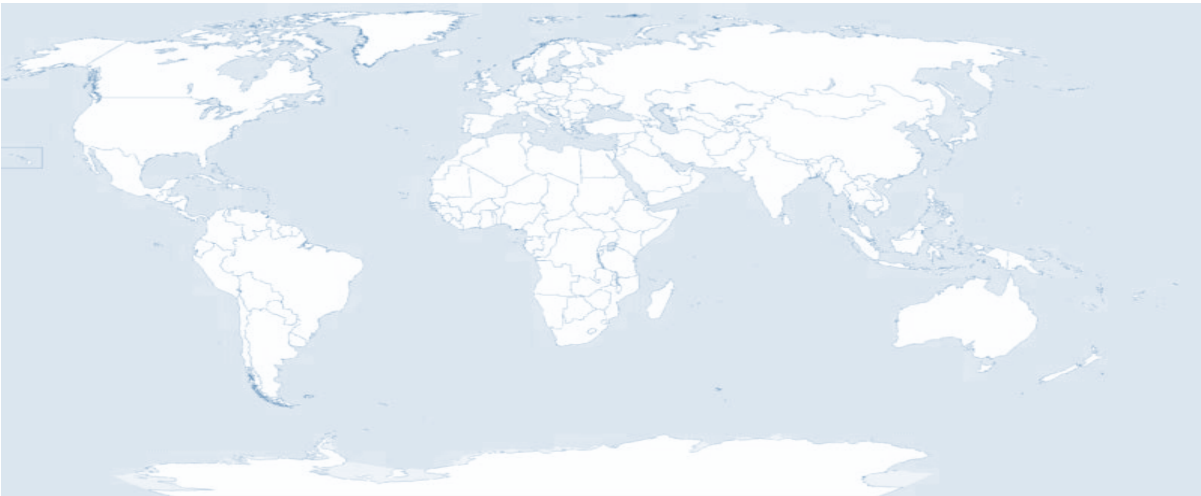
IVD AUSTRALIA

The industry where innovation saves more Australian lives



Australian In-Vitro Diagnostic Market Report 2014

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DISCLAIMER

While IVD Australia undertakes to provide reliable analysis and believes the material it presents is accurate, it will not be liable for any party acting on such information.

IVD Australia

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

Australia's leading pathology laboratory supply companies formed *IVD Australia* in July 2009 and we currently represent Australian manufacturers, multi-national and local distributors of Pathology tests, as well as regulatory consultants working in the IVD sector. Our members currently supply products valued at over AUD 1.2 billion per annum and employ over 3,000 staff in multinationals, local distributors, local manufacturers, exporters and regulatory consultant companies; many of which are SMEs.

In-vitro Diagnostic Tests

In vitro, literally 'in glass', diagnostics (also called diagnostic tests, Pathology tests) 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.

Diagnostic tests using Pathology tests, are performed in laboratories, hospitals, doctors' offices, clinics, in 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.

The Importance of Pathology tests to Australian Healthcare

Pathology tests are a key contributor to the Australian healthcare system, powering medical discoveries and transforming patient care. These tests are performed on samples taken from the body and are used in a broad range of applications. Diagnostic tests provide critical insights at every stage of medical care – prevention, detection, diagnosis, treatment and successful management of health conditions. Diagnostic 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.

