euroimmun media).

The above expression of high supplier power is moderated by the fact that some suppliers have made significant technology specific investments. For example, Bio-Rad has invested heavily in BioPlex technology and needs partners to reach broad based adoption, thus reducing their power. Bio-Rad has a lot riding in the success of its Bio-Plex platform and other EIA and IFA suppliers have a lot to lose. This tension between technologies increases competition between suppliers in the short term, reducing supplier power. Once BioPlex technology establishes itself or another technology prevails, supplier power will increase again.

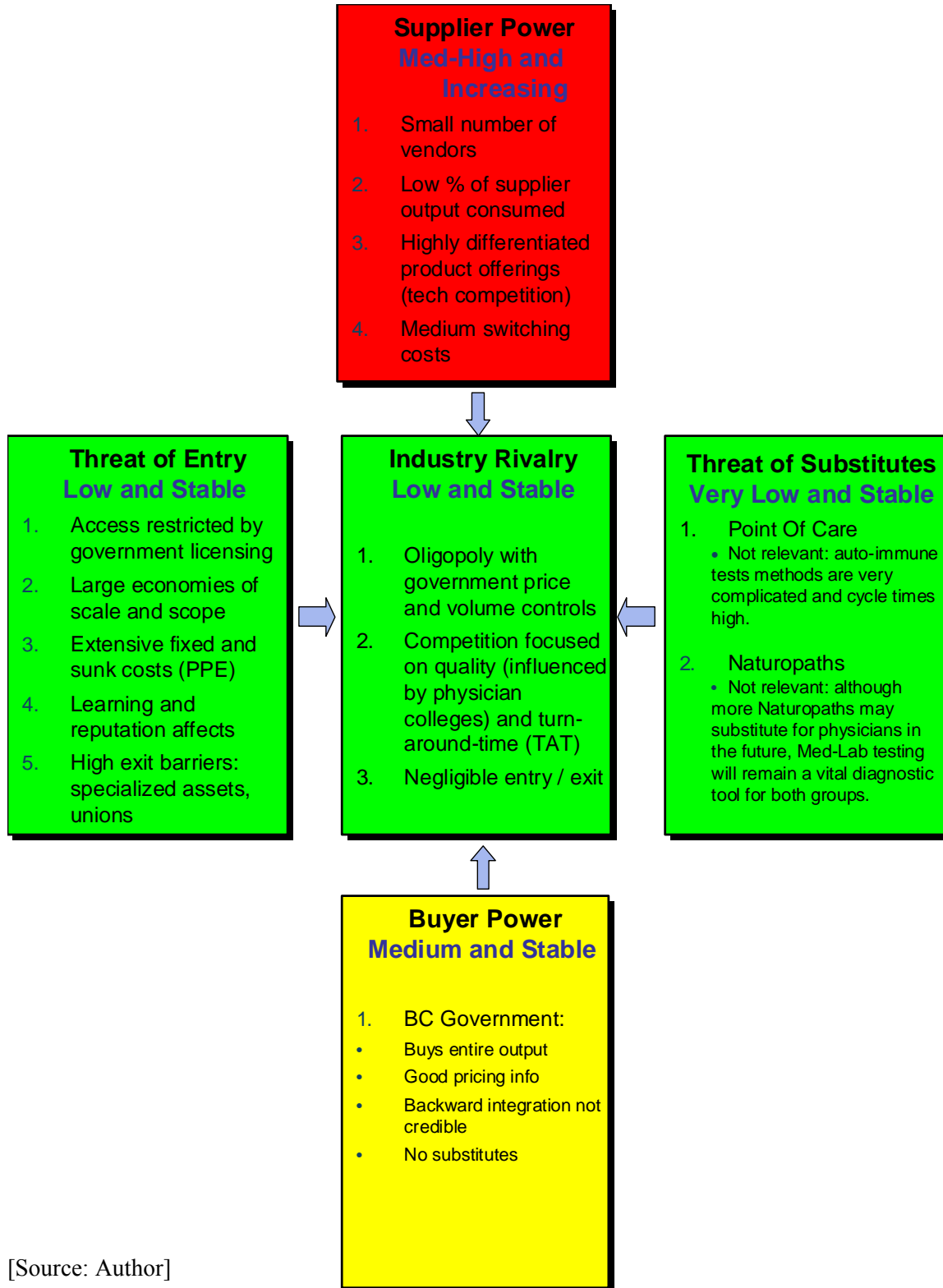
A final important consideration related to technology selection is the active role of the buyer's agent (physician) in this segment. The American College of Rheumatology (ACR) is an active participant in the technology debate (see Appendix B). Despite other techniques offering cost advantages to med-lab operators and utility advantages to family physicians, the ACR has published a position statement that strongly endorses IFA, calling it "...the gold standard for ANA testing..." (ACR, 2009). Such position statements have significant influence on market offerings and have the potential to stall new technology offerings such as BioPlex. In the long run, such statements are likely to reduce technology diversity, increasing incumbent supplier power.

