1. **Introduction**

1.1 We act for A C Mauff and Partners, an unincorporated practice of specialist pathologists who are registered with the Health Professions Council of South Africa ("HPCSA") under practice number 5201055 and who practise under the name of Lancet Laboratories ("Lancet Laboratories").

1.2 On 1 August 2014, the Panel ("Panel") for the Market Inquiry into the Private Healthcare Sector ("Inquiry") invited all those who wish to participate in the Inquiry to make submissions on the issues identified in the Statement of Issues ("Statement") published on 1 August 2014, read with the Terms of Reference ("Terms") published on 29 November 2013. Lancet Laboratories wishes to participate in the Inquiry and hereby makes submissions in accordance with the Call for Submissions ("Call") published on 1 August 2014. We enclose completed Form HI 1 (Registration Form for Written Submission).

1.3 Part 2 of this letter responds to items 1 and 2 in the Call. Part 3 sets out Lancet Laboratories' submissions on certain of the issues identified in the Statement. Lancet Laboratories reserves the right to supplement these submissions orally or in writing. Please note that certain of the information in these submissions is claimed to be confidential and we accordingly enclose a Form CC7 and Schedule for Lancet Laboratories in this regard. We have also placed confidential information provided in this letter in square brackets.

2. **Call for Submissions**

2.1 Lancet Laboratories operates in the private healthcare sector in South Africa. Lancet Laboratories provides specialist diagnostic and monitoring pathology services such as analytical chemistry, chemistry, coagulation, cytology, haematology, histology, microbiology, molecular biology, TB laboratory, virology and veterinary pathology.

2.2 These services are provided directly to patients who visit Lancet Laboratories' own facilities or testing facilities at third parties such as hospitals, clinics and pharmacy chains. Lancet Laboratories also provides pathology consulting services to physicians, as well as various value-added pathology services to employers (such as mining houses), managed healthcare providers, and insurers.

2.3 Lancet Laboratories processes up to 1.8 million tests per month and is accredited by the South African National Accreditation System (SANAS) and adheres to international criteria prescribed by the International Organization for Standardization (ISO) including Standards 15189 and 9001.

2.4 Lancet Laboratories was established approximately 60 years ago and initially operated from the Johannesburg central business district. In 1996, Lancet Laboratories' main laboratory moved to the Johannesburg suburb of Richmond,
which is strategically situated next to Johannesburg's main highway. This enables Lancet Laboratories to effectively service the whole of the Gauteng region.

2.5 In 2000, Lancet Laboratories merged with the Durban pathology practice of Pillay MacIntosh and Partners ("Pillay Partners"). This merger allowed Lancet Laboratories to expand its geographical footprint and consolidate pathology expertise. Pillay Partners commenced operations in 1986 and rapidly grew throughout KwaZulu-Natal. Prior to this merger, Lancet Laboratories and Pillay Partners operated a referral system between their respective laboratories.

2.6 In 2003, Lancet Laboratories merged with Niehaus Ungerer Pathologists Inc. and Medlab (Proprietary) Limited of Pretoria, as well as with P D Rambau and Partners Inc. and Independent Pathology Services (Proprietary) Limited of Alberton, Johannesburg. These mergers allowed Lancet Laboratories to extend its reach in Gauteng so as to deliver even more efficient turn-around times to the satisfaction of its clients.

2.7 In 2004, Lancet Laboratories bought back from Afrox Healthcare Limited and MedClinic Group Limited their joint 30% interest in Lancet Laboratories.

2.8 Lancet Laboratories now operates as a wholly pathologist owned partnership employing approximately 80 pathologists of whom 25 are also profit sharing partners in the partnership. All these pathologists are supported by 4 600 employees. The latter perform, inter alia, technical, finance, human resource, administrative and logistics functions.

2.9 Between 2008 and 2011 Lancet Laboratories acquired a 17.7% non-controlling shareholding in the Intercare Group, which operates 16 medical centres in the Eastern Cape, Gauteng, KwaZulu-Natal and the Western Cape. Qualified practitioners provide various medical services (such as general medicine, pathology, radiology, speech therapy, optometry, physiotherapy and psychology) from these centres. Most of these centres are conveniently located in shopping centres and close to a pharmacy. They also offer longer operating hours during the week and are open on weekends and public holidays.

2.10 In 2007, Lancet Laboratories acquired a 37% shareholding in HEALth-WorX Medical Centres (Proprietary) Limited ("HEALth-WorX"), which had commenced operations in 2006. HEALth-WorX is a medical practice management business. It offers outsourced practice and facility management and administration services to selected general practitioners with relatively large patient bases.

2.11 In addition to the foregoing, the medical specialists at Lancet Laboratories continue to grow and develop the practice, with a special focus on bringing cutting edge pathology services to the African continent. In addition to South Africa, Lancet Laboratories currently operates in Botswana, Ghana, Kenya, Mozambique, Nigeria, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe.