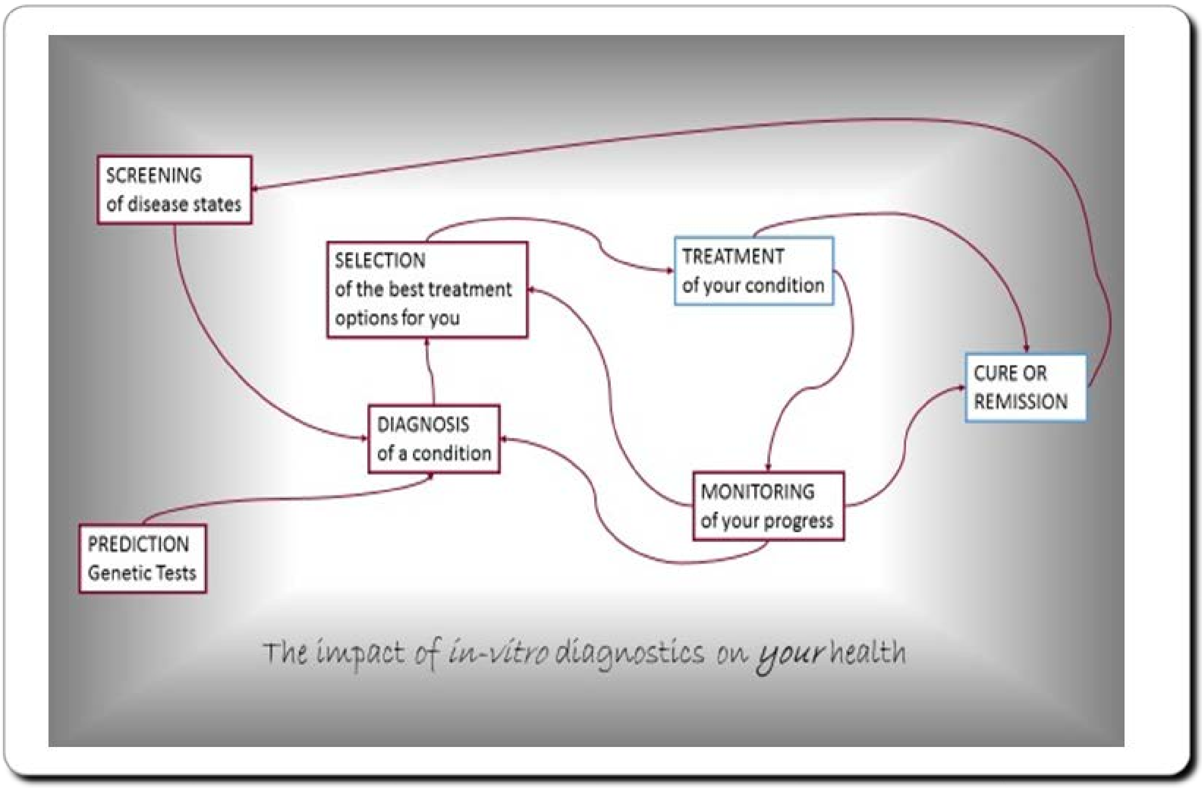
Whilst Australia can be justifiably proud of its achievements in the area of Health, at present the Australian health system with its focus on hospitals and acute disease is ill-equipped to deal with the emerging challenges in health; chronic disease, increasing costs and increasing demands from a better informed population. It remains focused on numbers of doctors, hospital beds, and acute hospital funding as the measures of success in the Health sector. However, 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 tests are essential in achieving that goal.

Diagnostics: A vital Australian Industry of Importance to everyone…

More than 60% of all Australians have used pathology testing in the past 12 months;

140,000 Australians a day rely on pathology

The Importance of Pathology tests to Your Healthcare



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. These tests make a significant contribution to the management of disease.

The IVD Industry is the R & D of Pathology

Diagnostic suppliers (IVD companies) provide the equipment, reagents and technical services to support the pathology providers across Australia.

These companies develop innovative solutions and reagents to meet the changing demands and often drive the disruption that has ensured pathology continues to deliver value to the healthcare system in Australia.

Early diagnosis of disease leads to improved healthcare outcomes and IVD companies are continuously improving the timeliness and accuracy of results in a rapidly evolving health landscape.

IVD companies are driving responsive, customer-centric solutions improving health outcomes through the focus on personalised medicine: stimulating the tailoring of existing drug therapies to individual patients and identifying patient populations that would likely benefit from drug treatment.

Technological advances and automation have made tests easier to use, more accurate, and have led to more precise and more timely reports. These advances have led to point of care tests that facilitate more rapid decision-making by medical practitioners. 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 needs, transforming modern medicine.

From the genetic tests that inform 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.

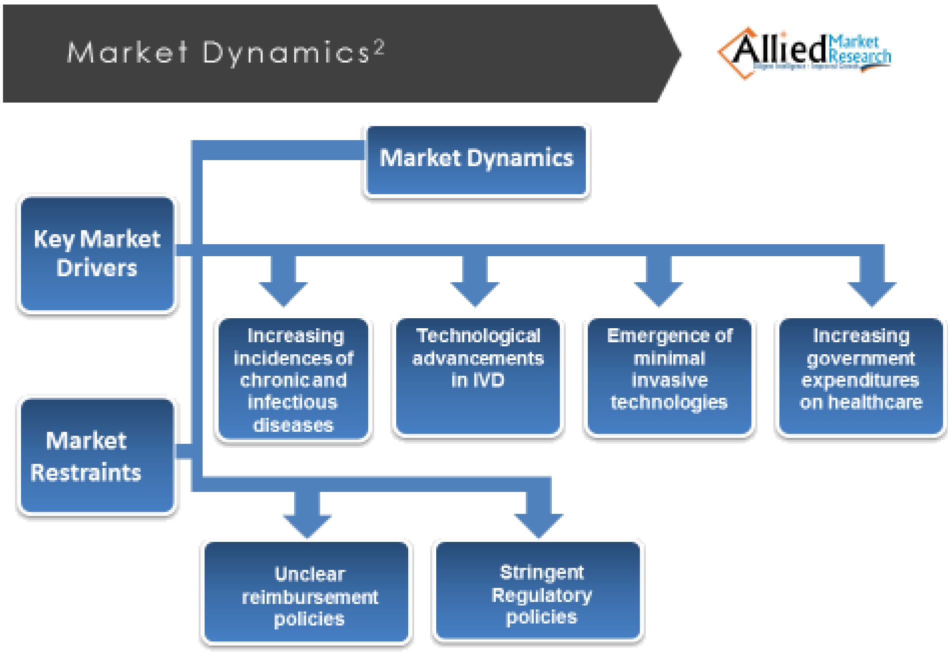
Companion diagnostics are an emerging area of IVD use receiving a lot of attention. Companion diagnostics are Pathology tests that provide information about genomic and proteomic characteristics to help inform use of a specific drug or therapy.

