

# ANNUAL REPORT 2014



CD20 (L26) and CD3 (2GV6) dual  
chromogen stain on spleen



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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 \$750,000,000 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 2014 fiscal year marks the close of the fifth year of operations of IVD Australia Ltd.

I am pleased to report that your industry association is in a sound position and that once again, we have achieved several major milestones over the last twelve months.

## Pathology Awareness

Last year, I reported that through the stewardship of IVD Australia, a group known as Pathology Awareness Australia Ltd (PAAL) had been formed, bringing together the major stakeholders of our industry. The goal of this group is to heighten the awareness of pathology and the value that pathology services deliver to the community and the wider healthcare system. During the year PAAL launched the 'Know Pathology, Know Healthcare' campaign and at the time of writing of this report, over ten thousand people have signed up via the web site and through the collection centre campaign as 'valuing pathology'. The Board of IVD Australia is very pleased with the progress of this world leading initiative and remain convinced that a bright future for our sector will be strongly correlated with increased awareness of the contribution of our products and that of our stakeholder partners to the wellbeing of all Australians.

## Value for Members

A key priority for the Board of IVD Australia is to be constantly striving to deliver value to our member companies. In 2014, we believe that we have made excellent progress on this objective, evidenced by:-

- The extension to the TGA IVD transition timeframe, collectively saving member companies millions of dollars and in many cases more than off-setting the costs of membership of the association.
- The launch of the Global Diagnostics Market Statistics (GMDS) program, at no additional cost to members. Whilst this initiative is still in its early stages, we have sixteen member companies signed up to contribute data. This information will become an important source of much needed market data.
- Leveraging our successful track record and our strong membership, we have launched an Associate Membership campaign for companies not directly involved in the *in vitro* diagnostic industry, but whom have business relationships with our member companies. Examples include freight and logistics providers and information system providers, just to name two. This campaign is designed to provide links for Associate Member companies to our membership in order to create mutually beneficial relationships. We hope that this results in a true win/win partnership for our full and Associate Members and it has the added benefit of generating income for IVD Australia without looking to our member companies.

## Governance

At last year's annual general meeting (AGM) a resolution was passed to amend the constitution, allowing an increase to the size of the Board. This has proven to be a sound decision as it has led to board renewal with several new Directors joining the Board. It has also allowed us to function effectively with the absence of various Directors due to travel and other work commitments.

A key priority for the Board in 2014 was to find a replacement for our CEO, whom we had agreed would retire during the second half of calendar year 2014. As you are aware, we have appointed Dr Wendy-Jane Morrow as our 'new' CEO and the Board is very pleased with her transition to her new role. We must acknowledge that following Dr Peter Harman in the CEO role is a tough task and the Board would once again like to formally recognise Peter for his outstanding contribution as our inaugural CEO since our formation in 2009.

I would like to close by thanking the member companies and their staff for their commitment to IVD Australia. Together as a purely *in vitro* diagnostics focused industry group, we are achieving more than has ever been achieved for the benefit of our industry. In the 2015 financial year, we will embark on development of a new Strategic Plan that will set our objectives for the future and I am excited by the progress we have made and what we can achieve over the next few years.

Bruce Evans  
Chairman, IVD Australia



# CEO'S REPORT

The 2013/14 Financial Year has seen further consolidation in the position of IVD Australia within the Australian therapeutic goods sector.

IVD Australia has continued to develop strong relationships with stakeholders within the health sector and the general community as the interest in IVD technology and the Know Pathology campaign has evolved. There has been increased interest in point-of-care technology with the announcement of self testing for HIV and also in companion diagnostics.

## Membership

Your Association continues to consolidate its position as the peak body representing the *in vitro* diagnostics industry. While there has been some loss of membership due to mergers and to financial pressure on member companies we have recruited some additional new members. At the end of June 2014, IVD Australia had 53 members in total; the same as in June 2013. The total turnover of members exceeds \$750,000,000 and we estimate that members provide well over 85% of all IVDs supplied to professional laboratories and over-the-counter to healthcare consumers. Most companies that supply IVDs are members but we continue to advocate the benefits of IVD Australia membership to those that are not.

