

## INDUSTRY OVERVIEW

*The information provided in this section is derived from various official, unofficial and private publications available to the Directors. Such information has not been prepared or independently verified by the Company, the Sponsor, the Underwriters or any of their respective affiliates or advisors.*

### BACKGROUND

Health care costs around the world have seen significant increases. It is estimated that health care now comprises 14% of the world's gross national product, which represents in excess of US\$1 trillion. In developed countries with higher per capita income, health care expenditures are also higher. It has also been observed where countries with higher health care spending have experienced an increase in the productivity of the workforce and hence a higher income and standard of living. Conversely, a higher income and standard of living would also increase the per capita health care expenditure. There is a significant correlation between the two. In countries of the developing world which depend on manual labour, this relationship is even stronger. Healthy people are able to work harder. With this in mind, countries such as Costa Rica, India and China have launched numerous healthcare improvement programmes.

### IN VITRO DIAGNOSTIC MARKET

The Group's testing services can be categorised as "in vitro diagnostics". In vitro diagnostics, also known as IVD, are diagnostic tests which are carried out outside the environment of the human body, or patient, in an artificial environment such as a test tube.

The IVD markets have seen stagnant growth in the 1990's. However, a readjustment has occurred in recent years bringing about growth worldwide led by the emerging IVD markets of China and India. Theta Reports estimates that the worldwide IVD market has rebounded and will continue to grow by approximately 6% annually. Theta Reports is a division of PJB Publications, an independent publisher of business news and information services for the medical device and diagnostic, human and veterinary pharmaceutical, and crop protection industries.

**Table 1 — Worldwide IVD sales by geographic region**

Geographic region	2000 IVD Sales (US\$ million)	2005 IVD Sales (US\$ million)	Compound annual growth rate (%)
North America	11,170	14,360	6
Western Europe	6,900	8,500	5
Japan	2,850	3,285	3
Latin America*	1,040	1,715	13
China	300	600	20
Eastern Europe	250	400	12
India	170	400	27
Rest of the World	3,305	4,995	10
<b>Total</b>	<b>25,985</b>	<b>34,255</b>	<b>6</b>

\* includes Mexico

Source: Theta Reports of April 2002

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In 2000, the growing IVD market in China totalled US\$300 million representing 1% of the worldwide IVD market share. Theta Reports expects this market share to grow at an annual rate of 20% to double its market share to 2% by 2005, indicating sales in the region of US\$600 million.

China's entrance into the World Trade Organisation will have a major impact in the country's IVD market. Among the main changes the World Trade Organisation will initiate is that soon foreign IVD companies will be able to form their own distribution networks in China, regulations regarding the importation of reagents for use in IVD testing will be relaxed, and tariffs on medical equipment will be reduced from a current average of 6.5% to 3.9% by January 2005.

The IVD market in Japan is mature with country sales ranking third worldwide in 2000 with a market share of 11%. Sales are expected to grow at an annual rate of 3% to US\$3.3 billion by 2005.

**Table 2 — Worldwide IVD sales by product area**

Product Area	2000 IVD Sales (US\$ million)	2005 IVD Sales (US\$ million)	Compound annual growth rate (%)
Clinical chemistry	6,535	6,930	1
Point-of-care: over-the-counter	3,910	6,310	12
Point-of-care: professional	2,280	3,200	8
Immunoassays: infectious diseases	1,860	2,990	12
Immunoassays: blood bank screening	490	560	3
Immunoassays: other	3,520	4,465	5
Microbiology/virology*	2,125	2,330	2
Histology/cytology	1,355	1,960	9
Haematology	1,300	1,400	2
Nucleic acid assays: infectious diseases	750	1,400	17
Nucleic acid assays: others	190	395	22
Coagulation	600	800	7
Blood typing/grouping	320	375	3
Flow cytometry	450	850	18
Radioimmunoassays	300	290	-1
<b>Total</b>	<b>25,985</b>	<b>34,255</b>	<b>6</b>

\* *Infectious disease/molecular infectious clones panels, rapid microbiology tests, blood culture tests, and traditional microbiology supplies*

Source: Theta Reports of April 2002

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In 2000, the largest product area in the IVD market is the clinical chemistry diagnostics segment in which many of the Group's testing services would be categorised, encompassing a quarter of all IVD product sales. But the high growth product segments are expected to be in the areas of immunoassays, molecular tests, lipid profiles, cancer diagnostics and diabetes self-testing which would also relate to the Group's existing and future testing services. These areas of high growth are expected to experience double digit annual growth through to 2005.