2.12 Lancet Laboratories is a member of the National Pathology Group of South Africa ("NPG"), which is the official pathology representative for the South African Medical Association "SAMA"). Membership of the NPG is open to all registered pathologists (clinical and anatomical) that are members of SAMA. The objectives of the NPG are to (i) promote the practice and professional interests of both clinical and anatomical pathology; (ii) promote the use of pathology as a diagnostic tool to both the medical profession and the lay public; (iii) establish professional relationships amongst pathologists and with medical aid schemes, public and private institutions, government authorities, the life insurance industry and university medical schools;
(iv) promote the establishment and maintenance of acceptable standards in respect of pathology education and practice in South Africa; and (v) assist in the promotion of good health practices within the population. For more information on the NPG, please refer to http://www.pathology.co.za.

Lancet Laboratories’ relationship with various stakeholders in the healthcare sector

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Nature of relationship</th>
<th>Name of firm(s) dealt with, where applicable</th>
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<tbody>
<tr>
<td>Medical Schemes</td>
<td>Service provider</td>
<td>&gt;80</td>
</tr>
<tr>
<td>Medical Scheme Administrators</td>
<td>Service provider</td>
<td>MHG, Discovery, Medscheme, VMED, etc.</td>
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<tr>
<td>Managed Care Companies</td>
<td>Service provider</td>
<td>Aid for Aids, Your Life, etc.</td>
</tr>
<tr>
<td>Health Insurers</td>
<td>Nil</td>
<td>n/a</td>
</tr>
<tr>
<td>Brokers</td>
<td>Nil</td>
<td>n/a</td>
</tr>
<tr>
<td>Facilities (e.g. hospitals)</td>
<td>Rental of premises</td>
<td>Life Healthcare, Netcare, Mediclinic, Lenmed, Clinix, NHN</td>
</tr>
<tr>
<td>Medical Suppliers</td>
<td>Procurement of goods and services</td>
<td>Roche, Abbott, Beckman, etc.</td>
</tr>
<tr>
<td>Primary care practitioners (General Practitioner / Dentist)</td>
<td>Provision of diagnostic services</td>
<td>Numerous practitioners</td>
</tr>
<tr>
<td>Medical Specialists</td>
<td>Provision of diagnostic services</td>
<td>Numerous practitioners</td>
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<td>Allied Professionals (specify)</td>
<td>Provision of diagnostic services</td>
<td>Numerous practitioners</td>
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<tr>
<td>Members of the public</td>
<td>Provision of diagnostic services</td>
<td>Numerous practitioners</td>
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3. Lancet Laboratories’ submissions

3.1 The Statement invited providers of healthcare products and services to make submissions on the following issues:

3.1.1 specialities and practitioner groups;
3.1.2 the impact of scarcity of specialist skills on competitive rivalry;

3.1.3 the impact of the rules and requirements of the HPCSA and the Allied Health Professions Council of South Africa ("AHPCSA") on competition;

3.1.4 coordination in tariff setting and adoption of coding systems, and the trade-offs that must be made between coordination and competition;

3.1.5 the relationship between practitioners and hospitals, particularly with regards to rules that prevent practitioners from being employed by hospitals; and

3.1.6 the level and structure of prices and underlying costs for key services offered by practitioners.

3.2 Lancet Laboratories' submissions below deal with each of these issues to varying extents under the following broad themes:

3.2.1 Practice and regulation of pathology services;

3.2.2 Costs and pricing of pathology services; and

3.2.3 Relationship with hospitals.

**Practice and regulation of pathology services**

3.3 The medical speciality of pathology requires a medical residency and should not be confused with biomedical science, which is not necessarily related to medicine. The practice of medical pathology is divided into a number of sub-disciplines, including -

3.3.1 Anatomical pathology, which is concerned with the diagnosis of disease based on the gross, microscopic, chemical, immunologic and molecular examination of organs, tissues, and whole bodies. Anatomical pathology is itself divided into subfields, the main ones being surgical pathology, cytopathology and forensic pathology.

3.3.2 Clinical pathology is concerned with the diagnosis of disease based on the laboratory analysis of bodily fluids such as blood and urine, as well as tissues, using the tools of chemistry, clinical microbiology, hematology and molecular pathology. Immunopathology, the study of an organism's immune response to infection, is sometimes brought within the domain of clinical pathology.

3.3.3 Molecular pathology is focused on the study and diagnosis of disease through the examination of molecules within organs, tissues or bodily fluids. Molecular pathology is often applied in a context that is as much scientific as directly medical. Molecular pathology is commonly used in diagnosis of cancer and infectious diseases.

3.3.4 Oral, dental and maxillofacial pathology focus on the diagnosis, clinical management and investigation of diseases that affect the oral cavity and surrounding maxillofacial structures.

