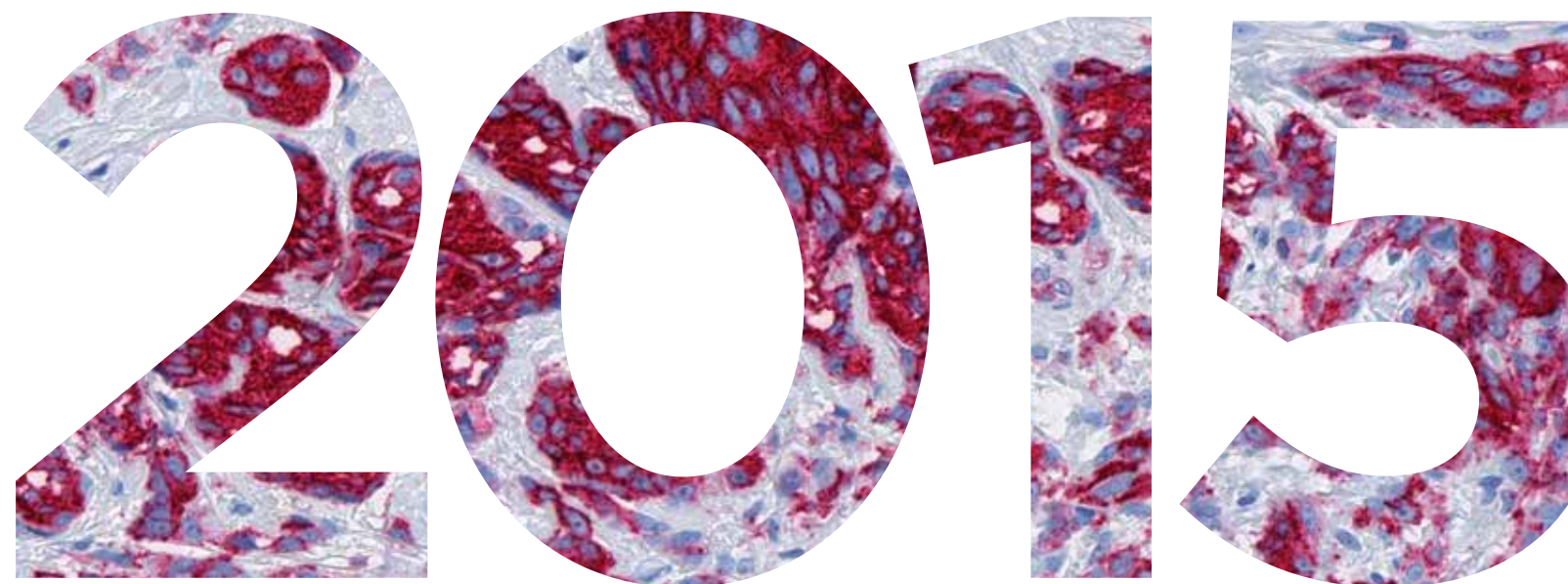


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ANNUAL REPORT



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IVD OVERVIEW

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

In vitro, literally “in glass” diagnostics (IVDs) comprise the instruments and reagents that are used to perform pathology tests requested by GPs, specialist physicians and other healthcare professionals. These tests are generally performed in accredited public and private pathology laboratories across Australia, but IVDs also include over-the-counter tests such as blood glucose meters for diabetes testing, home pregnancy test kits and other point-of-care tests. Supply of these products is regulated for the Government by the Therapeutic Goods Administration (TGA).

These tests influence over 70% of the medical decisions taken in respect of a patient's health and often comprise over 75% of a patient's health record. However they generally represent less than 15% of a patient's overall healthcare expenditure.

IVD Australia was formed in July 2009 and currently represents multinational companies, local distributors and Australian manufacturers of IVDs. Our members supply products valued at over 1.2 billion dollars per annum and they employ 2000 people across Australia.

IVD Australia seeks to develop an environment that progresses member companies' prosperity and delivers greater healthcare benefits to the Australian community.

CHAIRMAN'S

REPORT



The end of the 2015 fiscal year marks the close of the sixth year of operations of IVD Australia Ltd.

I will briefly touch on the key focal points for the Board of IVD Australia over the last twelve months.

The New CEO

One of the key roles of any Board is the appointment of the Chief Executive Officer (CEO). At this time last year, we farewelled Dr Peter Harman as our outgoing CEO and welcomed Dr Wendy-Jane Morrow as the incoming CEO. Twelve months on and I am happy and somewhat relieved to report that the Board is pleased with the performance of Wendy-Jane. As I mentioned last year, following Peter was never going to be easy, but Wendy-Jane has done an excellent job in transitioning to our industry and I am confident that we will see an even greater contribution now she has come to grips with our sector.

The Challenge for Recognition

Several years ago IVD Australia lead the formation of Pathology Awareness Australia Limited (PAAL), as a stakeholder group with the goal of improving the recognition of the value of pathology in the overall healthcare picture. Our contribution to funding and leadership of PAAL continues to be a priority for IVD Australia with our Vice-Chair John Crothers working as the Chair of PAAL and our CEO Wendy-Jane on the PAAL Board and our Executive Assistant Chami providing administrative support.

A Revised Strategic Plan

In late 2014 the Board and the CEO set about defining our Strategic Plan for the next three years. From this session emerged the revised Strategic Plan with the overall objective being the "future-proofing of the Australian IVD industry". We believe that we have identified the key activities that we must undertake in order to facilitate greater awareness of our sector, a favourable regulatory and political environment and the tools we need to promote a robust and profitable IVD industry. Of course there is only so much that we can achieve

with limited resources and to this end, your board has once again tried to balance our capacity to deliver positive outcomes for our industry with the fees we charge members. This topic is always very high on the Board's agenda as we strive to deliver value for our member's investment.

Changing of the Guard

Finally, I would like to acknowledge the contribution of our secretariat (Wendy-Jane and Chami), the many committee members who do important work in their areas of expertise and of my fellow Board members. In the coming twelve months we will see significant renewal at Board level as the changes made to the constitution in 2014 to limit Director's consecutive terms on the Board take effect. Two long-standing Director's namely Paul Cray (Roche) and Mark Volling (Alere) will retire at the 2015 Annual General Meeting (AGM). I would like to acknowledge and congratulate these two individuals for their outstanding contribution to IVD Australia and especially acknowledge Paul for his role in the formation of a stand-alone IVD focused industry association.

Bruce Evans
Chairman, IVD Australia

REPORT

CEO'S



I am honoured to be writing to you in my first (and your seventh) Annual Report as CEO of IVD Australia.

Before I review IVD Australia's accomplishments over the past 12 months and our vision for the next 12, I would like to say thank you all for your warm welcome, and particularly, Peter Harman, for his support as IVD Australia settled in to its new CEO.

During the past year IVD Australia has continued to evolve our strategy, and in parallel, invest in the promotion of the pathology industry to lay strong foundations for future growth. The strategic planning process was greatly facilitated by learning from members about the industry's needs and potential solutions for their concerns. Two key initiatives remain at the forefront of this strategic plan, the Know Pathology Know Healthcare campaign and the Global Diagnostic Market Statistics program.

Know Pathology Know Healthcare - More than words: the Value of our Industry

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. The impressive growth of this initiative in the past twelve

months has seen collection centre involvement grow to this is involvement of over 80% of all centres in Australia, and some sixteen laboratory tours with politicians across public and private laboratories have been conducted – all raising consumer and government awareness of the vital pathology industry in Australia.