### IN VITRO DIANOSTIC USING GENETIC AND MOLECULAR REAL TIME PCR TECHNOLOGY

The business environment of in vitro diagnostic tests, either presented as a testing service or in a kit form using genetic materials and real time PCR technology for clinical diseases is only in its infancy of development. There have been some relatively simple PCR clinical tests in the market at this moment for infectious diseases such as tuberculosis (TB), hepatitis C and certain venereal diseases. To the best of the Group's knowledge, there are no such clinical products relating to the detection of cancer or foetal maternal diseases.

### CANCER DIAGNOSTICS

As one of the leading causes of death, cancer is a disease many researchers are seeking to cure. Early screening of cancer is the number one factor in determining the long-term prognosis of a patient.

According to "Cancer Stat 2000" issued by Hong Kong Cancer Registry, Hospital Authority, during the life time in Hong Kong, the chance of developing a particular cancer assuming no other cause of death is 26.1% for men and 19.5% for women. Thus, approximately 1 of every 4 men and 1 of every 5 women are expected to develop cancer at some point during their life times. Similarly, in Hong Kong the risk of dying from cancer during life is 15.9% for men and 8.3% for women, representing 1 in 6 men and 1 in 12 women respectively.

**Table 3 — All new cases of cancers in Hong Kong**

Year	Male		Female	
	New cases	C.I.R*	New cases	C.I.R*
1995	10,296	333.8	7,971	259.5
1996	10,852	337.0	8,492	264.1
1997	11,086	342.6	8,835	271.5
1998	11,194	344.4	8,897	270.1
1999	11,329	347.0	9,197	275.2
2000	11,703	357.2	9,646	284.7

\* C.I.R = Crude incidence rate per 100,000 persons

Source: Hong Kong Cancer Registry, Hospital Authority, March 2003

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Epstein-Barr virus (EBV) is a common virus and has been found to associate with nasopharyngeal carcinoma and stomach cancer. Publications by the Chinese University demonstrated that the EBV genome can be detected in blood plasma.

Nasopharyngeal cancer (or NPC) is a type of cancer found in the soft tissues behind the nasal cavity, which is relatively common in Hong Kong and Guangzhou. The incidence of nasopharyngeal cancer in Hong Kong is significantly higher than in other parts of the world, occurring more than 80 times as frequent, on a per capita basis, as compared to North America, western Europe and Japan. For this reason, nasopharyngeal cancer is often referred to as the “Cantonese Cancer”. In 1999, around 24 out of 100,000 males in Hong Kong were diagnosed with nasopharyngeal cancer. This figure represented about 7 percent of all cancers in Hong Kong for 1999.

**Table 4 — All new cases of nasopharyngeal cancer in Hong Kong**

Year	Male		Female	
	New cases	C.I.R.*	New cases	C.I.R.*
1995	830	26.9	306	10.0
1996	856	26.6	321	10.0
1997	804	24.9	342	10.5
1998	809	24.9	312	9.5
1999	798	24.4	320	9.6
2000	797	24.3	329	9.7

\* C.I.R. = Crude incidence rate per 100,000 persons

Source: Hong Kong Cancer Registry, Hospital Authority, March 2003

NPC is highly radio-sensitive and therefore historically the mainstay treatment is radiotherapy. For patients presenting with early disease, radiotherapy alone achieves five-year survival rates of around 85%. However, more than 50% of the patients when being detected of the cancer are in advance disease stages, and for this group of patients the five-year survival figures are only around 50% after radiotherapy alone.

In Japan, stomach cancer is the second most common cancer in men and the most common cancer in women, with similar impact on the cancer mortality rate, please refer to table 5 below.