Thus, overall supplier power in the autoimmune segment is medium-high and increasing.

3.3.4.4 Autoimmune Segment Summary

The figure below presents the conclusion of high industry attractiveness (above average profitability) for the autoimmune segment, based on the positive elements of low rivalry, low threat of entry, and low substitute threat, partially offset by the negative elements of significant supplier power, and moderate buyer power. The future industry attractiveness for the segment is stable as no major threats to profitability have been identified.

Figure 3.3.4: Augmented Porter's 5 Forces Analysis of the Autoimmune Segment



[Source: Author]

Overall Assessment: Above Average (and Stable) Segment Profitability

3.3.5 Coagulation Segment Analysis

Med-lab testing in the coagulation segment is designed to diagnose and manage treatment for disorders of coagulation that can lead to an increased risk of bleeding (hemorrhage) or obstructive clotting (thrombosis).

3.3.5.1 The Threat of Substitutes (low-medium and increasing rapidly)

The coagulation segment of med-lab testing has three significant, yet very different, substitute threats.

The first is next generation pharmaceuticals, such as Edoxaban. These are still in development and have yet to prove claims of patient agnostic dosing. However, if they do they will disrupt the biggest portion of coagulation testing, PT/INR (previously defined in section 2.2.4.2), and thus should be considered a medium-high threat for the future.

The second is genomics which is likely to be able to screen for predisposition to current generation stroke medications such as warfarin (Coumadin) within the planning horizon of this paper (5-10 years). This would reduce med-lab test volumes for chronic disease monitoring (PT/INR) but not eliminate them, assuming that the current generation medications are not made redundant by next generations medications. Also, next generation pharmaceuticals may not be 100% government funded, driving many lower income individuals to stay with existing courses of therapy. Genomics thus represents a low-medium threat for the future.

Lastly there is POCT. As previously discussed, POCT refers to a technology and a related group of products, some of which are currently available, such as the Abbott i-STAT system, and some of which under development, that would modify the mode of test delivery for a major subset of the tests currently provided by med-lab testing. POCT represents a low-medium threat now, as it is already being used in an increasing number of acute care facilities to test PT/INR, and a high threat in the future.

Abbott has a point of care technology (POCT) product (I-STAT) that has the ability to test for PT / INR using a minute sample of whole blood which can be easily collected with a finger prick (Abbott, 2011). Although this test will be less sensitive than those of full sized equipment in the laboratory, it has very low impact on the patient and offers almost instantaneous results. This

makes it very compelling for physicians and patients alike. It is therefore possible to envisage a likely future where all chronic disease management related coagulation testing moves to POCT in patients' homes or local clinics, and all acute testing occurs in acute care clinics, with only marginal or complex cases being sent to the larger, higher sensitivity equipment that resides in large scale laboratories. If the main hematological tests such as CBC (Complete Blood Count, a broad based screen for disease) and PT / INR moved to POCT, it would reduce total test volumes in outpatient servicing laboratories by about 10% (LifeLabs, 2011)

To summarize the discussion and test conclusions drawn in the preceding section, Table 3.3.5 maps price and performance attributes against each substitute service. The table reinforces the suggestion that the best future state combination of tests, based on price-to-performance ratio, would be POCT testing for chronic disease management in patients' homes, POCT testing for acute conditions in acute care clinics, and high sensitivity, high specificity testing in centralized laboratories for complex or marginal cases (to reduce false negative and false positive test results). This assumes that next generation pharmaceuticals do not render chronic coagulation related disease monitoring redundant.