Global Diagnostic Market Statistics - Quantifying Australia's Place in International Trade

A key goal of IVD Australia is to 'drive industry development'. One of the ways in which we can focus better government attention and initiatives for our industry is to be able to quantify our contribution to the Australian economy. However, we can't achieve this without knowing the size of the Australian industry. The Global Diagnostic Market Statistics (GDMS) project being supported by IVD Australia is focused on determining a substantiated figure on the size of the Australian market. The IVD Industry in Australia needs this figure to underline its approaches to government for improved reimbursement and to facilitate innovation in our sector of industry.

IVD Australia is committed to funding member participation in the program. Member and industry reports were released in July, just after the end of this financial year and the industry figures will be utilised to underpin the development of projects to expand our Market Access projects. Market access is the lifeblood of our industry and is the focus of our Market Development Committee.

Industry Engagement - IVD Australia Policy, Technical Committees & Working Groups

IVD Australia fosters a sense of belonging and passion amongst our members by facilitating access to collaborative decision-making on regulatory and standards issues through a range of IVD Australia Committees and Working Groups. The work of these Committee members is pivotal in IVD Australia providing leadership in its regulatory and political endeavours. IVD Australia acknowledges and extends its appreciation to all committee and working group members for their dedication and hard work on behalf of industry. A full list of external and Secretariat committees and working groups is included in this report.

A focus on member engagement has seen the Committees and Working Groups continue to facilitate member ability to influence, respond to the increased demand for submissions, advance representation and ensure member positions on vital issues for the industry.

Looking Forward

It is vital to continue pushing the significant progress we have made this year and so, for the next twelve months, our key focus will be to enable significant progress in the IVD regulatory reforms, industry innovation and growth. You will also see continued focus on the branding of IVD Australia, stakeholder relationships and a growth in recognition of pathology and IVD Australia, never losing sight of the Strategic Priorities as defined by our Members.

CEO'S REPORT continued

From the strategic planning outcomes, we have also developed our Advocacy Agenda with the purpose of disseminating industry key messages, the document also being designed for the pre-election lobbying that will start in the second half of this financial year. The Agenda outlines four key areas where Government action is required in order to achieve our goal of a sustainable, vibrant, industry where innovation saves more Australian lives.

The definition of Advocacy is... a political process by which a group aims to influence public-policy and resource allocation decisions within political, economic, and social systems. It can include many activities that an organisation undertakes including media campaigns, public speaking, commissioning and publishing research. The IVD Australia Advocacy Agenda aims to:

- > Question the way policy is administered
- > Participate in the agenda setting by raising significant issues
- > Pave the way to propose policy solutions

The strategic framework described in the IVD Australia Advocacy Agenda provides a statement of commitment to the provision of a coherent, synergistic approach to sustainable growth in the in-vitro diagnostic Industry in Australia. To achieve its goal of an innovative, vibrant, compliant industry that holds its place in consumer health, the IVD industry has prioritised five areas needing action.

- Priority 1: Improving our Future Health through Innovation
- Priority 2: Health Economics and Evidence
- Priority 3: The IVD Industry is the R & D of Pathology
- Priority 4: Improving Consumer Health Now
- Priority 5: Sustainable Business Environment to Encourage Investment

Proactive government support of research, education and policy development can enable diagnostic initiatives to better consumer lives. As industry members will be aware, there are a number of barriers to growing this vital Australian industry, and our Advocacy Agenda pays particular interest in providing solutions to these barriers.

Acknowledgments

This annual report publishes our highlights and achievements. For me, it is also an opportunity to celebrate the commitment and dedication of our Committee Members in their seemingly tireless efforts. Their ongoing contribution we receive is essential to our effectiveness as an organisation. I wish to thank all of our members for their continued trust and commitment, these collective efforts make us confident that what we are doing today will make a difference.

The Board is responsible for setting the direction, strategy and financial objectives for IVD Australia. I wish to thank the Board for their support this year; they have given generously of their time, dedication, and advice, guiding our organisation towards a positive, sustainable future. The diligence and dedication of Chami, in her work for IVD Australia and Pathology Awareness, has been a contribution to our success.

Chami and I are set for another engaging year ahead and through the representation of our members, collaboration with regulators and industry stakeholders, will continue to progress development of the regulatory framework for in-vitro diagnostics. By developing submissions, industry agreed positions, and being proactive on relevant issues related to the IVD Industry, the work of the IVD Australia on behalf of industry will continue to be productive and results driven.



Dr Wendy-Jane Morrow
Chief Executive Officer



IVD AUSTRALIA BOARD

The Board of IVD Australia is elected by the membership from among the Corporate Representatives of Member Companies.

Board Members are elected for a two year term and appoint a Chair, Vice-Chair and Treasurer from among their number to serve a one year term. Current Board Members are:

Chair Mr Bruce Evans

Non-Executive Director, Abacus ALS Pty Ltd

Bruce Evans is a Director and a major shareholder of Abacus ALS Pty Ltd.

Bruce holds a Masters of Business Administration (USQ) and is a Fellow of the Australian Institute of Company Directors. He is a qualified Medical Laboratory Scientist(QUT), who commenced his career in a clinical Pathology laboratory and prior to founding his own business Abacus Diagnostics in 1998, worked in sales and marketing for what is now part of Siemens Healthcare Laboratory Diagnostics.

Bruce also holds the position of Director Asthma Foundation Queensland and was previously a Director of the Medical Technology Association of Australia (mtaa.org.au) and its predecessor, the Medical Industry Association of Australia. Through these directorships, Bruce has gained significant experience as a director in the not-for-profit sector.

Vice Chair Mr John Crothers

Regional Director, Abbott Diagnostics Pty Ltd

John Crothers is the Regional Director for Australia and New Zealand. Prior to the role in Australia, John was the Commercial Director for Asia Pacific and has also had several years in US Marketing. With over 25 years experience in the pathology industry in both the laboratory and IVD, the appreciation of the value of the industry in healthcare is a passion that John continues to pursue.

John has a BSc(MLS) from RMIT and a Graduate Diploma in Business Administration from Swinburne University.

Treasurer Mr Patrick Cook

Director, Macarthur Cook Group Pty Ltd

Patrick Cook has been in the in vitro diagnostics industry for over 30 years.

Patrick holds degrees in Applied Science, Marketing and is a Graduate of the Company Directors Course. He is a Fellow of the Australian Institute of Company Directors and has served on a number of not-for-profit boards.

Patrick worked as a medical scientist for both public and private laboratories and previously held sales & senior marketing positions at Abbott Diagnostics, Roche Diagnostics and Agen Ltd (an Australian publicly listed biotechnology manufacturer and exporter). In 1995 he established and operated his own medical devices import and distribution business. He is currently a business development consultant in biotechnology and in the medical devices area.

BOARD MEMBERS

Mr Paul Cray

Managing Director, Roche Diagnostics Australia Pty Ltd

Paul Cray is the Managing Director of Roche Diagnostics Australia Pty. Ltd. and Leadership Team member of Roche Diagnostics Asia Pacific.

Paul has over 25 years experience in the in vitro diagnostics industry, undertaking numerous overseas roles with increasing sales, marketing strategy and general management responsibility in the UK, Canada, USA, Switzerland and Germany. The most recent post was that of Senior Vice President, Global Marketing, Roche Diagnostics.

Paul holds a Bachelor of Science degree from University College of Wales, UK, and has undertaken numerous post graduate and executive courses at INSEAD, France, IMD, Switzerland and more recently Mt Eliza Advanced Management Programme, Melbourne Business School. Paul is a Member of the Australian Institute of Company Directors.