**Table 5 — Mortality from malignant neoplasms by age group and sex in Japan (1999)**

Site		Total
All cancers	Total	231.6
	Males	286.5
	Females	179.1
Esophagus	Total	8.0
	Males	13.8
	Females	2.4
Stomach	Total	40.4
	Males	53.4
	Females	27.9

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Site		Total
Colon	Total	18.5
	Males	19.3
	Females	17.8
Rectum	Total	9.7
	Males	12.3
	Females	7.1
Liver and intrahepatic bile duct	Total	27.0
	Males	38.3
	Females	16.1
Pancreas	Total	14.9
	Males	16.6
	Females	13.2
Trachea, bronchus and lung	Total	41.6
	Males	61.8
	Females	22.2
Breast	Total	7.1
	Males	0.1
	Females	13.9
Uterus	Total	8.0
	Females	8.0
Ovary	Total	6.4
	Females	6.4
Prostate	Total	11.4
	Males	11.4
Leukemia	Total	5.3
	Males	6.3
	Females	4.4

*Source:* Japan National Cancer Centre, February 2004

The relation of a portion of these stomach cancer cases with Epstein Barr virus has been well established. The effect of screening improves both the outlook of a 5 year survival and the stage of disease when diagnosed by 50%. Please refer to table 6a and 6b below.

**Table 6a — 5-year relative survival (%) and standard error in patients detected by screening**

	Total		Screening	
	Relative survival rate	Standard error	Relative survival rate	Standard error
Stomach	49.2	0.7	85.1	1.6

*Source:* Japan National Cancer Centre, February 2004

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**Table 6b — Clinical stage in patients detected by screening**

	Occasion of cancer detection	Localised	Regional	Adjacent	Distant	Total
			LN metastases	organ metastases	metastases	
Stomach	Screening (%)	71.4	20.0	3.9	4.7	100.0
	Total (%)	46.5	21.8	12.0	19.7	100.0

*Source:* Japan National Cancer Centre, February 2004

Similarly the incidence of stomach cancer in China and Hong Kong is high compared to western countries like Canada and the United States. Please refer to table 7 below.

**Table 7 — International comparison of cancer mortality by sex and site**

	Japan 1999	China 1994	Hong Kong 1995	Canada 1995	United States 1994
<b>Males</b>					
Total malignant neoplasms	286.5	142.3	194.5	213.7	220.7
Stomach	53.4	25.5	11.9	8.6	6.3
<b>Females</b>					
Total malignant neoplasms	179.1	90.2	119.8	177.2	190.5
Stomach	27.9	14.1	7.1	5.5	4.2

*Source:* Japan National Cancer Centre, February 2004

The business application of an in vitro diagnostic test suitable for a disease or diseases may depend on three major groups of factors.

The first group of factors relates to the incidence of new patients with the disease, the incidence of those that have survived the disease and the incidence of those that are prone to develop the disease. The incidence of new nasopharyngeal cancer cases in Hong Kong is slightly over 1,100 per year. The five-year survival rate of these cases is 85% for the earlier cases and about 50% for the more advanced cases. It can be estimated that there are more than 600 cases per year of nasopharyngeal cancer patients that survive after treatment and that are in need of consolidation treatment and long term observation. The total pool of actual nasopharyngeal cancer patients that need new or re-current testing and surveillance is therefore the sum of the new patients and the patients that survive in the previous five years, approximately 4,000 patients. The incidence of individuals that may develop or

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prone to nasopharyngeal cancer is difficult to calculate since it is hard to estimate all the patients with chronic ear, nose and throat symptoms, which are all parts of the characteristics of nasopharyngeal cancer and all those family clusters with a high incidence of nasopharyngeal cancer in their members. For the diagnosis of the EB virus associated with stomach cancer, it could be extrapolated from table 7 above that the incidence of new stomach cancer cases per year would be 50,000 in Japan, 320,000 in China and 650 in Hong Kong. Again, it would be difficult to estimate the number of individuals with family history or symptoms or signs of stomach cancer that may require an in vitro diagnostic test.

The second group of factors relates to the indications of the in vitro diagnostic test. For the detection of new patients and as a screening tool, a sensitive test with the lowest false positive is ideal. For the prognosis of a disease, a quantitative method that corresponds to the staging of the disease is important. For the monitoring of patients after treatment, a quantitative method that can more or less measure the real time amount of residual disease cells remaining in the body is essential.