The Global IVD Industry

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. The IVD industry is the R&D of pathology and drives both efficiency and diagnostic tests that are relevant and impactful on healthcare outcomes.

The IVD global market revenue was estimated at approximately AUD 76 billion in 2013 and with a compound annual growth rate (CAGR) of 5.34%, by 2020 this will be in the vicinity of AUD 107 billion.

The European IVD industry is a market worth around AUD 17 billion. The US diagnostics market was about AUD 34 billion in 2014, with a forecasted growth rate of 5.8% over the following five years. Geographically, North America accounted for the largest share of approximately 43% of the IVD market in 2014, followed by Europe, Asia-Pacific, and the Rest of the World.[1]



[1] MarketsandMarkets, *In Vitro Diagnostics (IVD) Market by Product (instruments, Reagents, Software, Service) Technology (Immunoassay, Clinical Chemistry, Molecular Diagnostics, Hematology) by Application (Diabetes, Cancer, Cardiology, Autoimmune Diseases) - Forecast to 2020*, July 2015, accessed from http://www.marketsandmarkets.com/Market-Reports/ivd-in-vitro-diagnostics-market-703.html.

[2] 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, Accessed 9 January 2014.

The Australian IVD Industry

There are more than 2,280 different diagnostic tests currently included on the Australian Register of Therapeutic Goods (ARTG) today and, in 2013-2014 alone, in excess of 126 million pathology services were delivered in Australia by private laboratories alone. Supply of Pathology tests in Australia is regulated for the Government by the Therapeutic Goods Administration (TGA).

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 Pathology tests in the world.

Of the approximately 520 million diagnostic tests performed each year[3], approximately

- 330 million tests are performed in private pathology laboratories; and
- 190 million tests are performed in public pathology laboratories.
- In 2014-15, the Commonwealth Government funded AUD 2.55 billion for 80 million pathology tests. This excludes public sector testing on public patients in hospitals and tests that are not reimbursed under Medicare due to coning rules.[4]
- Industry estimates that up to as many as 75 per cent of pathology test requests are coned out and therefore not paid for, or recorded by, the MBS, and more than 90 million tests are reimbursed in public pathology each year.

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[3] IVD Australia, 2016.

[4] Coning places the upper limit on the number of claimable services under the MBS. Where GPs order four or more tests, costs are generally absorbed by the pathology practice. The AAPP estimates $200 million in test costs is absorbed by pathology practices each year. Department of Health, *Pathology Questions and Answer* http://www.health.gov.au/internet/main/publishing.nsf/Content/pathqa Pathology Australia *Pathology in Australia* http://www.pathologyaustralia.com.au/wp-content/uploads/2015/09/141105_ref_Pathology-in-Australia.pdf p. 3. Accessed 25 September 2015

International Market Statistics Data Collection

Developed by European Diagnostic Manufacturers Association (EDMA), the **Global Diagnostic Market Statistics (GDMS)** programme provides a comprehensive overview of the latest market trends.

EDMA is an international, non-profit organisation representing the interests of the medical in vitro diagnostics industry in Europe. Its mission is to promote the value of Pathology tests in delivering sustainable and effective public health systems, and provide technical, regulatory and market research information to its members. The European IVD industry is a market worth around AUD 17 billion. Driven by research and development, 95% of the industry is comprised of small and medium size enterprises and approximately AUD 1.6 billion per year is reinvested in R&D. EDMA is a member of MedTech Europe, an alliance of European medical technology industry associations.[5]

For more information, visit

http://www.medtecheurope.org/industry-themes/topic/113

5 EDMA, *European IVD Market Report 2014*, http://www.medtecheurope.org/sites/default/files/resource_items/files/European%20IVD%20Market%20Report%202014.pdf, p. 18

Australia Market Statistics Survey 2014

TOTAL MARKET SIZE

In 2014 Australia was AUD 1.16 billion with a (C)AGR of 7.2%.

Some 58% of IVD Head Offices are located in NSW, 30% in Victoria, 10% in Queensland and only 2% in the rest of Australia.

With over 3,000 employees across 60+ companies, IVD companies are an integral component of the **Pathology value chain**.