Ms Holly Simmonds

Managing Director, Hologic (Australia) Pty Ltd
Resigned from Board October 2014

Holly Simmonds has worked in many aspects of the medical industry for the past 35 years, predominately in women's health.

In addition to 12 years as a Clinical nurse specialist in gynaecology oncology at RPAH, Holly has been employed in the medical industry since 1989 by

Imed and Valleylab in sales, Autosuture, Tyco in management, N.Stenning & Co as a product manager and Conceptus as a Managing Director and now the past 6 years with Hologic ANZ as the Managing Director.

Holly worked for a year on a world bank project in Java, Indonesia as an English teacher and remains very interested in the developments of women's health initiatives in Indonesia.

Mr Mark Volling

Regional Managing Director, Alere Pty Ltd

Mark has over 25 years experience within the Australian IVD industry including senior roles within global companies (Alere/Inverness Medical, Dade Behring), local manufacturing and export organisations (Alere/Panbio, Agen Biomedical) and distributor only organisations (In Vitro Technologies). He possesses an Associate Diploma in Clinical Laboratory Techniques (QIT), a Bachelor of Business in Finance/Accounting (USQ), a Graduate Certificate in Management (USQ) and a Masters of Technology Management (UQ)

Mr Simon Pratt

Division Manager, Clinical Diagnostic group - Pacific Region, Bio-Rad Laboratories

Simon Pratt registered as a medical scientist in NZ and has post graduate qualifications in business and human resources. He has held business development and sales management roles within Europe, during a seven year period in the UK, and was an early company representative with BIVDA during the start-up phase.

IVD AUSTRALIA BOARD continued

Currently, Simon is the Diagnostics Divisional Manager at Bio-Rad Laboratories, with ANZ sales and marketing responsibilities, a role which he has held for the last 5 years.

Mr Sebastian D'Angelo

Vice President, Diagnostics Division, Healthcare Sector, Siemens Ltd, Pacific Region.

Sebastian has over 30 years experience within the Australian IVD industry, having worked as a medical scientist in public pathology laboratories before moving to senior roles at Chiron Diagnostics and Bayer Diagnostics and now at Siemens Healthcare Diagnostics.

Sebastian holds a Bachelor of Applied Science (MLS) degree from RMIT University and a Master of Marketing degree from the Melbourne Business School. He is a Member of the Australian Institute of Company Directors.

Mr Kirk Kimler

President and General Manager ANZ.
Thermo Fisher Scientific

Mr Kirk Kimler has been with Thermo Fisher Scientific since 2013 and is currently the President of the Australia / New Zealand and Korean operations.

He manages an organisation of over 1000 employees who proudly serve the life science, healthcare and environmental/industrial process markets. Prior to his current role, Kirk was President of the Anatomical Pathology Division, a global manufacturing and commercial operation that provides cancer diagnostic products.

He was also President of Fisher HealthCare, (became a division of Thermo Fisher Scientific in 2006). During his tenure, Kirk also served as President of Athena Diagnostics, an esoteric neurological reference lab business that was successfully divested to Quest Diagnostics in 2011.

Prior to his positions at Thermo Fisher Scientific, Kirk held a variety of senior leadership roles at Ventana Medical Systems and Abbott Diagnostics, a Division of Abbott Laboratories. He served four years in the US Army as an officer before pursuing his business career. Kirk holds his undergraduate degree from the University of Notre Dame and a MBA from the University of Chicago. He holds several diagnostic patents and has served on two not-for-profit Boards.

Mr Tristan Duggan

Managing Director, Diagnostic Solutions Pty Ltd

Tristan has over 15 years' experience in the healthcare industry having worked in both large multinational corporate environments as well as independent distribution organisations. Tristan possesses a Bachelor of Business Management and his career roles have varied across sales, marketing, operations and management. Diagnostic Solutions is owned by Diploma Healthcare who also own Big Green Surgical and both companies operate in Australia and New Zealand.

CODE ADMINISTRATION COMMITTEE

As foreshadowed in last year's report, over the past year the Code Administration Committee (CAC) has been investigating new ways of assisting members to ensure that all staff engaged in Code-related activities are fully conversant with the requirements of the Code.

At its August 2014 meeting, the Board gave "in principle" support to a proposal from the CAC for a program to certify member companies' adoption of the Code, based on that developed by the Medical Technology Association of New Zealand (MTANZ). Following further development by CAC, members of the Board trialed the Code Certification Program in their own companies and I am pleased to report that the Program will shortly be introduced to all members.

The IVD Australia Code Certification Program (the Program) is a means by which members confirm that their company complies with the Code and has established mechanisms for ensuring compliance. The Program includes a Certification Form for completion by the company's IVD

Australia Member Representative to confirm that their company has established robust in-house compliance mechanisms and that comprehensive training has been provided to those employees who are engaged in Code-related activities. A brief PowerPoint presentation has been developed to assist companies with training. The presentation is suitable to use, for example, during staff training meetings.

CAC understands that some companies, particularly larger multinational companies, have internal Codes which may be significantly more onerous than the IVD Australia Code. The Code states that it "...is not intended ... to override the provisions of any internal code, should that mandate a higher level of performance or a stricter code of behaviour." Therefore, companies that are bound by an internal code that is stricter than the IVD Australia Code should have no difficulty in meeting the requirements of the Program.

CAC looks forward to obtaining member feedback on the Code Certification Program in the coming year.

Pam Davis
Chairman, Code Administration Committee

COMMITTEE MEMBERSHIP CODE OF CONDUCT ADMINISTRATION COMMITTEE

Pam Davis - Chair
North Shore Heart Research Foundation

Ross Brown
Institute of Haematology RPAH
Representing AIMS

Graham Bullman
Siemens Ltd. Australia and New Zealand
Healthcare Sector
Representing IVD Australia

Peter Graham
Representing AACB

George Koumantakis
Roche Diagnostics
Representing IVD Australia

Helen Mikolaj
Consumer representative

Bev Rowbotham
Representing RCPA

Melita Lambiris
Elitech Group P/L
Representing IVD Australia

Sepehr Tabrizi
Dept Microbiology & Infectious
Diseases Royal Melbourne Hospital
Representing NCOPP

TECHNICAL & REGULATORY STANDING COMMITTEE REPORT

Well, we’ve made it!! The transition period for compliance to the TGA Regulations for commercial IVDs has come to a close.

IVD Australia members are to be congratulated on the relative smoothness of the transition. While there were some spikes in submission rates at key time points for the most part it was a steady stream to the end. Well done everyone!

As I reflect back over the last 5 years the work of the TARSC committee has been extraordinary. Just some of the significant changes that TARSC has seen introduced are:

- Extension of the transition period for commercial IVDs changed from 4 years to 5 years, with in-house IVDs given until 2017 to comply
- Annual fees set to zero until 2017
- Local performance testing for Class 4 IVDs will not be included in pre-market assessments
- Class 4 in-house IVD assessments changed from TGA conformity assessments to a mandatory application audit on submission of an application for inclusion in the ARTG
- TGA Conformity Assessment certification no longer mandatory for Australian manufacturers
- HIV self-testing assays now allowed to be registered and supplied
- Proposed removal of the NNDSS as a criteria for classification of IVDs

In line with its policy of reducing regulatory burden, the Australian Government undertook a Review of Medicines and Medical Devices in late 2014. IVD Australia was specifically asked to meet the Review Panel to discuss the impact of the TGA Regulations on IVDs. Self-testing for HIV was of particular interest to the Panel in this meeting. With the release of the report to the government in March 2015, TARSC awaits further outcomes from the recommendations at the time of writing.

