IVD AUSTRALIA

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Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Availability of new, innovative and specialist cancer drugs in Australia

IVD Australia thanks the Senate Standing Committees on Community Affairs for the opportunity to comment on the *Availability of new, innovative and specialist cancer drugs in Australia*.

We look forward to working with you on this important initiative.

Yours sincerely

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IVD AUSTRALIA

The industry where innovation saves more Australian lives

IVD Australia Submission to the Senate Community Affairs References Committee on behalf of the IVD Industry in Australia

The availability of new, innovative and specialist cancer drugs in Australia

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Introduction to the IVD Industry in Australia

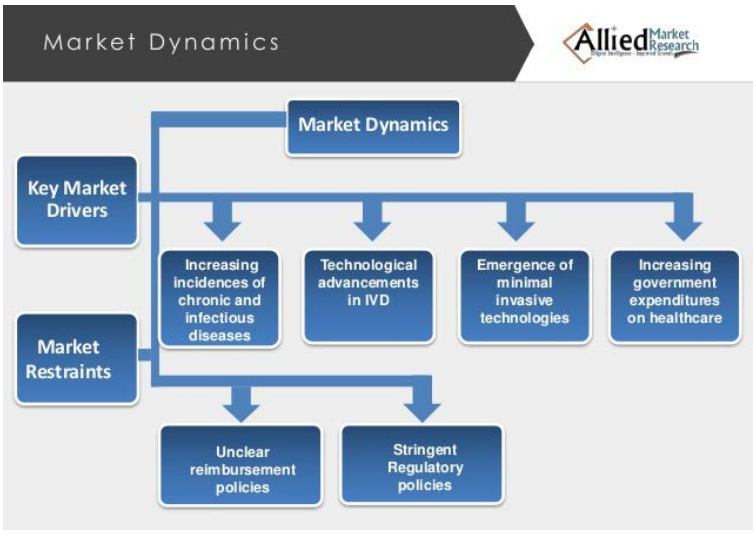
The IVD Industry supplies *in-vitro* diagnostic tests and devices to healthcare professionals and consumer sectors.

In vitro, literally 'in glass', diagnostics (*in-vitro* diagnostic tests, IVDs) comprise the instruments, reagents and consumables that are used to perform pathology tests requested by General Practitioners, specialist Physicians, or other healthcare professionals, tests undertaken in the home such as blood glucose or home pregnancy tests, or those tests undertaken as part of a government screening program, such as the Bowel Cancer Program.

The *in-vitro* diagnostics industry – both in Australia and internationally – is vibrant, innovative, and rapidly evolving to keep up with demand for better and faster testing and monitoring of diseases. The IVD industry is the R&D of pathology and drives both efficiency, efficacy and diagnostic tests that are relevant and impactful on healthcare outcomes in Australia.

The IVD global market revenue was estimated at approximately $USD 53 billion in 2013 and with a compound annual growth rate (CAGR) of 5.34%, by 2020 this will be in the vicinity of $USD 75 billion. Australia is estimated to comprise about 2% of the world market, putting Australian market revenue at close to $AUD2 billion.[1]

Global market drivers and restraints are shown to the right[2]:



It is estimated that the results obtained from pathology tests are responsible for 70% of all medical diagnoses and almost 100% of all cancer diagnosis and make a significant contribution to the management of disease.[3]

These pathology tests include the innovative areas of genetics and are typically performed in accredited Public and Private pathology laboratories across Australia, but IVDs also include the fast growing and game-changing point of care (POC) devices that can be used in general practice, healthcare clinics, as well as enabling the future of health in the home (HITH). In addition we provide over-the-counter devices such as blood glucose meters for patients to self-manage their diabetes.

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1 Allied Market Research, *Report Image Global In Vitro Diagnostics (IVD) Market (Technique, Product, Usability, Application, End User, and Geography) - Size, Share, Global Trends, Company Profiles, Demand, Insights, Analysis, Research, Report, Opportunities, Segmentation and Forecast, 2013 – 2020*, reported at http://www.alliedmarketresearch.com/ivd-in-vitro-diagnostics-market

2 Ibid.

3 Australian Association of Pathology Practices Inc, *Pathology in Australia*, 2008 http://pathologyaustralia.com.au/wp-content/uploads/2013/03/Pathology-in-Australia.pdf

Why Take Action? The Importance of IVDs to Australian Healthcare

IVD tests are a key contributor to the Australian health care system, powering medical discoveries and transforming patient care. These tests are performed on biological samples taken from the body and are used in a broad range of applications. IVD tests provide critical insights at every stage of medical care – prevention, detection, diagnosis, treatment, and successful management of health conditions. IVD tests are often the least expensive component of the health care pathway, yet they influence more than 70% of health care expenditures. They facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease, and reduce overall health care costs.