From the above assessment, it is clear that there is currently a low-to-medium threat to med-lab coagulation testing from substitute methods such as POCT and a substantially increasing threat from genomics, POCT, and next generation pharmaceuticals (to both med-lab and POCT) in the future, especially as the new technologies develop and costs drop.

Table 3.3.5: Price and Performance Comparison for Substitutes (Coagulation Segment)

Substitutes	Method	Instrument	Price	Convenience	Sensitivity	Specificity
POCT (chronic disease mgmt @ home or clinic)	Finger prick / stick	Abbott i-STAT	Free - MSP (Cost High)	<ul style="list-style-type: none"> × May not detect marginal issues ✓ Low pain ✓ At home ✓ Immediate results 	• Med	✓ High
POCT (acute care @ acute care clinic or hospital)	IV draw or Finger prick / stick	Abbott i-STAT	Free-MSP (Cost Med)	<ul style="list-style-type: none"> × Not capable of add-on testing ✓ Low pain ✓ Immediate results 	• Med	✓ High
Med Lab (chronic disease mgmt & acute care)	IV draw	Beckman Coulter (IL) ACL TOP, Siemens (Sysmex) CA-7000	Free - MSP (Cost Low)	<ul style="list-style-type: none"> × Painful and stressful × Separate location • Next day results 	✓ High	✓ High
Genomics (predisposition to therapeutic drugs)	IV draw or Finger prick / stick	?	Paid – Med (Cost Med)	<ul style="list-style-type: none"> × Separate location • Delayed results ✓ Enables less frequent monitoring in the long run 	✓ High	✓ High
Pharma (next generation therapeutic drugs)	n/a	n/a	Free – MSP? (Cost High)	<ul style="list-style-type: none"> ✓ Avoids constant monitoring • May have adverse effects on certain conditions • May have adverse drug interactions 	• n/a	• n/a

[Source: Author]

3.3.5.2 Buyer Power (medium–high and increasing)

The government can be considered to have significant bargaining power as it is very large and concentrated compared to med-lab service providers. It purchases 100% of coagulation segment output and has good information about public rival pricing. Although the government could threaten further backward integration, i.e. expansion of the public lab system, such a threat would not be considered to be credible as it would mean moving away from its core strength in acute care, and most likely result in an increase in the overall cost of service delivery. That said, a backward integration into POCT services that support the increasing trend towards community - based acute care centres (e.g. Joe Segal Outpatient Centre operated by Fraser Health Authority, and the Ladysmith Acute Care Centre operated by Vancouver Island Health Authority) is credible and likely, and increases buyer power into the future.

The price sensitivity of government is considered to be moderate. Although med-lab spending is a significant cost, the coagulation segment makes up a small portion of its overall health budget. This is also reinforced by the fact that substitutes such as POCT do not yet have good price-to-performance ratios, nor strong reputations for quality. This too is likely to change as POCT, genomics and next generation pharmaceuticals develop.

Overall, for the coagulation segment, the buyer power of government is considered to be medium-to-high and increasing.

3.3.5.3 Supplier Power (high and stable)

The very high concentration of suppliers capable of providing comprehensive laboratory test solutions for coagulation and the relatively low percentage of total supplier output consumed by the BC med-lab industry, leads to high supplier bargaining power. This is amplified by the fact that suppliers (Siemens, Danaher - owners of Beckman Coulter) are significantly larger than med-lab service providers. Although suppliers have extensive financial resources, threats to forward integrate would not be considered credible. They would result in the suppliers deviating from their core competency of test and instrument R&D and commercialization. Overall, supplier power in the coagulation segment is high.

Rivals in the industry are currently quite insensitive to price as few alternative products exist. Switching costs are moderate-high as the suppliers usually have broader involvement in the laboratories.

Looking into the future, supplier power is likely to stay high as coagulation is a specialized, high volume segment that has a small number of very well established big players. Thus, overall supplier power in the coagulation segment is high and stable.

3.3.5.4 Coagulation Segment Summary

The figure below presents the conclusion of medium industry attractiveness (average profitability) for the coagulation segment, based on the positive elements of low rivalry, low threat of entry and low-to-medium threat of substitutes, offset by the negative elements of significant supplier power and buyer power. The future industry attractiveness for the segment is decreasing due to an increasing threat of major disruption by substitute services (delivered via POCT, genomics or pharmaceuticals).