3.4 Although the vast majority of laboratory work and research in pathology concerns the development of disease in humans, pathology is of significance throughout the biological sciences. Two main catch-all fields exist to represent most complex organisms capable of serving as host to a pathogen or other form of disease,
namely veterinary pathology (concerned with all non-human animals) and phytopathology, which studies disease in plants.

3.5 The medical specialists at Lancet Laboratories are publicly regulated by the HPCSA, which was established under the Health Professions Act, No 56 of 1974 (as amended) ("HPA"). The HPCSA and its boards guide and regulate the health professions in South Africa in aspects pertaining to registration, education and training, professional conduct and ethical behaviour, ensuring continuing professional development, and fostering compliance with healthcare standards. All individuals who practise any of the health care professions incorporated in the scope of the HPCSA are obliged to register with the HPCSA. Failure to do so constitutes a criminal offence.

3.6 Notably, in terms of Rules 3(2)(a) of the HPCSA's Guidelines for Good Practice in the Healthcare Professions: Ethical and Professional Rules (published in Government Gazette R717/2006), a medical specialist who practises in one of the prescribed related specialities in medical pathology is excluded from the concession to form an incorporated practice in terms of section 54A of the HPA, or to form a partnership or association with a medical practitioner, a medical specialist or another practitioner who does not practise in one of the related specialities in medical pathology. This means that Lancet Laboratories is precluded from, for example, developing diagnostic centres in South Africa with other medical specialists such as radiologists. These centres could provide services to other medical professionals or the general public, which could be cheaper than using outpatient facilities at hospitals.

3.7 Lancet Laboratories is indirectly privately regulated by the College of Pathologists ("College"), one of the colleges of the Colleges of Medicine of South Africa ("CMSA"). The CMSA is the custodian of the quality of medical care in South Africa and is unique in the world in that it embraces 28 constituent colleges representing all the disciplines of medicine and dentistry. The duties and functions of the Council of the College include framing and revising regulations for the admission to and conduct of examinations leading to qualifications in the College for consideration by the Senate of the CMSA. Although Lancet Laboratories is not directly regulated by the College, to the extent that the College acts as gate-keeper to the entry into the profession of new pathologists, the College's admissions and examination requirements ultimately influence the services that are provided by Lancet Laboratories.

Costs and pricing of pathology services

Costs

3.8 Lancet Laboratories total costs to provide pathology services are broadly as follows and in the following proportions:

3.8.1 Salaries - between 30% and 40%;
3.8.2 Reagents - between 20% and 30%;
3.8.3 Practice management - less than 10%;
3.8.4 Bad debt - less than 10%;
3.8.5 Finance and insurance - less than 10%;
3.8.6 Premises - less than 10%;
3.8.7 Maintenance and depreciation - less than 10%;
3.8.8 Instrument rentals - less than 10%; and
3.8.9 Other - between 10% and 20%.

3.9 These costs exclude special items such as *ad hoc* purchases of laboratory equipment. For example, in the period from January to December 2013 Lancet Laboratories purchased, *inter alia*, the following equipment at then prevailing local and international prices:

3.9.1 laboratory equipment - R [CONFIDENTIAL];
3.9.2 vehicles - R [CONFIDENTIAL].

3.10 Lancet Laboratories’ costs constitute between 80% and 90% of its turnover.

*Codes*

3.11 As noted above, Lancet Laboratories is a member of the NPG. Together with the Anatomical Pathologist’s Group and pathologists in full time academic practice, the NPG publishes coding guidelines (*Guidelines*) aimed at achieving a uniform coding policy applicable to all pathology investigations. The Guidelines do not refer to any value to be ascribed to any procedure performed by a pathologist but only provides guidance on the utilisation of the correct codes.

3.12 The Guidelines are essentially a check list that should be completed per test. They are aimed at ensuring that the highest levels of quality are maintained in the pathology profession. The Guidelines therefore discourage the use by referring doctors of handwritten request forms as this sometimes leads to transcription errors, misreading of test requests, unnecessary tests and higher costs.

3.13 The Guidelines provide descriptor codes. Each descriptor code is linked to a specific service, which is linked to a unit value, which is in turn linked to a tariff. Tariffs are individually determined by each pathology practice and are typically negotiated with medical schemes and administrators. Generally, the unit values are similar throughout the pathology profession and are a remnant of the SAMA Doctors’ Billing Manual (*DBM*).¹ These units of "relativity" refer to the cost of performing a test in the very broad sense and include labour, materials, apparatus, time as well as expertise of the person performing the test. The aim of this is to ensure greater price transparency and fairness for all users of the process.