Technological advances and automation have made IVD tests easier to use, more analytically reliable, and have led to more precise and more timely reports. These advances include point of care tests that facilitate more rapid decision-making by medical practitioners at the time of patient consultation. Other advances, made possible by discoveries about the human genome, have opened the door to personalised medicine approaches that can tailor medical treatment to individual patient's biochemical and genetic response to specific diseases such as cancer and drugs, transforming modern medicine and ensuring the right treatment is offered to the right patient.

There are more than 1,600 different diagnostic tests currently included on the ARTG today and, in 2013-2014 alone, in excess of 126 million pathology tests (services) were delivered in Australia.[4] Supply of IVDs in Australia is regulated for the Government by the Therapeutic Goods Administration (TGA).

From the genetic tests that allow personalised cancer treatment to the blood analysis that identifies the right antibiotic to fight an infection, diagnostic tests provide critical insights at every stage of medical care – pre-disposition, prevention, detection, diagnosis, treatment and successful management of health conditions.

Diagnostic tests using IVDs, are performed in laboratories, hospitals, doctors' offices, clinics, on the field, and in the home. They facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease, and reduce overall health care costs.

Worldwide the IVD Sector is one of the most concentrated in the whole of the Health Sector. The ten largest IVD manufacturers represent over 75% of the total market and this concentration is increasing.

Thus, most IVD companies across the world are represented in Australia in one way or another – directly, via a subsidiary, via a distributor or via OEM sales to a third party. This has meant that there is substantial competition within the Australian market, perhaps in excess of any other developed market. This has resulted in effective price competition and in many cases the lowest cost IVDs in the world. For example, the product cost of a panel of specific IgE tests for allergy is around $18.50 in Australia but is typically around $38.50 in Europe.

An example of Current Cancer Research in the In-vitro Diagnostics Industry

The Actionable Genome Consortium (AGC) brings together Illumina with the Dana-Farber Cancer Institute, Memorial Sloan-Kettering Cancer Centre, MD Anderson Cancer Centre, and the Fred Hutchinson Cancer Research Centre. The aim is to define genomic changes in patients' tumours that will allow oncologists to choose optimal therapies and testing strategies. The hope is that defining an 'actionable tumour' will support

[4] In 2013-2014, Medicare was expected to record in excess of 126 million pathology services (up from 100 million in 2008-2009). IbisWorld, *Pathology Services in Australia: O8631*, 2009, p44

new diagnostics development and regulatory oversight for genomic testing in cancer. The resulting data will enable a recommendation on a set of genes that are required to be tested enabling a sensible reimbursement structure to be proposed to government and considered based on community agreement on clinically relevant targets for maximum efficiency and clinical benefit.[5]

Focus on Companion Diagnostics

Companion diagnostics are an emerging area of IVD use receiving a lot of attention. Companion diagnostics are IVDs that provide information about genomic and proteomic characteristics to help inform use of a specific drug or therapy. The Australian Department of Health defines these health technologies as co-dependent if their use needs to be combined (either sequentially or simultaneously) to achieve or enhance the intended clinical effect of either technology. For example, a drug/test combination where a new medicine seeking listing on the PBS may have a related pathology test that helps to determine the population group for that medicine.

Companion diagnostics allow for treatments to be targeted and therefore cost effective since they exclude those that the treatment is likely not to be effective. They are critical in establishing and justifying the availability, cost effectiveness of **new, innovative and specialist cancer drugs in Australia**.

Definition of a Companion Diagnostic

> *A companion diagnostic is a medical device, often an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product. The test helps a health care professional determine whether a particular therapeutic product's benefits to patients will outweigh any potential serious side effects or risks.*
>
> *Companion diagnostics can:*
>
> - *identify patients who are most likely to benefit from a particular therapeutic product;*
> - *identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or*
> - *monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness.*[6]

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5 Actionable Genome Consortium to guide NGS in cancer, *Nature Biotechnology* 32, 965 (2014) doi:10.1038/nbt1014-965d, October 2014. Accessed via http://www.nature.com/nbt/journal/v32/n10/full/nbt1014-965d.html?WT.ec_id=NBT-201410

6 FDA, *Companion Diagnostics*. Accessed via http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407297.htm

Executive Summary

The IVD Australia submission is focussed on the Inquiry's Terms of Reference (a) the timing and affordability of access for patients; and (b) the operation of the Pharmaceutical Benefits Advisory Committee and the Pharmaceutical Benefits Scheme in relation to such drugs, including the impact of delays in the approvals process for Australian patients.