The third group of factors relates to how well an in vitro diagnostic test can match the attributes of an ideal general population screening program, which would then determine the indication that can command the biggest market share. For this ideal screening test, the target disease should be a major health program, meaning that is a serious and common illness. It should be more treatable if detected early. It should be acceptable to those eligible, preferably by a non-invasive method. It should be inexpensive and affordable by the target population. It should have high sensitivity and specificity. It could be shown to reduce morbidity and mortality.

### FOETAL MATERNAL AND DOWN'S SYNDROME DIAGNOSTICS

The market of diagnostic products for foetal maternal diseases depend on the fertility rate of woman in the designated countries. The total fertility rate per woman is the number of children that would be born to each woman if she were to live to the end of her child-bearing years. The total fertility rate per woman for different countries and different economic backgrounds is summarised in table 8 below:

**Table 8 — Total fertility rate per woman**

Country/economic backgrounds	Total fertility rate (per woman)	
	1970 - 1975	2000 - 2005
Australia	2.5	1.7
United States	2.0	2.1
Canada	2.0	1.5
Japan	2.1	1.3
United Kingdom	2.0	1.6
France	2.3	1.9
Germany	1.6	1.4
Hong Kong SAR	2.9	1.0
Singapore	2.6	1.4
Korea	4.3	1.4
China	4.9	1.8

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Country/economic backgrounds	Total fertility rate (per woman)	
	1970 - 1975	2000 - 2005
<b>Developing countries</b>	5.4	2.9
Least developed countries	6.6	5.1
Arab States	6.7	3.8
East Asia and the Pacific	5.0	2.0
Latin America and the Caribbean	5.1	2.5
South Asia	5.6	3.3
Sub-Saharan Africa	6.8	5.4
Central & Eastern Europe & CIS	2.5	1.4
OECD	2.5	1.8
High-income OECD	2.2	1.7
High human development	2.5	1.8
Medium human development	4.9	2.4
Low human development	6.8	5.6
High income	2.2	1.7
Middle income	4.6	2.1
Low income	5.7	3.7
World	4.5	2.7

*Source:* United Nations Development Programme — Human Development Report 2003

Foetal maternal diagnostic products are, generally speaking, catered to the common diseases that affect the mother and the foetus throughout the pregnancy period leading to delivery. Some of the more important foetal disorders are the inherited blood disorders such as RhD incompatibilities and Thalassaemias, a whole group of X-linked recessive diseases such as Hemophilia, mental retardation disorders such as Down's syndrome with three copies of the chromosome 21 in each cell of the foetus (trisomy 21), trisomy 18, foetal developmental problems due to pre-term delivery and diseases affecting both the mother and the foetus such as pre-eclampsia and diabetes. Chromosomal abnormalities are one of the major causes of some of the above diseases and despite of the recent advancement in non-invasive maternal blood tests and ultrasound studies, chorionic villus sampling (CVS) and amniocentesis are the most accurate but invasive ways to diagnose these abnormalities.

The total market for the foetal maternal and Down's syndrome diagnostics is indeed murky due to the many methods used at present and the medical opinions as to the best way to diagnose these conditions. As shown above, there are a variety of diseases with different pathologies making a unified consensus impossible. Maternal age over 35 is a high risk factor. In the United States there are a total of 4 million live births a year with over 500,000 in the maternal age group of over 35. The cost per invasive test such as amniocentesis, depending on the method, varies between US\$300 to US\$900. For the non-invasive test there are also a variety of methods but none of them can isolate placental tissue, genetic materials or hormones truly from the fetus itself. The Group believes that if one method that can isolate true foetal material for testing and which can be done in a non-invasive way, it may have the capability to capture practically all of the foetal maternal market as it stands now. A fair estimate of the total market is the cost of the test or tests times the average number it has to be used throughout pregnancy times the pregnancy rate of that country.