3.14 The Guidelines are also aimed at preventing over-servicing. Indeed, in order to avoid the proliferation of medically questionable testing profiles and the use of unacceptable or unreasonable profiles, only profiles accepted by the NPG may appear on request forms. Notwithstanding this, referring doctors are free to request any tests that they consider necessary and appropriate, even if these do not appear on the request form, and may do so by requesting those tests in their own

¹ The DBM, last published in hard copy in 2009, was a comprehensive manual containing important information on the codes and descriptors for doctors’ services, interpretation of various billing guidelines, as well as relevant legislative and ICD-10 guidelines. Electronic versions of the 2011, 2012, 2013 and 2014 DBM are available, but are difficult versions to work with and incomplete in terms of rules and interpretive guidelines.
handwriting in spaces that are provided for this purpose. Doctors are also free to contact the laboratory personally and to interact with a pathologist to request the appropriate tests.

3.15 The NPG cannot impose any sanctions on its members for non-compliance with the Guidelines. A member that elects not to follow the Guidelines would simply then have to account separately to medical schemes and administrators in terms of the appropriateness of the tests and codes used.

**Tariffs**

3.16 Lancet Laboratories negotiates tariffs with medical schemes and administrators every year for the succeeding year. These tariffs are negotiated per test and while they may differ from fund to fund, these differences are not material. This is for two reasons. First, a single scheme administrator will more often than not effectively negotiate on behalf of several funds and so the tariff charged to these funds will usually be the same or extremely similar. Low-cost benefit options are the exception to the rule. Second, medical schemes and administrators typically only agree to a Consumer Price Index adjustment on the previous year's tariff and rarely agree to a complete recalibration on previous years' tariffs.

**Relationship with hospitals**

3.17 Broadly stated, only practitioners registered with the HPCSA may own shares or be partners or associates in a solo practice, a partnership, an association or an incorporated practice. A practitioner may, however, outsource the administration of a practice or establish a legal entity to do so, provided that the practitioner does not allow the entity to contravene the ethical rules of the HPCSA. In addition, the HPCSA has published a number of rules aimed at preventing the profits or income of a practice being shared with any third-party.

3.18 The Undesirable Business Practices Policy of the HPCSA of 2005 ("UBPP") provides that only the following may employ practitioners registered under the HPA: (i) the public service; (ii) universities / training institutions (limited for purposes of training and research); and (iii) practitioners that are registered with the HPCSA may employ fellow registered practitioners. The UBPP provides that any other agent, institution or person may lodge an application with the HPCSA to employ a registered practitioner, save that any employment that falls beyond professional practice, such as full-time employment with a medical scheme or a pharmaceutical company, does not require an application to the HPCSA.

3.19 This means that in South Africa hospitals are precluded from having an interest in a pathology practice or from employing pathologists to provide medical pathology services. In other jurisdictions this is allowed and is sometimes referred to as the "corporatisation of pathology practices" whereby pathology practices are integrated with other medical service providers, such as hospitals. Lancet Laboratories does not support this approach for the reasons set out below.

3.20 While the corporatisation of pathology practices might allow for less expensive and easier access to financing to fund the extremely expensive equipment and consumables required by pathologists to provide pathology services, this and other

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2 See generally the HPA (section 54A), the HPCSA Ethical Rules of 2006, the Undesirable Business Practices Policy of the HPCSA of 2005, and the Perverse Incentives Policy of the HPCSA.
possible benefits (such as the promise of lower test prices) are outweighed by the following:

3.20.1 Corporatisation is done firstly for the benefit of the shareholders, rather than the patients. The two interests are often very different. The corporation will therefore place emphasise on profitability, rather than clinical competence.

3.20.2 Corporatisation also provides endless opportunities for coercing or tempting pathologists to put other interests of the corporation ahead of those of their patients. Together with the pressure directed towards profitability, it seems likely that there would be over-servicing.

3.20.3 Corporatisation leads to fewer pathology practices. Privately run pathology practices tend to become unable to compete. They are offered large payments for their practices by corporations, hence the number of competitors in the market progressively reduces and only a few privately owned and run services remain.

3.20.4 Corporatisation may also lead to increased prices, not through a foreclosure effect, but by increasing the bargaining power of the corporations with medical schemes and administrators. Also, as with radiology/MRI scanners, etc., hospitals will compete with each other by offering more in-house esoteric pathology tests resulting in duplication of services and increased costs.

3.20.5 Corporatisation is often not limited to hospitals or large corporations buying out pathology practices, but is aimed at vertically integrating pathologists, radiologists, other specialities, as well as referring doctors (the objective being to provide a one-stop-shop for patients). The object of integrating pathologists with referring doctors is to obtain their customer base. In a competitive market however, pathologists should be competing for referrals from doctors. Integrating these general practice services therefore reduces competitive incentives.

4. Conclusion

We trust that the above preliminary submissions assist the Panel and Lancet Laboratories holds itself available to answer any questions that the Panel might have. Please direct these questions to the writer at the below email address.