For IVDs, the Medical Services Advisory Committee (MSAC) is the equivalent committee to the PBAC, and the Medical Benefits Scheme (MBS) is the equivalent to the PBS. Companion Diagnostics and their drugs are required to go through both systems for reimbursement.

Key Messages

IVD Australia's key message in this submission is that

Australians need timely and affordable access to specialised (personalised) treatments for cancer

… which in turn, relies on the timeliness and appropriateness of the reimbursement process and regulation.

Whilst Australia can be justifiably proud of its achievements in the area of Health, at present the Australian health system with its focus on hospitals and acute disease is ill-equipped to deal with the emerging challenges in health; chronic disease, increasing costs and increasing demands from a better informed population. It remains focused on numbers of doctors, hospital beds, and acute hospital funding as the measures of success in the Health sector. But hospital beds are expensive to create and expensive to maintain. Keeping people out of the acute medical system has to be one of the key goals that Australia aspires to over the next 20 years, and the use of pathology services and IVDs are essential in achieving that goal.

It has been acknowledged that over the past 20 year's growth in pathology outlays have been contained due to the investment by providers in efficiencies within the pathology sector. IVD Australia member companies have played an integral role as suppliers are enablers in achieving this result through the provision of highly automated pathology instruments coupled with world best practice in after sales support. As an example, in the 1980s, a clinical laboratory was able to analyse around 10 blood samples for creatinine - a renal function indicator in one day using quite senior clinical scientists to perform these. In 2015, a clinical laboratory can analyse >20,000 samples for creatinine in a single shift using a lot less staff with basic scientific knowledge.

IVD sponsors and manufacturers in Australia are already under significant cost pressures. It is widely acknowledged that, whilst Australia has world's best practice in its private and public pathology services, prices received by IVD suppliers are among the developed world's lowest. The increased costs confirmed from the introduction of the new TGA regulations for IVDs will add significantly to the cost of business by IVD suppliers over the next few years. Together, these margin pressures may mean that suppliers will withdraw tests from the market or not seek to introduce new tests with low reimbursement or low volume.

Reimbursement of Pathology testing to approved pathology providers (not to the IVD industry) in Australia has been subject to marked fee restraint. The schedule fee for an average pathology item of service is 4%

lower in 2008 than it was in 1988 – during this time CPI and AWE have increased by over 180%.[7] This indeed places extraordinary pressures to the Australian IVD suppliers as clinical pathology providers look at ways to increase margins and reduce costs.

Unless there is a financially viable IVD industry in Australia the world class pathology service currently provided to Australian healthcare consumers cannot be sustained. The key issues for the IVD Industry are:

- The underlying problems with reimbursement remain. These are the lack of:
  - Statistics that reflect the true use of pathology tests in Australia;
  - A straightforward methodology to allocate appropriate price to new tests;
  - A mechanism to correct longstanding, historical anomalies in reimbursement-setting;
  - Improved processes that reflect the dynamic nature of the industry; and
  - Direct payment of IVD products to the Australian sponsor (unlike medicines).

- The benefits of pathology driven diagnosis in keeping patients out of hospital are not recognised by the MBS system

  - There is no mechanism in the Australian health care system to move funds from areas where savings could be made to those areas such as pathology where the savings can be generated;
  - Lack of global and Australian data that provides legitimate detail on the impact that Pathology has on healthcare expenditure
  - Reimbursement of Pathology items on the MBS has fallen over the past 20 years as the rebates have not been increased but costs of staff and other costs in Pathology have escalated at least in line with the Consumer Price Index (CPI).

These key issues have a direct impact on medical diagnostic innovation and patient access to new diagnostic tests.

In-Vitro Diagnostics and Cancer Treatment

Genetic testing is the analysis of genes, chromosomes, or proteins to help predict the risk of disease, identify carriers (individuals who do not have the disease but have a copy of the disease gene), diagnose disease, or determine the likely course of, and treatment options for, a disease. Cytogenetics, Molecular Genetics, Cancer Genetics, Prenatal Screening, and Prenatal diagnosis are types of genetic tests that involve examining a person's genetic material, usually taken from cells in a sample of blood or tissue.