Your Association finished the 2013/14 Financial Year with a deficit of \$44,000 leaving us with an accrued surplus to \$206,000. However the Board is aware that we cannot continue to run deficits and have implemented a number of initiatives to address the shortfall.

We have continued to provide a range of activities for members, including;

- Three member networking meetings
- Two Training sessions on the IVD regulations
- Regular CEO newsletters to members.
- Co-operation with other Associations to provide joint programs

## Code of Conduct

IVD Australia has continued to respond in a number of ways to the changes outlined by the Trimmer Report and the expectation of the community in general. Revision of the IVD Australia Code occurred during 2013 in order to address some areas where clarification was required and to include areas that are missing such as ghost writing of articles and ownership of IVD companies by health professionals.

The new Abbott Government however is not interested in additional regulation around Codes, so the Sansom Committee established by Catherine King MP has not met since 2013. IVD Australia continues to promote the concept of a level playing field with both members and non-members subscribing to a common Code of Conduct.

## Value of Pathology Initiative

The Know Pathology Know Healthcare (KPKH) Campaign was officially launched in June 2014 with a function at Parliament House. This was the end result of a great deal of work by the Pathology Awareness Board, and particularly by our Vice-Chair, John Crothers, who has been tireless in promoting the program and getting sign-on from stakeholders.

IVD Australia is contributing to the KPKH campaign both financially and in kind by providing the secretarial and governance support.



## CEO REPORT continued

### IVD Regulation

After much discussion and consultation with TGA and the Government, the IVD transition was extended at the last moment (June 2014) by one year to 30th June 2015. IVD Australia argued strongly for this timeframe to also apply to in-house IVDs but the Government gave labs a further 2 years to comply with their modified conformity assessment requirements.

Over 1500 inclusions have been made but the final number will reach 2000. IVD Australia was very successful in negotiating a further extension of the Annual Charge Exemption policy for all included IVDs until 30th June 2017. This will save the IVD sector over \$6 million over the next 3 years.

We also remain concerned that TGA is still taking over 12 months to undertake Conformity Assessment of those applications that require this step.

Despite numerous discussions with the Department of Agriculture, Forestry and Fisheries, progress on changes to the risk profile and import regulations covering IVDs has been slow. IVD Australia was successful in getting the Biological Imports Program to expand the number of ICON cases and generate a set of Standard Permits, such that all IVDs should be covered by only 3 Permit lines - greatly reducing the number of permits and the overall cost to members.

### Government

IVD Australia has credibility in its advocacy relationships with Government, Regulators and Industry Stakeholders and has played a significant part in influencing Australia's policy settings and regulatory framework. Through our leadership, representation and initiatives we have been able to influence government policy and regulations.

In addition to our regular meetings with the TGA, IVD Australia has met with the Department of Health (DoH) on a number of occasions, with the Biological Imports Program, with the Department of Industry, and with the Medical Services Advisory Committee (MSAC) and other Government bodies.

This has resulted in a number of achievements:

- Representation on the Pathology Services Table Committee
- Representation on the Vitamin D and B12/folate MSAC Reviews.
- Participation in Health Technology Assessment activities undertaken by MSAC.
- Recommendation by MSAC of the use of HbA1c for the diagnosis of diabetes
- Representation on the NPAAC Drafting Subcommittee on Point-of-Care Testing.
- Announcement by the Minister of approval for self-testing for HIV.

### Global Issues

The issues faced by IVD Australia members are not only local but also global ones and are shared by our members' principals overseas. IVD Australia has continued to develop our relationships with sister organisations such as the British In Vitro Diagnostics Association (BIVDA), AdvaMedDx (the IVD arm of the US Medical Device Association) and with the European Diagnostic Manufacturers Association (EDMA). We have been invited to attend the 2014 General Meeting of EDMA at which there will be a collective meeting of IVD Associations from Europe, North America, Japan, China and Africa.