Figure 3.3.5: Augmented Porter's 5 Forces Analysis of the Coagulation Segment



[Source: Author]

Overall Assessment: Average (and Decreasing) Segment Profitability

3.3.6 Porter's Forces Analysis Summary

The following table summarizes forces and trends in each segment, thus highlighting common themes across, and contrasts between, segments.

Table 3.3.6: Porter's 5 Forces Analysis by Industry Segment

Segment	Strongest Forces	Current Attractiveness	Change Drivers	Future State
Allergy	<ul style="list-style-type: none"> ● Supplier Power ● Buyer Power 	<ul style="list-style-type: none"> ● Medium (average profitability) 	<ul style="list-style-type: none"> × POCT × Specialist administered tests 	<ul style="list-style-type: none"> × Low-medium (below-average profitability)
Autoimmune	<ul style="list-style-type: none"> ● Supplier Power 	<ul style="list-style-type: none"> √ High (above-average profitability) 	<ul style="list-style-type: none"> ● Instrument technology 	<ul style="list-style-type: none"> √ High (above-average profitability)
Coagulation	<ul style="list-style-type: none"> ● Supplier Power ● Buyer Power 	<ul style="list-style-type: none"> ● Medium (average profitability) 	<ul style="list-style-type: none"> × POCT × Next Gen Drugs × Genomics 	<ul style="list-style-type: none"> × Low (below-average profitability)

Based on the summary above, supplier power is the most prominent and common current and future threat to med-lab appropriation of value, closely followed by buyer power. Substitutes, enabled by new technologies, are the most significant threat to the future creation of value by the med-lab industry.

3.4 Political Landscape Analysis

Since the health budget makes up approximately 35% of the total provincial budget, the government will continue to be very interested in containing costs and getting the best possible value for money out of the health system (Province of British Columbia, 2011). For the med-lab, the most direct method of cost control is via the pricing and volume controls previously discussed. However, other government initiated cost reduction activities are under way and more are likely.

An important example of an active government initiated cost reduction program is the Lower Mainland Laboratory Consolidation Project which is aimed at consolidating public med-lab testing in the lower mainland (Ministry of Health Services, 2009). Greater public med-lab system integration would improve efficiency through back-office consolidation and the retirement of excess med-lab capacity. Excess capacity exists in the industry directly as result of the time critical and life and death nature of the services provided, especially in hospital settings which require significant excess capacity to deal with peaks in demand. Thus, excess capacity can never be eliminated but it can be reduced by consolidating med-lab facilities and blending urgent inpatient work with less urgent outpatient work.

A strong provincial government push for greater system integration is currently unlikely due to the current political instability in the incumbent and opposition parties. However, it remains a strong possibility for the future. In the mean time, the Lower Mainland lab consolidation project is likely to proceed at a slow pace, delivering mainly back-office consolidation savings. It is not likely to deliver any significant retirement of capacity as the centralized, large scale, laboratories and collection networks that would be required do not currently exist within the public system. Private involvement or integration with the public would deliver some of the missing scale and collection network benefits so the government is likely to consider it. However, once again, it would take political courage that is currently lacking in provincial leaders due to recent leadership instability and the potential for announcement of an early provincial election. In the long run both the NDP and the Liberal party are likely to consider broader private involvement. However, it is far less likely to move forward under the NDP as they would run the risk of disenfranchising some of their key constituents – the unions.

The above described government efforts to contain cost are most likely to have no net impact on future profitability of the med-lab industry in BC as they will likely be achieved through initiatives to improve efficiency and effectiveness.

4: Conclusions and Recommendations

4.1 Industry Level Summary

The preceding analysis revealed that medical diagnostic laboratory testing industry in British Columbia is a mature industry and currently has a medium-to-high level of attractiveness (above average profits), primarily as a result of low rivalry and low threats to entry.

Looking into the future, the value created by the health system is likely to grow because of incremental advancements in the utility of med-lab services and improvements in the quality of physicians' decision making, enabled by integrated data (EMR). However, the value created by med-lab incumbents is likely to decrease because of a stable or reduced willingness-to-pay by the government, and an increase in input costs.