The growth of companion diagnostic genetic testing is being driven by the scientific understanding of cancer biochemical pathways and the increasing adoption of novel oncology therapies that are specific for these. Other drivers include the aging population, greater treatment options, clinical and research data supporting use of “off label” drugs for genetically similar cancers that are generally approved for a specific organ and a general move away from organ based oncology management to genetic pathway management. The increase is also related to increased survival rates and the availability of new treatment options and patients having a better understanding of their own disease and not wanting to accept “standard treatment” without the information that it is effective.

[7] *An Analysis of Pathology Test Use in Australia*, A paper by the Australian Association of Pathology Practices Inc, utilising data from the BEACH program, Family Medicine Research Centre, University of Sydney, 2008.

Companion Diagnostics in Cancer Treatment

Improvement in both throughput and cost has led to a dramatic rise in the availability of genomic and companion diagnostics.[8] Over the next several years the number of these tests is expected to rise exponentially. Research in cancer therapies now involves the creation of biological molecules that can target specific biochemical pathways. These new therapies are now dependant on the availability of an IVD test to identify the patients that will benefit from their new molecular entity. Pharmaceutical companies are now required to introduce a companion diagnostics alongside their latest gene therapy in order to improve its effectiveness or reduce unwanted side effects in specifically targeted patients. In the past, IVD tests were generally developed over several years, and pathologists and the health system could adopt new tests at a measured rate. These new IVD tests are now being developed at the time of drug discovery and must be ready when the drug is being prescribed to the patient.

Due to these advancements in IVD and genomic technology, new tests are being introduced every day, and old ones superseded. IVD Australia believes that pressure from patients and healthcare practitioners will lead to increased demands for these newer and better tests. Funding of these within the Australian context will of course require applications to be made through MSAC.

Currently there are currently a number of companion diagnostics listed on the Medicare schedule and each has had a significant impact on the outcome for cancer management, these targets and tests are critical to maintain the value, effectiveness, and efficiency of cancer treatment. They include BCR-ABL, HER2, BRAF V600, KRAS and EGRF and details of the utility of these markers is outlined separately.

These specific classes or categories of mutations are listed in the schedule for organ defined cancers, but the these genetic mutations are seen in many other cancers, additionally as the medical field delves deeper into the genetics of cancer, a greater number of mutations will needed to be identified and the complexity of the testing will increase. To maximise the benefits of new treatments, relevant tests need to be accessible to all the relevant stakeholders in a timely basis.

While the reimbursement of these genetic markers have been approved based on drug approvals for cancers that generally fall into the “most common” category, there is much debate about the application of genetic tests to assist in defining treatment options for cancers that are considered to be of “unknown” origin or rare, which collectively make up a significant part of the cancer incidence and which have limited treatment options, unless genetic characterisation is used to give meaningful and cost effective options.

Improving Cancer Survival through Targeted Therapies

Historically, our understanding of disease aetiology was predicated on observations of physiological changes and homeostatic imbalance. Over the past century this concept has been replaced with the understanding that disease causality and onset is a complex multi-component process. For example, breast cancer,

[8] The cost of gene sequencing has fallen dramatically over the 8 years since the completion of the Human Genome project. It is now possible to sequence the genome of an individual for less than $10,000 within a week, and this cost and the time required are expected to fall considerably over the next few years.

historically seen as a single disease, is now categorised into at least five distinct subtypes and it is possible that there may be many other unique molecular types, still being identified.[9]

Our endeavours to unravel the complexity of disease onset, progression, and its ensuing treatment has led to escalating healthcare costs. In turn this has had a concomitant impact on all strata of society, but particularly it has negatively affected the poor and elderly.[10]

Additionally, the intention of regulation is to safeguard consumers, however this inevitably leads to higher costs and greater efforts for manufacturers. With the implementation of regulation of IVDs in Australia, it will take IVD manufacturers years and increasingly higher investment to take an IVD to consumers.

The more regulation, the greater the impact on innovation with the result that larger investments are needed; this will have severe impact on the ability of (especially smaller) innovative companies to discover and develop biomarkers, including those used in cancer diagnosis.