Table 2: **IVDs dominate the Medical Devices Industry**

WW Medtech Sales by EvaluateMedTech Device Area: Top 15 Categories & Total Market (2013/20) [6]

		WW Sales ($bn)		CAGR	WW Market Share			Rank
	Device Area	2013	2020	% Growth	2013	2020	Chg. (+/-)	Chg. (+/-)
1	In Vitro Diagnostics (IVD)	47.4	71.6	+6.1%	13.0%	14.0%	+0.9pp	-

		WW Sales ($bn)		CAGR	WW Market Share			Rank
	Device Area	2013	2020	% Growth	2013	2020	Chg. (+/-)	Chg. (+/-)
1	In Vitro Diagnostics (IVD)	47.4	71.6	+6.1%	13.0%	14.0%	+0.9pp	-
2	Cardiology	39.9	57.3	+5.3%	11.0%	11.2%	+0.2pp	-
3	Diagnostic Imaging	35.5	47.0	+4.1%	9.8%	9.1%	-0.6pp	-
4	Orthopedics	33.8	45.9	+4.5%	9.3%	8.9%	-0.4pp	-
5	Ophthalmics	24.5	37.7	+6.3%	6.7%	7.3%	+0.6pp	-
6	General & Plastic Surgery	19.1	26.7	+4.9%	5.3%	5.2%	-0.1pp	-
7	Drug Delivery	17.8	23.5	+4.1%	4.9%	4.6%	-0.3pp	-
8	Endoscopy	15.9	23.2	+5.5%	4.4%	4.5%	+0.1pp	-
9	Dental	12.5	18.0	+5.3%	3.4%	3.5%	+0.1pp	-
10	Diabetic Care	11.9	16.4	+4.7%	3.3%	3.2%	-0.1pp	+1
11	Wound Management	12.0	16.0	+4.2%	3.3%	3.1%	-0.2pp	-1
12	Nephrology	11.1	14.9	+4.3%	3.0%	2.9%	-0.1pp	-
13	General Hospital & Healthcare	8.3	10.8	+4.0%	2.3%	2.1%	-0.2pp	-
14	Ear, Nose & Throat (ENT)	7.2	10.8	+6.1%	2.0%	2.1%	+0.1pp	-
15	Neurology	6.1	9.8	+7.1%	1.7%	1.9%	+0.2pp	+2
	Top 15	303.0	429.7	+5.1%	83.3%	83.7%	+0.4pp	
	Other	60.7	83.8	+4.7%	16.7%	16.3%	-0.4pp	
	Total WW Medtech Sales	363.8	513.5	+5.0%	100.0%	100.0%		

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6 Evaluate Ltd, *EvaluateMedTech World Preview 2014, Outlook to 2020 – The Future of Medtech*, accessed from https://www.evaluategroup.com/public/Reports/EvaluateMedTech-World-Preview-2014.aspx.

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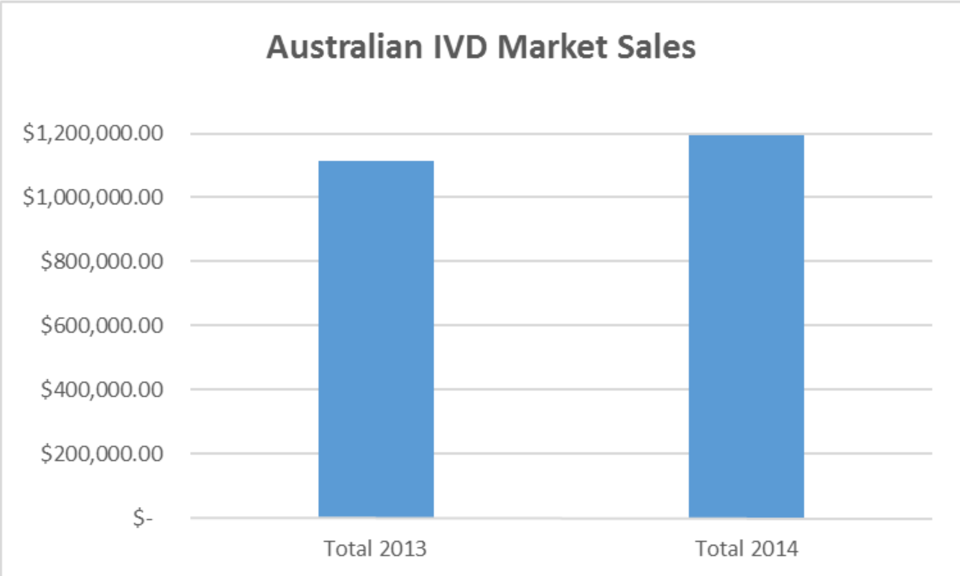
The IVD Industry is extrapolated to have AUD 1.196 billion sales in 2014, up from 1.116 in 2013, with a (C)AGR of 7.17% [7].



"Our best estimate of the number of tests done in Australia currently stands at about 520 million per year (2015)."

Source: IVD Australia, 2016

[7] This Inaugural report covers 2013 – 2014 calendar years.