Despite the predicted downward pressure on incumbent profitability, opportunities to capitalize on changes and create new value exist. The most immediate opportunity in a number of segments is for incumbents to diversify into POCT-enabled substitutes. Willingness-to-pay for POCT delivered tests for chronic disease management is likely to be high. Incumbents could provide POCT services under MSP or charge consumers for a premium mode of service delivery (private providers only), even if the government does not support funding POCT above the current, conventional med-lab level.

4.2 Allergy Segment

4.2.1 Conclusion

The analysis in Chapter 3 revealed that the allergy segment is in a growth phase and currently has medium industry attractiveness (average profitability), based on the positive elements of low rivalry and low threat of entry, offset by the negative elements of significant buyer power and supplier power.

The future industry attractiveness for the segment is decreasing primarily due to an increasing threat of significant disruption by substitute services delivered via POCT. POCT threatens to make current core med-lab assets – large allergy test platforms – redundant by enabling buyer agents (allergy specialists) to deliver quick and convenient services directly to the patient, thus eliminating med-labs from most consultations.

Environmental factors are resulting in a trend increase in the prevalence of allergy, increasing the growth of demand for testing in the segment. The segment is expected to grow at an annual rate of 10% in the near future. If the med-lab industry does not diversify into POCT service delivery, most of this additional demand is likely to be captured by buyer agents (physicians).

4.2.2 Recommendation

The key to maintaining the medium level of attractiveness of allergy segment in the future is for med-lab incumbents to take advantage of their superior capabilities and know-how in managing licensing and accreditation, operating instrumentation, and accessing capital. The recommendation below takes advantage of these capabilities.

It is recommended that med-lab providers collaborate with allergy specialists to install POCT allergen testing capability at locations close to the specialists' place of practice. This would be of value to patients as it would give them nearly instant results that they could quickly take, virtually or physically, to the allergy specialist. It would be of value to the allergy specialist because they would be able to dedicate the time they would normally spend on skin prick testing (SPT) to seeing more patients. They would avoid purchasing and running an instrument, including specialized staffing, and they would avoid the complexity and cost of achieving DAP accreditation and managing instrument quality control (QC) and maintenance. The co-location of

POCT and med-lab collection would also make collection of additional specimens for confirmations or components testing very convenient for the patient and physician.

It is also recommended that med-lab providers engage POCT suppliers, such as Phadia and Abbott, capable (now or in the near future) of servicing the allergy segment to identify equipment that would best service patient and physician needs. Med-lab providers should continue to procure higher capacity centralized instruments, such as the Phadia ImmunoCap 250. However, specifications should complement rather than duplicate POCT. Since suppliers to the segment are highly concentrated, med-lab service providers are advised to maintain active relationships with two parties.

4.3 Autoimmune Segment

4.3.1 Conclusion

The analysis in Chapter 3 revealed that the autoimmune segment is in the mature phase and currently has high industry attractiveness (above average profitability), based on the positive elements of low rivalry, low threat of entry, and low substitute threat, partially offset by the negative elements of significant supplier power, and moderate buyer power.

The future industry attractiveness for the segment is stable, as no major threats to profitability were identified. One moderate threat to future economic profits of the industry could come from further concentration of the already concentrated supplier base. Key actors in this instance are the buyers' agents (American College of Rheumatology, BCMA). They have the ability to reduce input options by endorsing a very limited subset of available technologies, as has been the case with IFA. If such endorsements continue in the long run (50% probability), they are likely to reduce technology diversity and thus increase incumbent supplier power.

In addition, population demographics, a fundamental demand driver for the segment, are favourable. A growing and aging population will require more autoimmune disease testing and management to maintain or improve quality of life. The segment is expected to grow at an annual rate of 3-5%.

4.3.2 Recommendation

The key to maintaining the high level of attractiveness of autoimmune segment in the future is for med-lab incumbents to take advantage of their extensive in-house know-how and experience with alternative technologies.

It is recommended that med-lab providers educate family physicians and rheumatology specialists regarding the benefits and best uses of complementary test methods (such as IFA and Bio-Plex), as well as how to interpret results from those methods. By educating and influencing physicians regarding the complementary value of different technologies, med-lab providers could mitigate the threat of continued single-test technology endorsements. Initially, med-lab providers could explain the value of using new, highly specific BioPlex technology to rapidly screen for the most clinically significant antigens and allow conventional, highly sensitive IFA technology to examine outlier conditions and confirm diagnosis.