2015 has seen TARSC, along with all other Medical Device associations, push for better guidance around significant changes to TGA Conformity Assessment and changes to ARTG entries. While the guidance documents have not yet been published by TGA, much progress has been made. TARSC provided TGA with advice on re-classification of assays impacted by the removal of the NNDSS from the classification rules. TARSC has been contributing to TGA Business Improvement programs, the first of which is looking at the process of TGA Conformity Assessment.

In early 2015, TARSC investigated some import clearance delays and learnt the Department of Agriculture underwent a centralization of activities in late 2014 with assessors from any State reviewing import papers regardless of the entry port. Assessors are now assigned based on knowledge/experience not location.

Vendor Credentialing activities by customers using 3rd party intermediaries led to meetings between Standards Australia, MTAA, IVD Australia and other associations to address potentially onerous and costly programs being implemented for Medical Device suppliers in general.

Finally, thanks to all for their contributions in 2015. As always we welcome new members to the Technical and Regulatory Standing Committee.

COMMITTEE MEMBERSHIP THE TECHNICAL AND REGULATORY STANDING COMMITTEE

Sally Jennings - Chair Abbott Australasia P/L	Hiram Chipperfield Alere Australia P/L	Fouzia Khan Siemens	Karen McLeod MP Biomedicals
George Koumantakis Roche Diagnostics Australia P/L	Hoon Koh Siemens Healthcare	Brett Kennedy Illumina	Dario Pedulla ThermoFisher
Walter Shepherd Immuno P/L	Peter Lowe GenProbe/Hologic Inc	Kasey Kime ThermoFisher NZ	
Karen McLeod MP Biomedicals	Peter Traynor ThermoFisher Scientific ANZ P/L	Libby McDermott ESL Bio Science	
Lilies Chen BioRad Laboratories P/L	Susan Alder Minerva Medica P/L	Paul Cohen Roche	

MARKET DEVELOPMENT WORKING GROUP (MDWG) REPORT

The Market Development Working Group (MDWG) is focused on the issues that affect the development of the market for in vitro diagnostics in Australia.

This covers the availability of reimbursement for pathology testing through the Medical Benefits Schedule as well as access to the market via the MSAC process. It also covers restrictions on access due to Government and other policies.

John Emmerson, from London Agency, together with John Crothers, Chairman of the Pathology Awareness Australia, have provided much feedback on the Know Pathology, Know Healthcare Campaign. The Working Group was involved in International Pathology Day, 5 November, 2014.

The 2015-16 focus for this Committee is on Market Development Strategies, the two key mechanisms are to:

1. Increase awareness within current markets
2. Develop markets



The Working Group has identified that a critical component is **Market Intelligence**, and, is involved in ensuring the success of the Global Diagnostic Market Statistics (GDMS) and the development of a Health Economics Project.

COMMITTEE MEMBERSHIP

IVD AUSTRALIA MARKET DEVELOPMENT WORKING GROUP

Jim Kakaflikas QIAGEN (Chair)	Brooke Troth Bio-Rad	Angus Hastie Cepheid	Kathryn Humphries Alere
John Crothers Abbott Diagnostics (Board Member)	Christine Johnson Abacus ALS	Jennifer Carson Siemens	Marie James ThermoFisher

POINT OF CARE TESTING (PoCT) REPORT

If Point of Care Testing (PoCT) in Australia was given an end of year School Report Card it would probably say “has done well, but could try harder”.

This is not a reflection of the continued efforts of the IVD Australia PoCT Working Group which since 2012 has helped promote PoCT amongst Healthcare Professionals and to improve education, training and networking throughout Australia. Moreover, it is the Regulatory and Logistical obstacles placed in the way of PoCT that prevent PoCT from thriving (as it does in other Countries) and frustrates the Healthcare professionals, their patients and members Companies that are involved.

During 2014/15 the PoCT WG has continued to canvas Government bodies involved with developing guidelines for Medical Services and Diabetes Monitoring. The ultimate goal is to obtain meaningful reimbursement for all PoCT. Healthcare Professionals could then use PoCT appropriately and with the backing of their local Pathology Laboratory and Medical Device Supplier. Simplistic costing models previously used to evaluate PoCT efficacy that focus on a “Cost per test” basis must surely be updated. Our hope is to show the overall clinical and cost benefits of having a test result that the Clinician can act immediately, saving time, bed occupancy, travel, money and maybe even lives.

Once again IVD Australia is proud to announce that the PoCT WG has been invited to attend the ACRRM annual Congress in Adelaide. GP's from The Australia College of Rural and Remote Rural Medicine will have the opportunity to get hands on experience with a variety of PoCT devices and attend lectures covering aspects of PoCT including Infectious Disease testing, INR, Glucose/Ketones, HbA1c, Cardiac Markers, etc. PoCT has to be seen as a main stay of effective healthcare delivery in Australia.

Within the International PoCT community, Australia continues to develop a meaningful presence. At the recent Blood Gas & PoCT symposium in Versailles and the IFCC/EuroMedLab congress in Paris, several Australian Biochemists and PoCT specialists attended and ensured we had a voice. This included the IFCC WP that is looking into one of the hot topics at the moment of “Glucose meters in Critical Care”.

So our Report Card can now read “the PoCT WG is trying harder, and harder”.

My thanks go to all WG members for their efforts in supporting the Working Group and the IVD Secretariat in this important area for IVD Australia members.

COMMITTEE MEMBERSHIP THE PoCT COMMITTEE

Martin Roccliffe AMSL (Chair)	Daniela Symons-Troy Cepheid	Rachel Coxon Abbott	Tim Hinrichs Abbott Diagnostics
Peter Merrilees POCD	Mark Volling Alere	Robyn Smith Alere	Barry Wilson Abbott Diagnostics
Adrienne Ripley Roche	Danielle Brown HemoCue	Helen Persano BioMérieux	Adam Barrett HemoCue

FINANCE, AUDIT & RISK MANAGEMENT (FARM) REPORT

The Finance, Audit and Risk Management Committee (FARM) is a sub-committee of the Board.

It comprises three nonexecutive Directors appointed by the Board two of which must be the Board Chair and the Treasurer. In addition, the Board has approved the appointment of an external party as a fourth member of the Committee. Members are appointed for such terms as the Board may determine. Each member is expected to be financially literate. The Chief Executive Officer, also attend its meetings.

The Chairperson of the FARM Committee is a non-executive Director other than the Chairman of the Board, and the quorum for holding a meeting of the Committee is two non-executive Directors. Members are appointed by the Board of Directors, and the performance of the Committee is reviewed by the Board as part of its periodic self-evaluation process.

The Committee meets one week prior to a full Board meeting but frequency may vary according to need. The FARM meetings are held by teleconferencing. Proxy attendees are not permitted.

ROLE

The primary responsibility of the Finance Audit and Risk Management Committee is to assist the Board in its governance role of ensuring that the organisation operates effectively, efficiently, ethically and legally. It does this by setting the standards for, and monitoring:

- the quality of financial reporting and compliance with statutory and regulatory requirements, codes of conduct;

- the control and management of all financial and audit risks emanating from the operations of IVD Australia Ltd, including keeping the Board informed of effective economic liabilities;

- the ability of the Finance function to produce data and information that allow the effectiveness of the organisation's programs to be analysed both operationally and strategically by Management;

- the effective management of the organisation's finances and investments, including initiatives that enhance the fund-raising capacity of the organisation;

- the effectiveness of risk management policies and procedures; and

- the work of Internal and External Auditors.