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According to a report by Vysis Inc. and Abbott Laboratories, the Directors believe that over 700,000 amniocentesis tests are performed in Europe and the United States per year. Abbott Laboratories, founded by a young Chicago physician, Dr. Wallace Calvin Abbott, in 1888, Abbott Laboratories is a healthcare company that discovers, develops, manufactures and markets innovative products and services that span from prevention and diagnosis to treatment and cure. Vysis, Inc., a wholly owned subsidiary of Abbott Laboratories, is a leading Genomic Disease Management company that develops, commercialises and markets DNA-based clinical products providing information critical to the evaluation and management of cancer, prenatal disorders and other genetic diseases. An amniocentesis is a test whereby a small amount of amniotic fluid is drawn from within the placental membrane surrounding the foetus. The amniotic fluid contains cells and genetic materials shed by the foetus. Amniocentesis can be used to detect foetal anomalies such as Down's syndrome, genetic diseases such as beta-thalassaemia. Often an amniocentesis test is recommended to women over 35 years of age due to the increased risk of carrying a Down's syndrome baby and is performed around 15 to 18 weeks into the gestation period. The medical community has observed that historically, 1 in 1,000 babies born are affected by Down's syndrome. However, amniocentesis tests are invasive and the test itself can pose a risk to the unborn baby. Pregnant women undergoing this test may experience psychological stress and an increased risk of miscarriage.

Besides chromosomal abnormalities, there are other common foetal disorders that have not been diagnosed or predicted by any existing methods of testing, such as the conditions of pre-eclampsia and pre-term delivery. Pre-eclampsia is a multi-system disorder specific to pregnant women, which usually subsides rapidly after delivery. It remains one of the most important causes of maternal and foetal mortality and morbidity in developed countries. The pathogenesis of this condition is not fully understood but a lot of evidence points to underlying pathological changes that occurs in the placental bed. Consequently placental hormones and their specifically activated translating RNAs (how genetic information is generating the proteins that work in the human body) may be a good source where the diagnosis can be based. Such placental hormones similarly may play an important role in the determination of pre-term delivery, which accounts for up to 11% of all births and a leading factor in neonatal morbidity and mortality.

In recent years, and with the advent of new information generated by research in this field, non-invasive method using the genetic materials circulating in the maternal blood plasma has been able to diagnose the RhD blood incompatibilities and X-linked recessive diseases with nearly 100% accuracy. Similar techniques were able to predict some of the DNA and RNA changes in trisomy 21 or Down's syndrome, Thalassaemias, pre-eclampsia and a host of other foetal maternal disorders.

A recent article with a randomised trial involving 534 pregnant women published in the journal of Lancet (24 January, 2004) further provides proof that even for the more invasive, risky and expensive methods such as CVS and amniocentesis, the cost effectiveness of such methods justify an expansion of these tests to a much larger group of pregnant women regardless of their age and risk level. It could be safe to conclude that, if there were new tests available that could replace these risky, invasive and costly foetal maternal procedures, they likely would be applicable to most, if not all pregnant women.

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The market for such new non-invasive foetal maternal diagnostic products could be estimated by the size of the pregnant women population in the targeted countries. In developed countries, the number of deliveries is about 1% of the total population per year. This figure will go up to over 2% in the less developed countries. For each targeted country, the accurate number of pregnant women per year could be deduced by the fertility rate as shown in the table above multiplying the female population of that country and divided by their life span.

### REGULATORY REQUIREMENTS

#### Hong Kong

The Group's business and the laboratory scientists employed by the Group are required to register and have registered with the Medical Laboratory Technologists Board of the Supplementary Medical Professions Council pursuant to the Supplementary Medical Professions Ordinance (Chapter 359 of the Laws of Hong Kong) as the testing services provided by the Group have to be performed by experienced laboratory scientists and the Group's business falls within the definition of a medical laboratory of such ordinance. In order to be so registered and licensed, the Group's laboratory scientists are required to fulfil certain criteria in respect of relevant qualification in medical laboratory science or biomedical science and possession of sufficient practical experience. The Directors confirm that the Group's business is in compliance with the Hong Kong laws and regulations, and the Group has obtained all relevant permit and licences for it to conduct its testing business in Hong Kong. The Directors further confirm that the Group currently has no other business operation located elsewhere other than in Hong Kong.