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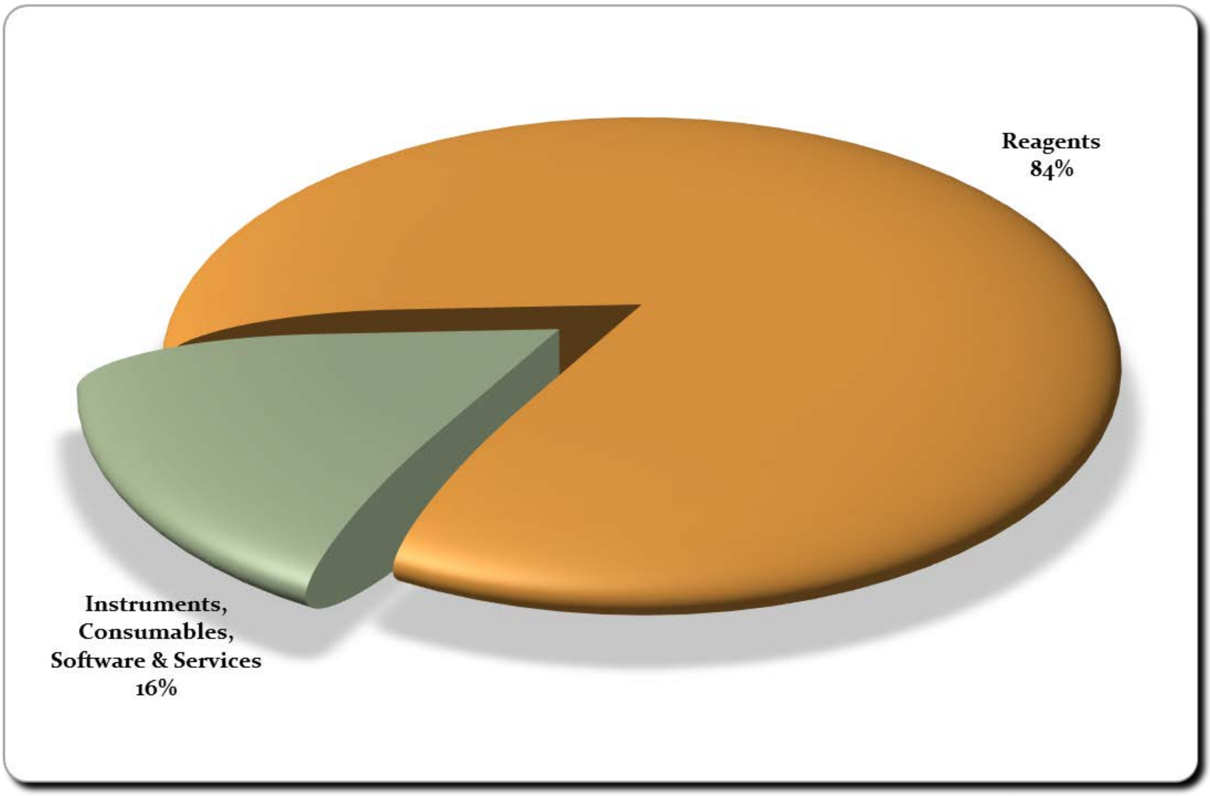
INSTRUMENTS, CONSUMABLES, SOFTWARE & SERVICES

These figures remained static over 2013 – 2014, with 0.16% growth in the category *Instruments, Consumables, Software & Services* and 0.16% decrease in the category *Reagents*.