It also:

- recommends to the Board the appointment and where appropriate the replacement of the external auditors;

- approves audit plans and reviews audit reports; and

- reviews capital expenditure proposals which fall outside the delegated authority of the Chief Executive Officer, and makes recommendations

REPORTING

The Committee is accountable to the Board of Directors. The Chairperson of the Committee reports to the Board Meeting following a meeting of the Committee on the matters discussed and makes any recommendations to the Board which have been agreed by the Committee. Detailed minutes

are recorded for each meeting and are available to the Board for review as required.

The Committee does not have the authority to commit the Board or management to the implementation of any of its recommendations except where such authority is specifically delegated to it by the Board.

OPERATING PROCEDURES

In discharging its responsibilities the Committee meets on a regular basis to consider various matters.

a) Financial Reporting

The Committee makes recommendations to the Board on the acceptance of, or amendments to, the Annual Accounts as a result of the annual review carried out with management and the external auditors.

b) Financial and Investment Management

The Committee monitors the financial performance of the IVD Australia Ltd during the year both against budget and by reviewing key performance drivers.

c) Audit Management

The Committee acts as the conduit between the Board of Directors and the external auditors. As well, the Committee makes recommendations to the Board from time to time on internal audit arrangements and the use of outside internal audit expertise.

d) Risk Management

The Committee assesses periodically and reports at least annually to the Board on the internal processes and controls for determining, managing and mitigating key financial and operational risk areas

e) Business Policies and Practices

The Committee reviews Company policies as they relate to financial, investment and audit matters from time to time and recommends acceptance or changes to the Board in line with legislative requirements and business needs. In so doing it may draw upon expert external assistance where necessary.

f) Other Matters

The Board may require the Committee to examine specific issues which are outside its normal terms of reference. The Committee may also identify specific issues and recommend to the Board that it be authorised to consider them.

COMMITTEE MEMBERSHIP FARM COMMITTEE

Patrick Cook
Macarthur Cook (Chair)

Bruce Evans
Abacus ALS

Mark Laubscher
Abacus ALS

Tristan Duggan
Diagnostic Solutions

VALUE OF PATHOLOGY

IVD Australia continues to be a major contributor to the success of the campaign to raise the awareness of the value that pathology plays in the health of 50% Australians every year.

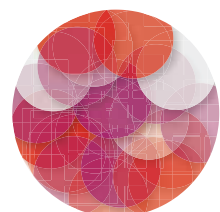
We have continued to meet milestones established by the Pathology Awareness Australia (PAA) Board and we will make a significant impact in coming months through the *business card* roll-out to over 70% of collection centres across Australia. This is by far the most significant step in the three years of the *value of pathology initiative*. With unanimous support from the members of PAA, we will make an impact, with 12 million Australians having at least one pathology test in the next 12 months. Every time a patient visits a “live” collection centre in Australia they will receive a *Know Pathology Know Healthcare* business card providing them with valuable insights into their pathology test(s). This aligns well to the “informed” patient having access to credible, government supported, information accessible from *Lab Tests Online* through the *Know Pathology Know Healthcare* website. Our testing has indicated that approximately 1 in 10 patients receiving the business card will visit our website. When they do, the most popular link is “what is pathology” – exactly where we want people to spend time.

In addition to raising awareness through general public engagement, we have continued to raise awareness with Federal politicians. In the last 12 months we have had over 20 MP's visit laboratories throughout Australia. This has been well supported by patients and other key stakeholders associated with the institutions involved. These visits have included the Health Minister Ms Ley, the shadow health minister Ms King and the new leader of the Green's Dr Richard Di Natale.

We continue to have strong support from Healthcare Consumer Organisations with the recent commitment from the Health Consumer Forum (HCF) and the National Blood Authority (NBA) joining our list of 35 supporters who all value the contribution pathology makes to their respective members.

Not underestimating what is ahead of us. Rome wasn't built in a day and nor will the wide understanding of the critical role that pathology plays in healthcare. Pathology has been the black-box of healthcare for a very long time. The ability to shed some light on the engine room of healthcare will require the concerted effort of all stakeholders and the associated 25,000 people that work in the pathology profession. Every little bit helps and therefore your own investment can make that incremental impact that collectively moves the needle so that one day PEOPLE GENUALLY VALUE PATHOLOGY.

Thank you for your continued support through IVD Australia and I appreciate your efforts in driving awareness of the VALUE of PATHOLOGY.



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FINANCIAL

STATEMENTS

FOR THE PERIOD
ENDED 30 JUNE 2015

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The financial statements cover IVD Australia Limited as an individual entity.
The financial statements are presented in the Australian currency.
The financial statements were authorised for issue by the directors on 15 September 2015.
The company has the power to amend and reissue the financial statements.

30 June 2015

DIRECTORS'

REPORT

The directors present their report on the company for the financial year ended 30 June 2015.

1. General information

(a) Directors

The names of the directors in office at any time during, or since 30 June 2015 are:

Names	Appointed/Resigned
Mr Bruce William Evans (Chair)	8 July 2009 to present
Mr John Crothers (Deputy Chair)	14 October 2011 to present
Mr Patrick Ian Cook (Treasurer)	22 October 2010 to present
Mr Paul Cray	8 July 2009 to present
Mr Tristan Duggan	15 October 2014 to present
Mr Mark Volling	10 December 2009 to present
Mr Simon Pratt	17 October 2013 to 10 July 2015
Mr Sebastian D'Angelo	20 February 2014 to present
Holly Simmonds	18 October 2012 to 15 October 2014
Mr Kirk Martin Kilmer	20 February 2014 to 13 February 2015

(b) Company secretary

Wendy-Jane Morrow was appointed as company secretary on 1 July 2014 and held the position of company secretary for the entire year.

(c) Principal activities

The principal activity of IVD Australia Limited during the financial year during the financial year involved facilitating the growth and development of the in-vitro diagnostics industry in Australia. No significant changes in the nature of the Company's activity occurred during the financial year.

(d) Short term objectives

- The Company's short term objectives are to:
- To retain and grow the diversity of members by June 2016
 - To maintain a Reserve Fund of \$240,000
 - To present TGA Regulatory Training to members as required in 2015-16
 - To ensure regular ongoing meetings with Members to determine their the industry's key issues
 - To work with Pathology Awareness Australia and other stakeholders to maintain the 'Know Pathology Know Healthcare' program

(e) Long term objectives

- The Company's long term objectives are to:
- To cultivate the Association to a sustainable future and maintain a financially viable Association
 - To provide up-to-date industry and regulatory information
 - To increase public and government knowledge and understanding of the value of the IVD industry
 - To maintain recognition as the peak body representing the IVD industry
 - To provide leadership in the commercial technical and regulatory environment in which members operate
 - To operate a Code of Conduct that is representative of the IVD and wider community with an equitable and transparent complaints process
 - To demonstrate strong corporate governance of the sector
 - To influence di rect regulatory policy to the benefit of members

(f) Strategy for achieving the objectives

- To achieve these objectives, the Company has adopted the following strategies:
- Grow current membership base by creating clearly identifiable benefits of IVD Australia membership
 - Set and manage budgets that include a contingency fund
 - Actively encourage and support participation by all members
 - Provide easily accessible relevant and current industry information to members
 - Provision of quality training and networking opportunities for members
 - Engage with RCPA, NCOPP and PA to build active co-operation and consultation on reimbursement issues
 - Engage with all levels of government to ensure IVD Australia is recognised as a key stakeholder in the pathology industry
 - Develop relevant publications on topics that can demonstrate IVD Australia's benefits to the community such as PoCT, the role of diagnostics in prevention and treatment of chronic disease and the IVD Australia code of conduct
 - As the peak body for the IVD Industry, work with regulatory agencies and participate in government committees, taskforces and working groups, forums, committees and one-on-one meetings
 - Monitor legislation and policies for their effect on IVDs
 - Ensure that timely and transparent ballots are held for the Board and all Committees
 - Create a clear and transparent Code of Conduct process
 - Ensure fair and equitable representation of all members
 - Create opportunities for members to proactively engage in Association activities
 - Develop an understanding of IVD benefits within the Consumer Health Community
 - Develop links with and enhance knowledge of the benefits of IVDs within the Health and Insurance sectors
 - Develop and promote a range of policies that support the IVD Sector including POCT, Chronic Disease, Pharmacogenomics and reimbursement.