Although the testing services of the Group may be considered as a tool used for the diagnosis of any form of diseases, the Directors confirm that this tool does not fall within the ambit of regulation by the Department of Health or the Medical Council of Hong Kong under the Medical Registration Ordinance (Chapter 161 of the laws of Hong Kong) and Medical Clinics Ordinance (Chapter 343 of the Laws of Hong Kong) as these ordinances have been implemented for the registration of medical practitioners and non-profit making medical clinics in Hong Kong which are related to direct care of patients in premises and not related to the Group's business of laboratory testing services. The Group has received confirmation from the relevant government authority that the Medical Clinics Ordinance only applies to clinics that are non-profit making or non-profit sharing in nature. Chui & Lau, one of the Company's legal advisers as to Hong Kong laws have advised that the Group has complied with the requirements under the Supplementary Medical Professions Ordinance (Chapter 359 of the Laws of Hong Kong). As further advised by Chui & Lau, they believe that the Group's testing laboratory should not fall within the ambit of the Medical Clinics Ordinance so as to require registration of its testing laboratory as a "medical clinics" under the Medical Clinics Ordinance and that the Group's operation should not fall within the ambit of the Medical Registration Ordinance or that its personnel would have to be registered under the Medical Registration Ordinance.

As at the Latest Practicable Date, a director of Plasmagene and two technicians working at its laboratory are registered under Part I in April 1991 and Part II in July 2001 and November 2002 of the Register pursuant to the Supplementary Medical Professions Ordinance (Chapter 359 of the Laws of Hong Kong) respectively.

### The PRC

Under PRC law, any entity or individual intending to conduct medical diagnosis and treatment activities has to obtain a medical treatment institution practice licence (“Practice Licence”) from the Regional Health Administrative Departments at or beyond county level (the “Regional Departments”) in order to establish a corresponding type of medical treatment institution. Otherwise, any entity or individual without such a licence is prohibited from conducting any kind of diagnosis and treatment activities within the PRC.

The PRC government exercises extensive supervision and administrative control over the medical treatment industry in the PRC and the Group’s business will fall within the definition of diagnostic and treatment activities under PRC law. The Ministry of Health (“MOH”) and the Regional Departments are each empowered under PRC law to supervise and regulate the operations and activities of medical treatment institutions at a national and regional level, respectively, under the Regulations of Medical Treatment Institution (the “Regulations”) and the Implementation Rules for the Regulations of Medical Treatment Institution (the “Rules”). Accordingly, the Group’s intended expansion into the PRC must comply with the provisions of such Regulations and Rules.

The PRC government has, at present, further opened up the medical treatment industry to foreign investors on a limited basis. Pursuant to PRC law recently implemented, foreign investors who intend to establish a medical treatment institution within the PRC have to form joint ventures with PRC counterparts. A medical treatment institution solely funded by non-PRC entities will currently not be approved. According to the regulations of joint ventures, the percentage of shareholding for Chinese party shall not be less than 30%.

The establishment of such joint ventures will require applications to the MOH and subsequently to the Ministry of Commerce (“MOC”) for each of their approval. Once the approvals are granted and the approval certificates are issued, applicants may register the joint venture entity at the administration of industry and commerce, and apply to the specific health department for the Practice Licence in accordance with the conditions and procedures specified by the Regulations and Rules. Any entity operating diagnosis and treatment programmes by entering into contracts with foreign entities without the approval from the MOH and MOC will be deemed as illegal and subject to sanctions under the Regulations and Rules. The sanctions imposed including cessation of operation, confiscating illegal earnings, medicines and medical appliances and imposing fines.

In considering the Group’s expansion plans to introduce its testing services into the PRC, the Directors intend to comply with all PRC laws and regulations. The Group has commenced the preparation work for a new submission of the *EBgene* and *EBeasy* test kits to be approved by the State Food and Drug Administration (SFDA) of PRC and the submission is expected to be made in the second quarter of 2004. The Group is not expected to operate any treatment or testing facility in the PRC and the test kit will be shipped as a finished commercial product if SFDA approval is obtained. As far as the Directors understand, the usual time for it to be processed is approximately six months to one year.