Both the pharmaceutical and in-vitro diagnostic industries needs time to bring diagnostic and therapeutic research together. Regulation should leave room to develop companion diagnostics in various business models, not only co-development. Regulation to increase safety is in itself a good thing, but it is also important to provide opportunities for small innovative enterprises to enter the market safely.[11]

The Impact of Companion Diagnostics on Cancer Treatment

There is the potential for a broad impact on savings in the health system. Medical practitioners have long observed substantial variation in patient response to treatments for cancer (as well as other common conditions, such as hypertension, heart failure, depression, high cholesterol, and asthma). While there is broad variation across different diseases, it is known, anecdotally, that between 30% and 70% of all patients will fail to respond to a drug. Finding the best medication for a given patient often involves trial and error and sometimes a medical practitioner may exhaust all possibilities without finding an effective treatment. The ability to distinguish *in advance,* those patients who will benefit, from those who will incur cost and suffer side effects with no benefit, could both reduce costs and improve quality of care.[12]

Focus on Australian Issues

> *…patients living with cancer, medical professionals caring for patients living with cancer, and the medicines industry have expressed concerns about the increasing challenges in gaining timely, affordable and equitable patient access to new cancer medicines under current regulatory and reimbursement arrangements in Australia (e.g. Kefford 2012; Tillett 2013; Prostate Cancer Foundation of Australia 2013).*[13]

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9 Culbertson, A., Valentine, S. and Naylor, S. *Personalized Medicine: Technological Innovation and Patient Empowerment or Exuberant Hyperbole?* Drug Discovery World, Summer Edition: 16-31 (2007).

10 Ibid.

11 Collins, P, *Personalized Medicine: From Biomarkers to Companion Diagnostics*, Genetic Engineering & Biotechnology News, 2013. Accessed via http://www.genengnews.com/gen-articles/personalized-medicine-from-biomarkers-to-companion-diagnostics/4820/

12 Francis, G, *Personalised Medicine in Oncology*. Accessed via http://genomicsforlife.com.au/patient-caregivers/personalised-medicine

13 Deloitte Access Economics, *Access to cancer medicines in Australia,* Medicines Australia Oncology Industry Taskforce, July 2013. Accessed via http://medicinesaustralia.com.au/files/2013/07/Access-to-oncology-medicines-1707-FINALV3.pdf, p. i

The difficulties faced by the medicines industry are compounded with the addition of a companion diagnostic. Although, the development of companion diagnostics is surging across the developed world, regulation and reimbursement, in Australia, of both the pharmaceutical and diagnostic raise issues:

- In many cases the number of patients are small and developing acceptable clinical evidence and scientific validity for the diagnostic assays is difficult; and
- Despite the implementation and the promise of the new common Health Technology Assessment Access Point portal by the Department of Health specifically aimed at facilitating a more efficient handling of such technologies the approval processes between PBAC (for the drug) and MSAC (for the IVD) are still very lengthy and many times not aligned.

IVD Australia actively participated in the Review of Health Technology Assessment (HTA) undertaken jointly by the Department of Health and Ageing and the Department of Finance in 2009. IVD Australia was broadly supportive of the 16 recommendations that came out of the review and the Government's undertaking to implement 13 of them.

However, IVD Australia continues to have concerns about the implementation of the recommendations from the 2009 review and Medical Services Advisory Committee processes:

- the reforms undertaken by MSAC are not altering the speed of the process overall. In fact, we believe that the reforms have simply moved the delays in the system from the middle of the process where the assessment of the evidence was undertaken, to the front of the process where there will be lengthy delays in the Protocol Advisory Subcommittee (PASC). Hence the overall speed of assessment and recommendation of an IVD will not (and have not) change dramatically.
- reports that applications to the Pharmaceutical Advisory Committee (PAC) that involve a co-dependent technology such as an IVD are being delayed unless the IVD application is submitted at the same time as the PAC submission.
- During a co-dependant submission if the drug is delayed by PBAC then the MSAC decision is withheld even if the evaluation and recommendation has been formulated.

Even with the new process, 'the complexity and lack of responsiveness of the current system have already resulted in Australia falling behind in the adoption of medical technologies that have been well established in other countries.'[14]

Examples of currently approved IVD companion diagnostic devices

HER-2 tests to determine whether a patient may be a candidate for Herceptin (trastuzumab) therapy, which is indicated for treatment of metastatic breast cancer and gastric cancer. Herceptin lacks effectiveness in the HER-2 marker negative population, and also has the possibility of causing severe adverse effects. Therefore it is important to use an IVD companion diagnostic device to identify only those patients who could benefit from the therapy.

Diagnostic fluorescence in situ hybridisation (FISH) testing for Anaplastic Lymphoma Kinase (ALK) in advanced non-small cell lung cancer (NSCLC) to determine eligibility for crizotinib treatment. Here ALK FISH testing identifies tumours that carry the ALK rearrangement obtained from patients with advanced NSCLC.