(g) Business Review

- (i) Operating results
- The Company continued to engage in its principal activity, the results of which are disclosed in the attached financial statements.

The net surplus of the Company for the financial year ended 30 June 2015 amounted to **\$15,932** (2014: net deficit of \$44,699).

- (ii) Dividends
- The Constitution of the Company does not permit the payment of dividends.

DIRECTORS' REPORT continued

(h) Significant changes in state of affairs

No significant changes in the Company's state of affairs occurred during the financial year.

(i) Events subsequent to reporting date

No matters or circumstances have arisen since the end of the financial year which significantly affected or may significantly affect the operations of the Company, the results of those operations or the state of affairs of the Company in future financial years.

(j) Likely developments

The Company will continue to pursue its principal activities at a surplus. It is not expected that the results in future years will be adversely affected by the continuation of those operations.

Future disclosure of information regarding likely developments in the operations of the Company in future financial years and the expected results of those operations is likely to result in unreasonable prejudice to the Company. Accordingly, this information has not been disclosed in this report.

(k) Environmental regulations

The Company's operations are not regulated by any significant environmental regulation under Australian Law.

(l) Indemnification and insurance of officers and auditors

Insurance Premiums

During the financial year, the company has paid or agreed to pay premiums in respect of such insurance contracts for the year ended 30 June 2015. Such insurance contracts insure against certain liability (subject to specific exclusions).

The Directors have not included details of the nature of the liabilities covered or the amount of the premium paid in respect of the directors' and officers' liability insurance contracts, as such disclosure is prohibited under the terms of the contracts.

Indemnification

Since the end of the previous financial year, the Company has not indemnified or made a relevant agreement for indemnifying against a liability any person who is or has been an officer or auditor of the Company.

(m) Members guarantee

Each member of the Company undertakes to contribute to the assets of the Company in the event of it being wound up, while he/she is a member, or within one year after he/she ceases to be a member, for the payment of debts and liabilities of the Company, charges and expenses of a winding up, and for the adjustment of the rights of the contributions among themselves, such amounts as may be required not exceeding twenty five dollars (\$25.00).

(n) Information on directors

The names of each person who has been a director during the year and to the date of this report are:

Mr Bruce William Evans (Chair) Non-Executive Director, Abacus Pty Ltd.
Bruce Evans is a Director and a major shareholder of Abacus ALS Pty Ltd. Bruce holds a Masters of Business Administration (USQ) and is a Fellow of the Australian Institute of Company Directors. He is a qualified Medical Laboratory Scientist(QUT) , who commenced his career in a clinical Pathology laboratory

and prior to founding his own business Abacus Diagnostics in 1998, worked in sales and marketing for what is now part of Siemens Healthcare Laboratory Diagnostics.

Bruce also holds the position of Director Asthma Foundation Queensland and was previously a Director of the Medical Technology Association of Australia (mtaa.org.au) and its predecessor, the Medical Industry Association of Australia.

Through these directorships, Bruce has gained significant experience as a director in the not-for-profit sector.

Mr John Crothers (Deputy Chair)

Regional Director, Abbot Diagnostics Pty Ltd.

John Crothers is a Regional Director for Australia and New Zealand. Prior to the role of Australia, John was the Commercial Director for Asia Pacific and has also had several years in US Marketing.

Experience in the IVD Industry: 2 years clinical pathology laboratory experiences, 10 years sales and marketing IVD experience, 15 years general management and company director to IVD industry experience.

With over 25 years experience in the pathology industry in both the laboratory and IVD, the appreciation of the value of the industry in healthcare is a passion that John continues to pursue.

John has a BSc(MLS) from RMIT and a Graduate Diploma Administration from Swinburne University.

Mr Patrick Ian Cook (Treasurer)

Director, Macarthur Cook Group Pty Ltd.

Patrick Cook has been in the in vitro diagnostics industry for over 30 years. Patrick holds degrees in Applied Science, Marketing and is a Graduate of the Company Directors Course. He is a Fellow of the Australian Institute of Company Directors and has served on a number of not-for-profit boards.

Patrick worked as a medical scientist for both public and private laboratories and previously held sales & senior marketing positions at Abbott Diagnostics, Roche Diagnostics and Agen Ltd (an Australian publically listed biotechnology manufacturer and exporter).

In 1995 he established and operated his own medical devices import and distribution business. He is currently a business development consultant in biotechnology and in the medical devices area.

Mr Paul Cray

Managing Director, Roche Diagnostics Australia Pty Ltd.

Paul Cray is the Managing Director of Roche Diagnostics Australia Pty. Ltd. and Leadership Team member of Roche Diagnostics Asia Pacific. Paul has over 25 years' experience in the in vitro diagnostics industry, undertaking numerous overseas roles with increasing sales, marketing strategy and general management responsibility in the UK, Canada, USA, Switzerland and Germany.

The most recent post was that of Senior Vice President, Global Marketing, Roche Diagnostics. Paul holds a Bachelor of Science degree from University College of Wales, UK, and has undertaken numerous post graduate and executive courses at INSEAD, France, IMD, Switzerland and more recently Mt Eliza Advanced Management Programme, Melbourne Business School.

Paul is a Member of the Australian Institute of Company Directors.

DIRECTORS' REPORT continued

- Mr Tristan Duggan

Managing Director, Diagnostic Solutions Pty Ltd.
Tristan has over 15 years' experience in the healthcare industry having worked in both large multinational corporate environments as well as independent distribution organisations.
Tristan possesses a Bachelor of Business Management and his career roles have varied across sales, marketing, operations and management.
Diagnostic Solutions is owned by Diploma Healthcare who also own Big Green Surgical and both companies operate in Australia and New Zealand.
- Mr Mark Volling

Regional Managing Director, Alere Pty Ltd.
Mark has over 25 years' experience within the Australian IVD industry including senior roles within global companies (Alere/Inverness Medical, Dade Behring), local manufacturing and export organisations (Alere/Panbio, Agen Biomedical) and distributor only organisations (In Vitro Technologies).
He possesses an Associate Diploma in Clinical Laboratory Techniques (QIT), a Bachelor of Business in Finance/Accounting (USQ), a Graduate Certificate in Management (USQ) and a Masters of Technology Management (UQ).
- Mr Simon Pratt

Division Manager, Clinical Diagnostic group - Pacific Region, Bio-Rad Laboratories.
Simon Pratt registered as a medical scientist in NZ and has post graduate qualifications in business and human resources. He has held business development and sales management roles within Europe, during a seven year period in the UK, and was an early company representative with BIVDA during the start-up phase.
Currently, Simon is the Diagnostics Divisional Manager at Bio-Rad Laboratories, with ANZ sales and marketing responsibilities, a role which he has held for the last 5 years.
- Mr Sebastian D'Angelo