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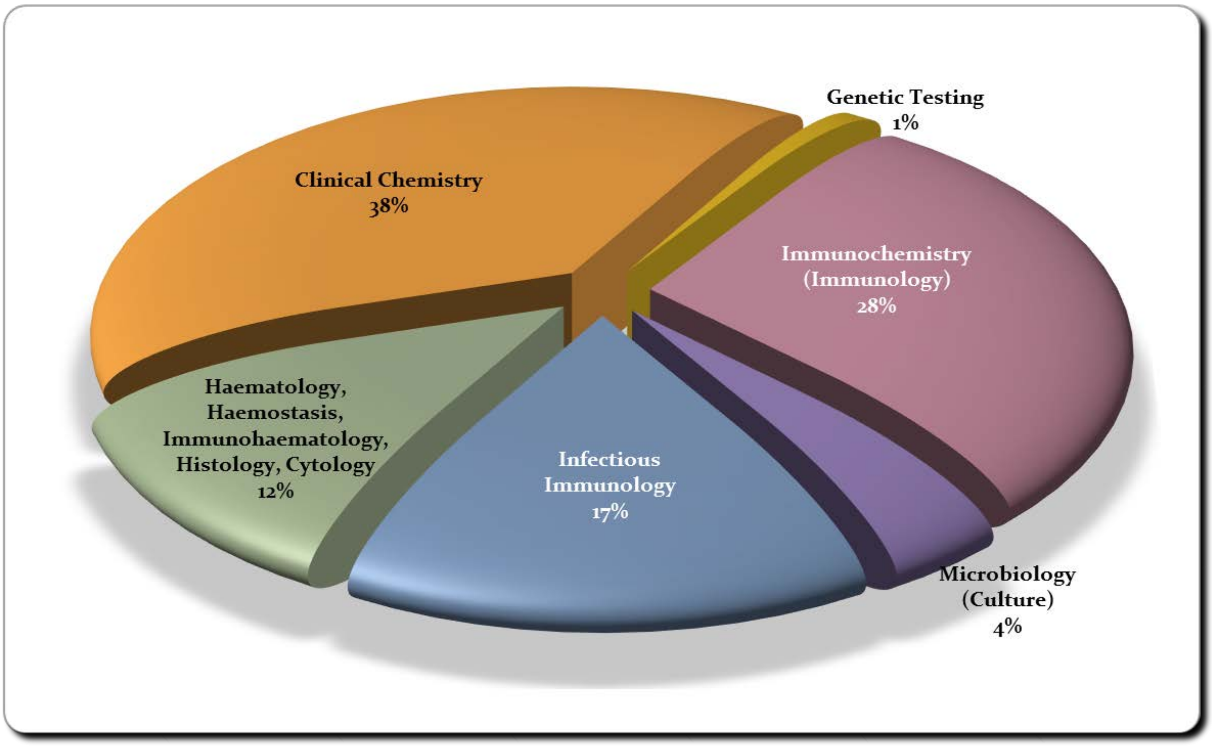
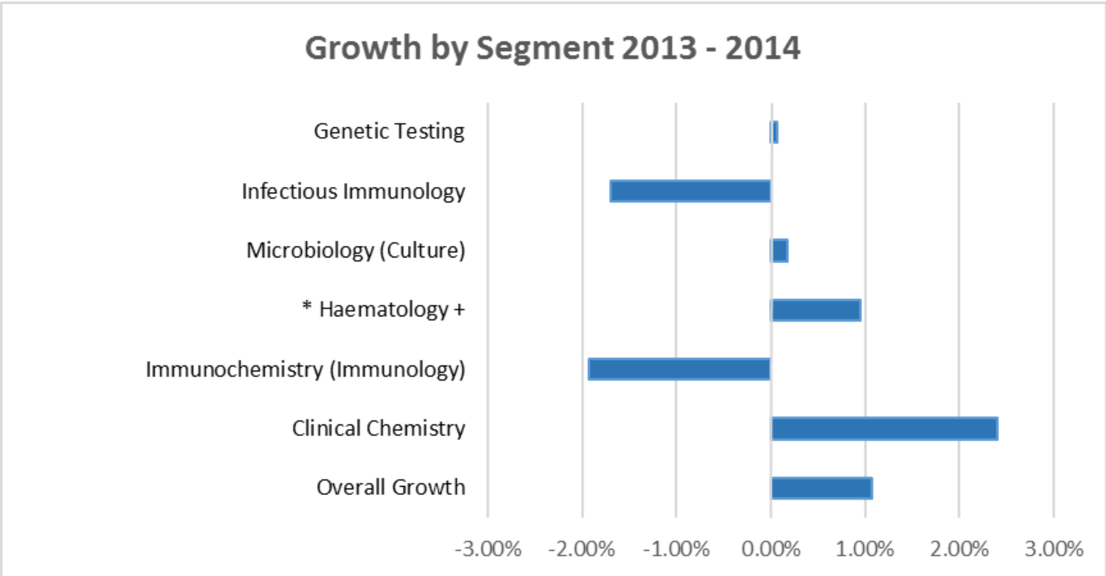
REAGENTS