### Japan

The testing services the Group intends to offer in Japan will be governed by the Law Concerning the Clinical Testing Technicians and the Hygienic Testing Technicians etc. (Law No. 76, 1958 as amended) and the related rule and ordinance. The Group's testing services must be performed by a clinical testing technician or a hygienic testing technician respectively licensed by the Minister of Health, Labour and Welfare under the instruction and the supervision of medical professionals. The clinical testing technicians and hygienic testing technicians are required to pass the national examination for such licence or have certain educational qualification in order to obtain the relevant licence. Any laboratory which the Group intends to set up in Japan must be registered with the relevant municipal government in the relevant region where such laboratory is located before it may commence testing services in Japan. In addition, the Ministry of Health, Labour and Welfare of Japan sets certain requirements for the registration of a laboratory under the Ministerial Ordinance which must be fulfilled to ensure that the relevant laboratory in fact has sufficient capacity to conduct proper testing activities. In the event of failing to meet such criteria, registration of the relevant laboratory will not be granted. Furthermore, the registered laboratory will be under the continuing supervision of the relevant municipal government in the region in which such laboratory is located once registration has been approved. The Directors would comply with the laws, regulations and rules in Japan in all material respects should the Group introduce its services to the Japanese market.

### Australia

The sale and use of the testing services of the Group will most likely require some regulatory approvals in Australia, prior to their launch in that country. Certain regulatory bodies may impose standards and requirements in respect of diagnostic tests, the provision of medical and pathology laboratory services as well as requirements in respect of government reimbursement for the provision of such services to the Australian public.

Australia has in place a universal healthcare system, Medicare, under which the provision of medical services to Australian residents are subsidised and in some circumstances fully paid for by the Australian Commonwealth government. In respect of medical and pathology services the Australian Commonwealth government fully subsidises a medical or pathology test provided it qualifies as a Medicare benefit. Qualification as a Medicare benefit is usually critical to the commercial success of any diagnostic tests and services in Australia, particularly if the test is a specialist test commonly ordered by medical practitioners or medical specialists.

Under the Health Insurance Act 1973 (the "Health Insurance Act"), certain approved administrative arrangements must be in place before Medicare benefits can be paid for a pathology service and applications and undertakings must be submitted to, and accepted by, the responsible Minister in order to qualify for such arrangements. Section 16A of the Health Insurance Act states that the pathology service must be provided in an accredited pathology laboratory in order to access payment through the Medicare system. Such accreditation will be through the National Association of Testing Authorities ("NATA") on the basis of the laboratory's capacity to perform a specific range of services for example biochemical or histological testing to ensure the competency and the accuracy

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of the laboratory and the tests undertaken. Whilst the method or process for performing tests may be part of determining the accuracy and competency of the laboratory, the process itself need not be approved by any such body. Accordingly, the accreditation process is effectively results based in that so long as the process is accurate in producing a result it is available for use by a laboratory.

NATA accredits medical testing and imaging laboratories against the internationally recognised standard IOS/IEC 17025:1999. The laboratories are accredited by technical and scientific experts after application documentation has been lodged in accordance with NATA Accreditation Requirements (“NAR”), depending upon the category of laboratory and the accreditation being applied for. Accreditation is an ongoing requirement for all laboratories in Australia.

For the Group’s testing services to qualify as a Medicare benefit, a submission detailing various information about the diagnostic tests must be made to the Australian Health Insurance Commission (the “HIC”) which will then consider the application and determine whether the particular test will be listed as a Medicare benefit and the subsidy which the Australian Commonwealth government will pay. The Group intends to use all reasonable endeavours to comply with all regulations and accreditation criteria to qualify as a Medicare benefit in all material respects when required to do so.

Whilst the Group’s testing services are at present marketed in Hong Kong only, it is intended that the provision of such testing services be extended to other countries or regions in the future. Each of the Group’s testing services may therefore be regulated according to the country or region in which it is sold or provided and subjected to local and foreign laws and regulations which may affect its research and development capabilities including those governing environmental matters. The Group will endeavour to comply with all laws and regulations applicable to its business in all material respects and obtain all licences and permits required to operate its business in the country or region in which it proposes to enter and market its testing services.