Vice President, Diagnostics Division, Healthcare Sector, Siemens Ltd, Pacific Region.
Sebastian has over 30 years' experience within the Australian IVD industry, having worked as a medical scientist in public pathology laboratories before moving to senior roles at Chiron Diagnostics and Bayer Diagnostics and now at Siemens Healthcare Diagnostics.
Sebastian holds a Bachelor of Applied Science (MLS) degree from RMIT University and a Master of Marketing degree from the Melbourne Business School. He is a Member of the Australian Institute of Company Directors.
- Holly Simmonds

Managing Director, Hologic (Australia) Pty Ltd.
Holly Simmonds was the Managing Director of Hologic Australia. Holly holds a Master of Business specialising in Marketing and has worked in many aspects of the medical industry for the past 25 years, predominately in women's health.
Apart from 12 years as a clinical nurse specialist in gynecology oncology at RPAH, Holly has been employed in the medical industry since 1989.
- Mr Kirk Martin Kilmer

President, ANZ and Korea for Thermo Fisher Scientific.
Scientific Bachelor degree from the University of Notre Dame and a MBA from the Univeristy of Chicago. Over 25 years of diagnostic industry experience.
Holds several diagnostic patents and served on several not-for-profit Boards.

2. Meetings of Directors


During the financial year, 7 meetings of directors (including committees of directors) were held. Attendances by each director during the year were as follows:

	Directors' Meetings	
	Number eligible to attend	Number attended
Mr Bruce William Evans (Chair)	7	7
Mr John Crothers (Deputy Chair)	7	6
Mr Patrick Ian Cook (Treasurer)	7	7
Mr Paul Cray	7	7
Mr Mark Volling	7	6
Holly Simmonds	2	-
Mr Sebastian D'Angelo	7	5
Mr Simon Pratt	7	6
Mr Tristan Duggan	6	4
Mr Kirk Martin Kilmer	6	6


3. Auditor's independence declaration

The lead auditor's independence declaration in accordance with section 307C of the *Corporations Act 2001*, for the year ended 30 June 2015 has been received and can be found on page 9 of the financial report.

Signed in accordance with a resolution of the Board of Directors:



Director,
Bruce William Evans (Chair)



Director,
Patrick Ian Cook (Treasurer)

Dated
15 September 2015



The Board of Directors
IVD Australia Limited
PO Box 298
Parramatta CBD BC NSW 2124

Date: XX September 2015

Dear Board Members

Auditors Independence Declaration under Section 307C of the Corporations Act 2001

In accordance with section 307C of the Corporations Act 2001, we are pleased to provide the following declaration of independence to the directors of IVD Australia Limited.

As lead audit partner for the audit of the financial statements of IVD Australia Limited for the financial year ended 30 June 2015, we declare that, to the best of our knowledge and belief, during the year ended 30 June 2015, there have been no contraventions of:

- (i) the auditor independence requirements as set out in the *Corporations Act 2001* in relation to the audit; and
- (ii) any applicable code of professional conduct in relation to the audit.

Yours sincerely

Nexia Court & Co
Chartered Accountants

Joseph Santangelo
Partner

Sydney

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Independent member of Nexia International



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Independent Audit Report to the members of IVD Australia Limited

Report on the Financial Report

We have audited the accompanying financial report of IVD Australia Limited, which comprises the statement of financial position as at 30 June 2015, the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Directors' Responsibility for the Financial Report

The directors of the company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. These Auditing Standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance about whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation of the financial report that gives a true and fair view in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Independence

In conducting our audit, we have complied with the independence requirements of the *Corporations Act 2001*. We confirm that the independence declaration required by the Corporations Act 2001, which has been given to the directors of IVD Australia Limited, would be in the same terms if given to the directors as at the time of this auditor's report.

Auditor's Opinion

In our opinion the financial report of IVD Australia Limited is in accordance with the *Corporations Act 2001*, including:

- (a) giving a true and fair view of the Company's financial position as at 30 June 2015 and of its performance for the year ended on that date; and
- (b) complying with Australian Accounting Standards - Reduced Disclosure Requirements and the *Corporations Regulations 2001*.

Joseph Santangelo
Partner

Sydney

Date: 15 September 2015

DIRECTORS' DECLARATION

In the opinion of the directors of the Company declare that:

1. The financial statements and notes, as set out on pages 31 to 39, are in accordance with the *Corporations Act 2001* and:
 - a) comply with Australian Accounting Standards - Reduced Disclosure Requirements and
 - b) give a true and fair view of the financial position as at 30 June 2015 and of the performance for the year ended on that date of the Company.
2. There are responsible grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors.



Director,
Bruce William Evans (Chairperson)



Director,
Mr Patrick Ian Cook (Treasurer)

Dated 15 August 2015

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the Year Ended 30 June 2015

	Note	2015 \$	2014 \$
Revenue	2	425,066	394,739
Total Income		425,066	394,739
Employee benefits expense	3(a)	(252,551)	(253,595)
Depreciation expense	3(b)	(1,678)	(3,118)
Administrative expenses		(152,526)	(149,644)
Travel expenses		(1,777)	(33,081)
Loss on sale of non-current asset	7(a)	(602)	-
Total Expenses		(409,134)	(439,438)
Surplus/(Deficit) for the year		15,932	(44,699)
Other comprehensive income			
Other comprehensive income		-	-
Total comprehensive income for the year		15,932	(44,699)

STATEMENT OF FINANCIAL POSITION

As At 30 June 2015

	Note	2015 \$	2014 \$
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	4	364,699	277,971
Trade and other receivables	6	15,684	38,224
Other assets	5	-	18,000
TOTAL CURRENT ASSETS		380,383	334,195
NON-CURRENT ASSETS			
Property, plant and equipment	7	3,511	4,386
TOTAL NON-CURRENT ASSETS		3,511	4,386
TOTAL ASSETS		383,894	338,581
LIABILITIES			
CURRENT LIABILITIES			
Trade and other payables	8	45,704	68,755
Employee benefits	9	10,015	10,015
Other liabilities	10	99,804	47,372
TOTAL CURRENT LIABILITIES		155,523	126,142
NET ASSETS		228,371	212,439
EQUITY			
Retained earnings		228,371	212,439
TOTAL EQUITY		228,371	212,439

STATEMENT OF CHANGES IN EQUITY

For the Year Ended 30 June 2015

2015	Retained Earnings \$	Total \$
Balance at 1 July 2014	212,439	212,439
Loss for the year	15,932	15,932
Balance at 30 June 2015	228,371	228,371
2014	Retained Earnings \$	Total \$
Balance at 1 July 2013	257,138	257,138
Loss for the year	(44,699)	(44,699)
Balance at 30 June 2014	212,439	212,439

STATEMENT OF CASH FLOWS

For the Year Ended 30 June 2015

	Note	2014 \$	2013 \$
CASH FROM OPERATING ACTIVITIES:			
Receipts from customers		518,342	422,950
Payments to suppliers and employees		(440,583)	(453,325)
Interest received		10,200	12,381
		87,959	(17,994)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property, plant and equipment		(1,233)	(2,157)
		(1,233)	(2,157)
CASH FLOWS FINANCING ACTIVITIES:			
Net increase (decrease) in cash and cash equivalents		86,726	(20,151)
Cash and cash equivalents at beginning of year		277,971	298,122
Cash and cash equivalents at end of financial year	4	364,697	277,971

NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 30 June 2015

1 Summary of Significant Accounting Policies

(a) General Information

The financial report covers IVD Australia Limited as an individual entity. IVD Australia Limited ('the Company') is a Company limited by guarantee, incorporated and domiciled in Australia. The company is primarily involved in facilitating the growth and development of the in-vitro diagnostics industry in Australia.