* Haematology / Haemostasis / Immunohaematology / Histology / Cytology

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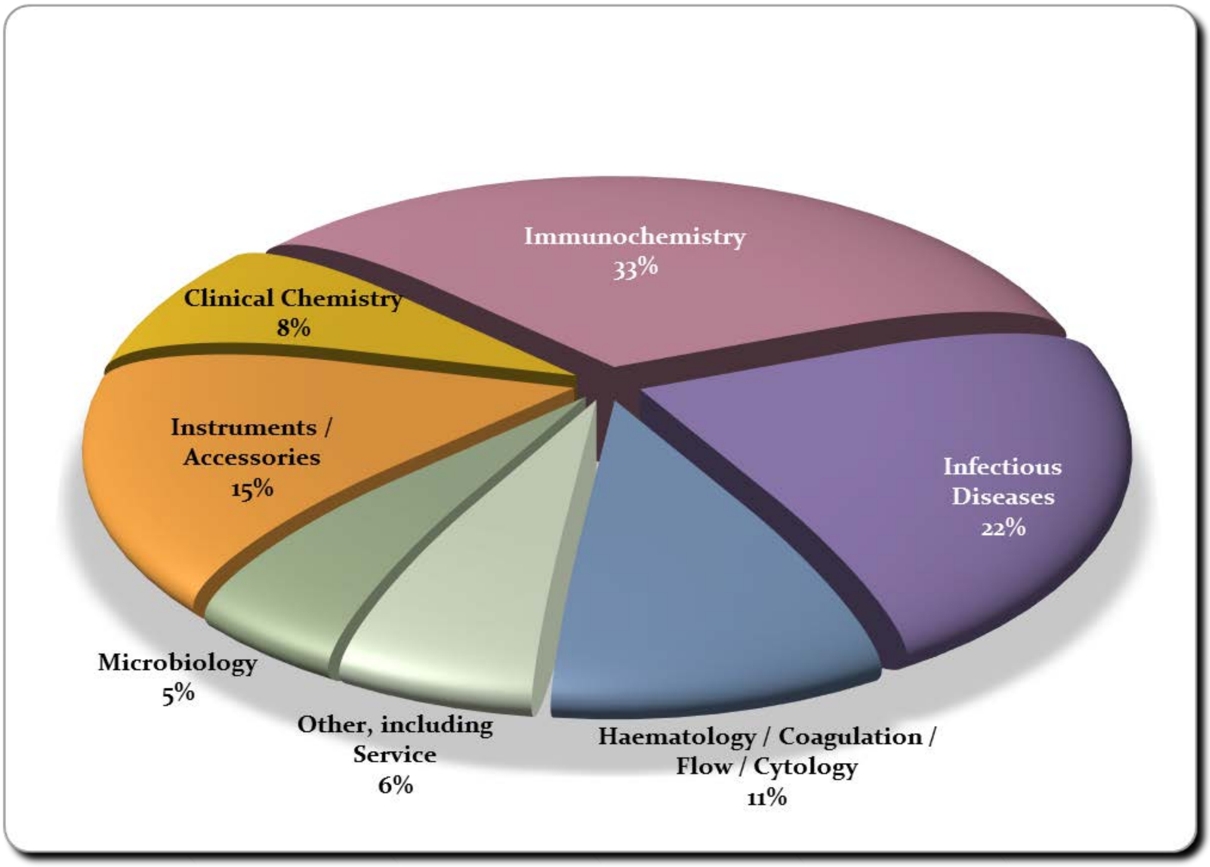
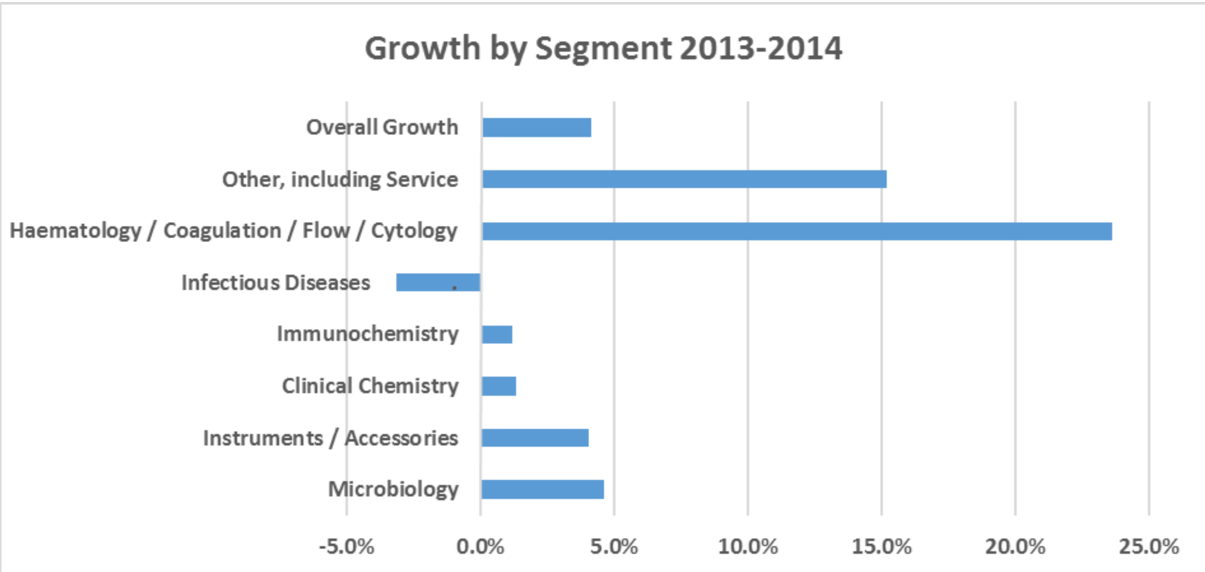
LABORATORY (excluding Rapid Testing)