It is also recommended that med-lab providers continue to work with IFA providers while they begin to engage BioPlex technology as a complement, with the aim of running both in parallel until one technology prevails or their complementary nature is validated in practice. The latter state is most likely and clearly preferable from the supplier power mitigation perspective.

4.4 Coagulation Segment

4.4.1 Conclusion

The analysis in Chapter 3 revealed that the coagulation segment is in the mature phase and currently has a medium level of attractiveness (average profitability), based on the positive elements of low rivalry, low threat of entry and low threat of substitutes, offset by the negative elements of significant supplier power and buyer power.

The future industry attractiveness for the segment is decreasing due to an increasing threat of major disruption by substitute services delivered via pharmaceuticals, genomics or POCT.

Next generation pharmaceuticals, such as Edoxaban, are still in development and have yet to prove claims of patient agnostic dosing. However, if they do they will disrupt the biggest portion of coagulation testing, PT/INR, and thus should be considered a medium-high threat for the future.

Genomics is likely to be able to screen for predisposition to current generation stroke medications such as warfarin (Coumadin) within the planning horizon of this paper (5-10 years). This would reduce med-lab test volumes for chronic disease monitoring (PT/INR) but not eliminate them, assuming that the current generation medications are not made redundant by next generation medications. Also, next generation pharmaceuticals may not be 100% government funded, driving many lower income individuals to stay with existing courses of therapy. Genomics thus represents a low-medium threat for the future.

POCT threatens to make current core med-lab assets – large coagulation test platforms – redundant by enabling substitute service providers to deliver quick and convenient services directly to the patient (at their home, long term care facility or local or mobile clinic), thus eliminating med-labs from most therapeutic drug monitoring tests, including PT/INR. POCT represents a low-medium threat now, as it is already being used in an increasing number of acute care facilities to test PT/INR, but a high threat in the future.

However, population demographics are favourable. A growing and aging population will require more chronic heart and stroke disease monitoring (PT/INR) and other med-lab coagulation services. The segment is expected to grow at an annual rate of 3-5%.

4.4.2 Recommendation

The key to improving the medium level of attractiveness of coagulation segment in the future is for med-lab incumbents to take advantage of their superior capabilities and know-how in managing licensing and accreditation, operating instrumentation, and accessing capital. The recommendation below takes advantage of these capabilities. Although this approach is very similar in principle to that employed in the allergy segment, the circumstances in the coagulation segment are very different.

It is recommended that med-lab providers collaborate with regional health authorities to install POCT coagulation (PT / INR) testing capability at locations close to or within community acute care clinics, as well as at nominated patient service centres, and throughout the long term care facility network that they service. This would be of value to patients as it would give them nearly instant results that they could quickly take, virtually or physically, to their family physician or specialist to identify an appropriate adjustment to their level of medication. It would be of value to the family physician as they would be able to dedicate the time they would normally spend consulting in person to seeing more patients, and they would avoid purchasing and running an instrument themselves, including specialized staffing. Physicians would also avoid the complexity and cost of achieving DAP accreditation and managing instrument quality control and maintenance. Much like for the allergy segment, the co-location of POCT and med-lab collection would also make collection of additional specimens for confirmations or additional testing very convenient for the patient and physician.

It is also recommended that med-lab providers engage POCT suppliers, such as Abbott, who are capable of servicing the coagulation segment to identify equipment that would best service patient and physician needs. Med-lab providers should continue to procure higher capacity centralized instruments, such as the Sysmex CA-7000. However, specifications should complement rather than duplicate POCT. Since suppliers to the segment are highly concentrated, med-lab service providers are advised to maintain active relationships with two parties.