[14] Ibid, p. xi

Cetuximab is used to treat patients with metastatic colorectal cancer (CRC). Cetuximab is a personalised medicine tailored to the genetic make-up of a patient. A patient's cancer cells must therefore be tested to see if they contain the normal ("wild-type") or a mutant form of a gene called RAS. Cetuximab is only used to treat metastatic CRC patients who have a normal RAS gene. Colorectal cancer, commonly known as colon or bowel cancer, is a cancer formed by uncontrolled cell growth in the colon or rectum (parts of the large intestine), or in the appendix. Symptoms of colorectal cancer typically include rectal bleeding and anemia, sometimes associated with weight loss and changes in bowel habits. Metastatic cancer is cancer that has spread from the place where it first started to other place(s) in the body. The symptoms and signs of metastatic colorectal cancer depend on the location of the tumour in the bowel and on where it has spread elsewhere in the body.

RAS (Kirsten RAS and Neuroblastoma RAS) mutation testing for eligibility for panitumumab treatment in previously untreated metastatic colorectal cancer patients. The RAS mutation test is a combination of genetic tests, conducted on a biopsy sample, to tell whether a tumour carries a RAS mutation(s). KRAS and NRAS are highly related members of the RAS oncogene family which have an important role in the development and continued growth of colorectal cancer. The KRAS gene is found to be mutated, or changed, in about 40% of people with colorectal cancer. The NRAS gene is found to be mutated in an additional 10-15% of patients. The other ~50% of people have a non-mutated (sometimes called "wild type") RAS genes. Widespread colorectal cancer is treated with chemotherapy and patients may receive several sequential courses of different types of chemotherapy as the disease progresses. For patients with widespread disease the prognosis is poor with only 10% of patients still alive 5 years after diagnosis.

Epidermal Growth Factor Receptor (EGFR) testing to determine eligibility for afatinib treatment in patients with locally advanced or metastatic non-small-cell lung cancer. This service is for the genetic testing of mutations in the EGFR gene in locally advanced (stage IIIB) or metastatic (stage IV) NSCLC patients to determine eligibility for treatment with the irreversible EGFR tyrosine kinase inhibitor (TKI) afatinib. Testing for EGFR gene mutations in patients with NSCLC requires collection of an appropriate sample of tumour tissue, preparation of the tissue sample and conducting the test. There are several techniques used to determine the presence of EGFR mutations in tumour tissue, including screening technologies which detect all EGFR mutations, e.g. direct DNA sequencing, or targeted technologies which detect known specific mutations. The medical service involves the use of an in-vitro diagnostic test to determine eligibility for the pharmaceutical afatinib. Lung cancer carries a significant morbidity and mortality burden. Approximately 70% of patients are diagnosed with locally advanced or metastatic disease. NSCLC is the most common type of lung cancer, comprising approximately 75% of all cases in Australia. The EGFR family of tyrosine kinases regulates many developmental, metabolic and physiological processes. The frequency of EGFR mutations has been estimated as approximately 27% in all lung cancer patients. EGFR mutations are more common in (but not exclusive to) patients who are never (or former light) smokers, patients with adenocarcinoma histology, females and Asians, but are uncommon in patients with squamous cell carcinoma histology. The high frequency of EGFR mutations in NSCLC has driven the development of EGFR TKIs. Afatinib is a novel irreversible EGFR TKI. It is proposed as a treatment option in patients who have EGFR mutations.

Testing for V600 status in patients with locally advanced or metastatic melanoma for access to appropriate therapies. BRAF V600 mutation testing for locally advanced unresectable stage III or IV melanoma to determine eligibility for access to dabrafenib (co-dependent technology). Melanoma in its advanced form has a poor prognosis. It is increasing in incidence in Australia and globally, and occurs when mutations accumulate in the melanocytes of the skin, mainly as a result of exposure to ultra-violet radiation from sunlight. When mutations accumulate they can eventually deregulate growth and cell cycle control genes, and to lead to tumour formation through proliferation and metastasis of cells.

About IVD Australia

IVD Australia is the peak body representing sponsors and manufacturers of in vitro diagnostics based in Australia.

IVD Australia was formed in July 2009 and currently represents Australian manufacturers, multi-national and local distributors of IVDs, as well as regulatory consultants working in the IVD sector. Our members currently supply products valued at over $800,000,000 per annum and they employ over 2500 staff in multinationals, local distributors, local manufacturers and exporters and regulatory consultant companies; the majority of which are SME's.