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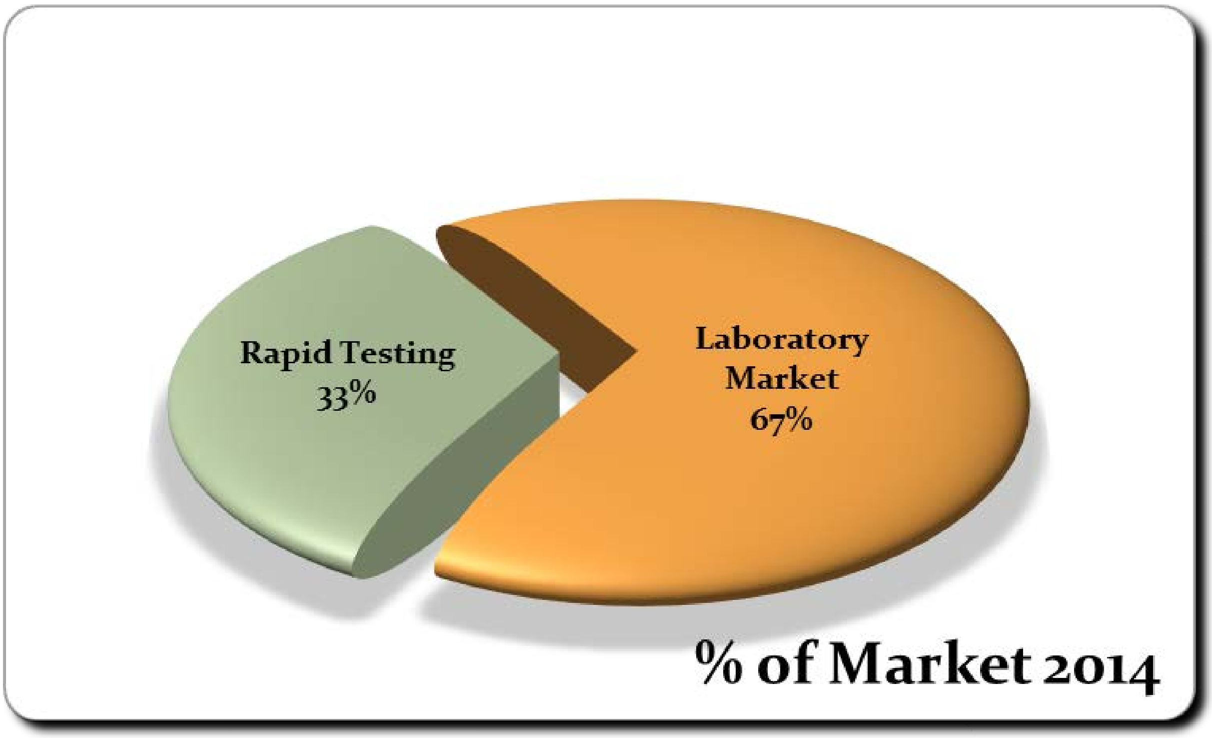
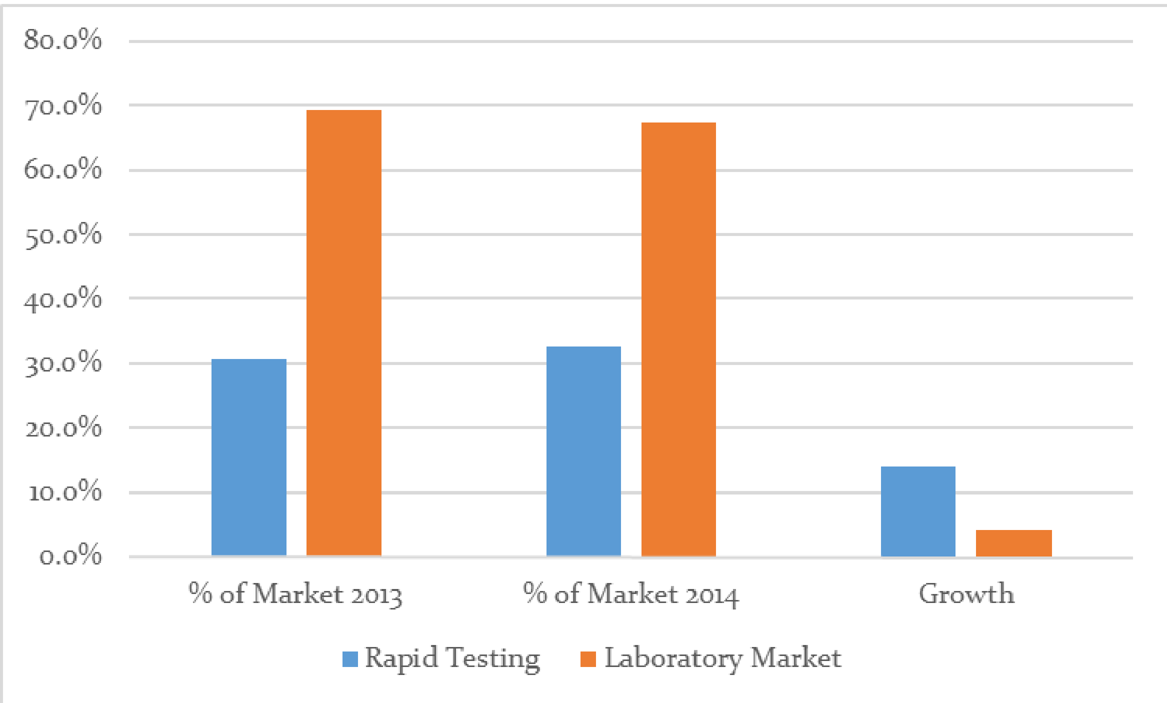
RAPID TESTING (including Point of Care)





IVD Australia

is a founding member of Pathology Awareness Australia, a group that represents interests across the entire field of pathology in Australia. This body is conducting the Know Pathology, Know Healthcare Campaign on behalf of public pathology laboratories, private pathology companies, pathology professionals and manufacturers and suppliers to industry.