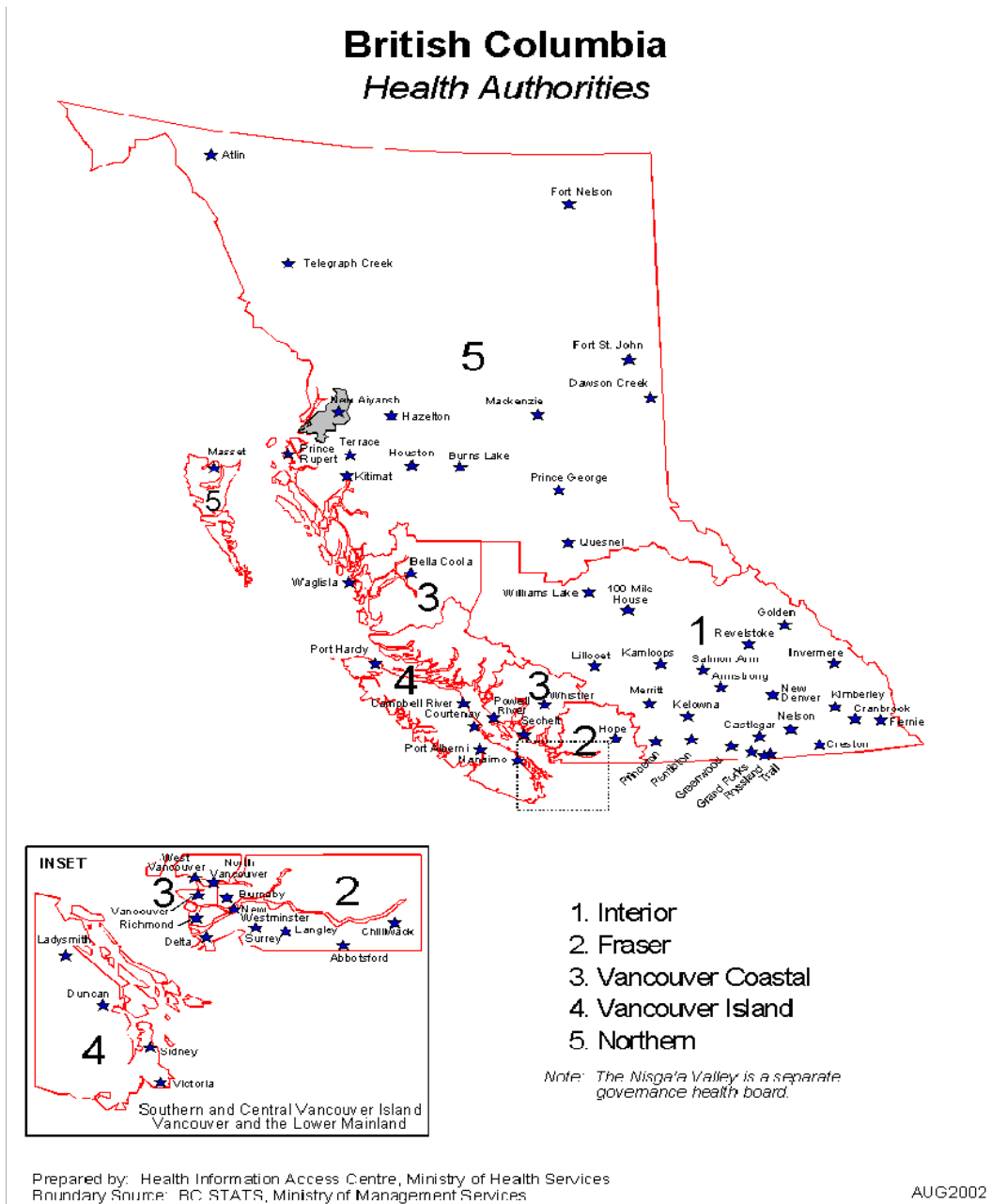
It is further recommended that med-lab providers exploit opportunities to engage in activities that are adjacent to theirs, even if they use different technologies. Much like the application of molecular diagnostics in microbiology, it is recommended that med-lab providers build capabilities in genomic screening for warfarin predisposition and the like.

5: Further Analysis

Although it was the clients' explicit request to not tackle internal analysis as part of this study, it is recommended that a follow-up internal analysis of LifeLabs' resources, capabilities and strategies, and a subsequent scenario analysis of different possible future industry environments be conducted to assure that the unique competitive advantages of the client firm are considered as part of the strategy formulation process. An internal analysis will identify the sources of sustainable competitive advantage that the client possesses, and thus enable the evaluation of how those strengths should be applied to mitigate the threats that were discussed in the preceding external analysis

6: Appendices

6.1 Appendix A



6.2 Appendix B

American College of Rheumatology

POSITION STATEMENT

SUBJECT: Methodology of Testing for Antinuclear Antibodies

PRESENTED BY: American College of Rheumatology

FOR DISTRIBUTION TO: Members of the American College of Rheumatology
Medical Societies
Managed Care Organizations and Third Party Carriers
Laboratories

SUMMARY:

The immunofluorescence antinuclear antibody (ANA) assay is the gold standard for ANA testing with greater sensitivity than solid phase assays.