(b) Basis of Preparation

The financial statements are general purpose financial statements that have been prepared in accordance with Australian Accounting Standards - Reduced Disclosure Requirements, Australian Accounting Interpretations, other authoritative pronouncements of the Australian Accounting Standards Board and the *Corporations Act 2001*.

The financial statements of IVD Australia Limited comply with Australian Accounting Standards - Reduced Disclosure Requirements as issued by the AASB.

(c) Function and Presentation

These financial statements are presented in Australian dollars, which is the Company's functional currency.

(d) Revenue and other income

Revenue is measured at the fair value of the consideration received or receivable and is presented net of returns, discounts and rebates.

Interest revenue is recognised using the effective interest rate method. All revenue is stated net of the amount of goods and services tax (GST).

(e) Income Tax

The company is exempt from Income Tax on its membership income under the tax law principle of mutuality. Due to its limited non-member income and deductible expenditure the company has no income tax payable.

(f) Goods and Services Tax (GST)

Revenue, expenses and assets are recognised net of the amount of goods and services tax (GST), except where the amount of GST incurred is not recoverable from the Australian Taxation Office (ATO).

Receivables and payable are stated inclusive of GST.

The net amount of GST recoverable from, or payable to, the ATO is included as part of receivables or payables in the statement of financial position.

Cash flows in the statement of cash flows are included on a gross basis and the GST component of cash flows arising from investing and financing activities which is recoverable from, or payable to, the taxation authority is classified as operating cash flows.

NOTES TO THE FINANCIAL STATEMENTS continued

(g) Cash and cash equivalents

Cash and cash equivalents include cash on hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts.

(h) Plant and Equipment

Plant and equipment is stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the company and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the Statement of Profit or Loss and Other Comprehensive Income during the financial period in which they are incurred.

Depreciation of assets is calculated using the straight-line method to allocate their cost, net of residual values, over their useful lives, as follows:

- Office Fixtures	3-5 years
- Computer Equipment	3 years

The assets' residual value and useful lives are reviewed and adjusted, if appropriate, at each reporting date.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

(i) Trade and other payables

Trade creditors and other payables, are recognised at the nominal transaction value without taking into account the time value of money.

(j) Employee benefits

Provision is made for the Company's liability for employee benefits arising from services rendered by employees to the end of the reporting period. Employee benefits that are expected to be settled within one year have been measured at the amounts expected to be paid when the liability is settled.

(k) New Accounting Standards and Interpretations

The AASB has issued new and amended Accounting Standards and Interpretations that have mandatory application dates for future reporting periods. The directors have decided against early adoption of these Standards, but does not expect the adoption of these standards to have any impact on the reported position or performance of the Company.

(l) Critical Accounting Estimates and Judgements

The Directors evaluate estimates and judgments incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and based on current trends and economic data, obtained both externally and within the Company.

2 Revenue

	2015 \$	2014 \$
Member subscriptions	400,753	374,206
Associate member	14,250	-
Training income	3,785	7,934
Interest revenue	6,278	12,599
	425,066	394,739

3 Expenses**(a) Employee benefits expense**

Wages and salaries	230,294	211,935
Other associated personnel expenses	300	21,835
Superannuation	21,957	19,825
	252,551	253,595

(b) Depreciation expense

Depreciation - computer equipment	1,131	2,404
Depreciation - furniture and fixtures	547	714
	1,678	3,118

4 Cash and Cash Equivalents

Cash at bank	124,699	37,971
Term deposits	240,000	240,000
	364,699	277,971

5 Other Assets

Lease guarantee	-	18,000
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6 Trade and other receivables

Trade receivables	-	3,922
GST paid	15,684	34,302
	15,684	38,224

NOTES TO THE FINANCIAL STATEMENTS continued

7 Plant and equipment

	2015 \$	2014 \$
Furniture, fixture and fittings - at cost	2,589	3,589
Accumulated depreciation	(1,572)	(1,422)
	1,017	2,167
Computer equipment - At cost	10,377	12,204
Accumulated depreciation	(7,883)	(9,985)
	2,494	2,219
Total property, plant and equipment	3,511	4,386

(a) Movements in carrying amounts of plant and equipment

Movement in the carrying amounts for each class of plant and equipment between the beginning and the end of the current financial year:

	Furniture, Fixtures and Fittings \$	Computer Equipment \$	Total \$
Balance at 30 June 2015			
Balance at the beginning of year	2,167	2,219	4,386
Additions	-	1,836	1,836
Disposals - written down value	(602)	-	(602)
Depreciation expense	(547)	(1,562)	(2,109)
Balance at the end of the year	1,018	2,493	3,511

8 Trade and other payables

Accrued expenses	9,495	24,450
GST/PAYG collected	20,919	40,046
PAYG Payable	12,704	4,259
Other payables	2,586	-
	45,704	68,755

9 Employee Benefits

Provision for annual leave	10,015	10,015
----------------------------	--------	--------

10 Other liabilities

Income in advance	99,804	47,372
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11 Auditors' Remuneration

	2015 \$	2014 \$
Payable to the auditors of the company - Nexia Court & Co		
- Audit services	9,494	9,000
- Non-audit services	-	5,200
	9,494	14,200

12 Superannuation Commitments

The company has a legal obligation to contribute superannuation for all employees. The company contributes to complying accumulation superannuation plans.

13 Key Management Personnel Compensation**(a) Key Management Personnel Remuneration**

Key management personnel include the directors and the Chief Executive Officer. All Directors are honorary and as such no payments are made to the Directors. Short term benefits received by key management personnel during the year were: \$205,306 (2014: \$202,676). No other benefits were received or provided.

(b) Transactions with Related Entities

The only transactions with related parties of IVD Australia Limited were membership subscription fees received from organisations in which the Directors are employed.

14 Contingent Liabilities**Operating lease commitments subsequent to year end**

Payable - minimum lease payments		
- not later than one year	-	6,240

15 Events Occurring After the Reporting Date

No matters or circumstances have arisen since the end of the financial year which significantly affected or may significantly affect the operations of the Company, the results of those operations or the state of affairs of the Company in future financial years.

IVD MEMBERS

at 30 June 2015

Abacus ALS	Immuno
Abbott Diagnostics	Integrated Sciences
Acrapack	Life Bioscience
Agena Biosciences (Asia Pacific)	Logical Freight Solutions #
Alere	London Agency #
Archer Emery and Associates	Macarthur Cook Group
Astral Scientific	Merck Millipore Australia
AsureQuality	MP Biomedicals
Atomo Diagnostics Australia	Paragon Therapeutic Technologies
Australasian Medical and Scientific	PerkinElmer
bioMerieux	Point of Care Diagnostics
Bio-Rad Laboratories	Prohealth Asia Pacific
Blackaby Diagnostics	Qiagen
Brandwood Biomedical	Randox
Catapult-BI #	R-Biopharm
Cepheid	Roche Diagnostics
Clinical Genomics	Siemens Healthcare Diagnostics
Dako / Agilent Technologies	SJ Alder
Diagnostic Solutions	Southern Cross Diagnostics
Dutec Diagnostics	SpeeDx
ESL Biosciences	Sysmex Australia
Grifols Australia	ThermoFisher Scientific
Health World	Universal Biosensors
Helena Laboratories	Vela Diagnostics
Hologic	Werfen Australia
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