HEp-2 cells have approximately 100 to 150 possible autoantigens. These cells are used to detect ANAs by the immunofluorescence (IF) method, in which both pattern and titer can be described, and to display a variety of autoantigens not present in multiplex ANA tests.

Many commercial laboratories and some hospital laboratories have switched their ANA screening test to solid phase immunoassays, such as a multiplex platform. The latter technique can screen and process large volumes of clinical specimens more quickly and at less cost than the traditional immunofluorescence ANA test using fixed HEp-2 cells as substrate.

These multiplex assays can detect only the specific autoantibodies directed against the limited number (typically 8-10) autoantigens that are displayed.

Laboratories should indicate the method used when reporting ANA results.

BACKGROUND:

The methodology of the tests for the detection of antinuclear antibodies has changed over the years from the LE cell prep, to immunofluorescence utilizing sections of various rodent organs (e.g. rat or mouse liver or kidney, etc.) to cell lines, in particular HEp-2. HEp-2 cells contain approximately 100 to 150 autoantigens. These cells are used to detect ANA by the immunofluorescence method, in which both pattern and titer can be described, and to display a variety of autoantigens not present in the multiplex ANA tests.

Researchers have seen the evolution of methodology of test for the detection of particular ANAs hemagglutination, to various solid phase immunoassays.

Over the years, numerous investigators and commercial organizations have attempted to develop solid phase immunoassays for the detection of ANA and specific ANAs, which are easier and cheaper to perform of the literature by the committee indicates that up to 35% of patients with SLE and a positive ANA by immunofluorescence (IF) were negative on solid phase assays (1-4, 6-21, 23). Many commercial laboratories and some hospital laboratories have switched their antinuclear antibody (ANA) screening test to solid phase immunoassays, such as a multiplex platform, for the reasons noted above, and since the latter technique can screen and process large volumes of clinical specimens than the traditional immunofluorescence ANA test using fixed HEp-2 cells as substrate.

Various national and international organizations have also been involved in the standardization of these tests for the harmonization of laboratory results. These include World Health Organization Centers for Disease Control, Dutch Red Cross and the International Union of Immunological Societies (5). Any laboratory test, to be most useful, must maximally distinguish patients with a particular disorder from related disorders. It is understood that both commercial and hospital laboratories are interested and committed to providing the best laboratory tests for the diagnosis of rheumatic diseases.

The immunofluorescence ANA test is the gold standard for ANA testing. When performed with a history and physical, it identifies almost all patient with systemic lupus erythematosus (sensitivity over 95%)(22), although the specificity of this assay is only 57% for SLE when compared to patients with related rheumatic and autoimmune disorders(22). In addition, the IF ANA is an important test for the screening and diagnosis of systemic sclerosis (sensitivity 85%), polymyositis and dermatomyositis (sensitivity 61%) primary Sjogren's syndrome (sensitivity 48%), juvenile idiopathic arthritis (sensitivity 57%), drug-induced lupus (sensitivity 100%), mixed connective tissue disease (sensitivity 100%), and autoimmune hepatitis as well as being important in monitoring and assessing prognosis in individuals with Raynaud's phenomenon.

RECOMMENDATIONS:

The immunofluorescence (IF) ANA test should remain the gold standard for ANA testing.

Hospital and commercial laboratories using bead-based multiplex platforms or other solid phase assays for detecting ANAs must provide data to ordering physicians on request that their assay has the same or improved sensitivity and specificity compared to the IF ANA.

In-house assays for detecting ANA as well as anti-DNA, anti-Sm, anti-RNP, anti-Ro/SS-A, anti-La/SS-B, etc. should be standardized according to national (e.g., CDC) or international (e.g. WHO, IUIS) standards.

Laboratories should specify the methods utilized for detecting ANAs when reporting their results.

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