We have continued to participate in the Global Medical Technology Alliance (GMTA) which provides a forum in which global industry associations meet to exchange information on worldwide medical technology trends, and jointly develop and advocate policies that encourage innovation to address patients' healthcare needs.

### **The Challenges Ahead**

IVD Australia has continued to build on the progress made over the past four years..

However there are always challenges. We must continue to promote the importance of the pathology sector to the overall healthcare community, in particular the vital role that IVD suppliers play.

IVD Australia will continue to closely monitor the remaining transition period for the IVD Regulations. We have spent considerable time educating members regarding the regulations and the need to transition products in a timely manner. We remain concerned that there will be significant numbers of critical products that are not transitioned, and are cognizant of the impact that this may have on laboratories and healthcare in general.

The results of the past 12 months have not been achieved without a great deal of hard work, and I would like to acknowledge the support provided by our Executive Assistant, Ms Chami Gunasinghe. I would also like to acknowledge the support given to me by the Board of Directors, particularly our Chair, Bruce Evans, and I offer my thanks for their assistance and support. Finally, I would like to thank the Members for their contribution in terms of staff time during the year.

As members will be aware, I have decided to retire

from full time work as of end June 2014. I have had a fantastic five years as CEO of IVD Australia, and have enjoyed helping the Board grow the Association in size and influence. It has been gratifying to be part of such a vibrant industry, full of wonderful people. I wish my successor, Dr Wendy-Jane Morrow every success with the role and urge members to offer her the same level of support that I have been given.

A handwritten signature in black ink, appearing to read 'P Harman', with a stylized flourish at the end.

Peter Harman  
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

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

Apart from 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.

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.



# CODE ADMINISTRATION COMMITTEE

The latter part of 2013 saw the Code Administration Committee heavily involved in completing the review of the 2nd Edition of the Code, which was adopted by members at the AGM in December 2013.

The relative calm after this busy period has given us the opportunity to reflect on the lessons learnt over the past three years. We particularly welcome the involvement of those members of the CAC who represent external stakeholder groups, giving us the opportunity to view the Code and its operation from varying perspectives.

Issues which have concerned the CAC in the past year include the IVDA online training program, which has not been widely embraced by members since its introduction some two years ago. Reasons given for the low member engagement in Code training include the cost of enrolment, the time commitment required and the fact that many companies include Code

training as part of their internal company induction programs. The CAC is currently 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.

Over the past year, the CEO has continued to provide advice to members on Code issues, with input from the CAC Chair and members as required. Through engagement with members at conferences and other events, the CEO has reported a high degree of member commitment to Code compliance. The challenge for the CAC and IVDA is to find ways to quantify and demonstrate this commitment. As previously reported, it is evident that our Code is not and is unlikely to become "complaints driven", so the outcome of Code complaints cannot be used as a measure of Code compliance (or non-compliance).

The CAC looks forward to developing new programs in the coming year to assist our members to comply with the Code.

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 it came down to the wire but the proposed amendment to extend the transition period for compliance to the TGA IVD Regulations finally came through on the 29th May 2014.

The TGA IVD Working Group meeting on the 8th May was a nail-biting affair as we were assured by TGA the extension was to go before the Executive Committee by the end of the month.

The extension gives commercial IVD sponsors of all classes of products until 30 June 2015 to have a valid application for inclusion on the ARTG submitted to the TGA. Although a little disappointed that in-house manufacturers were given an extension until 30 June 2017, TARSC was pleased to be advised the Annual Fee to maintain an ARTG inclusion for IVDs would be retained at \$0 until 2017.

TGA continues to move forward with the other amendments outlined in the consultation document from 2013 "Proposed Amendments to the new regulatory framework for *in vitro* Diagnostic Medical Devices (IVDs)". A Regulatory Impact statement has been prepared and TARSC anticipates this being released by the end of 2014.

As well as all the usual activities undertaken by TARSC, considerable time and effort was spent preparing for the TGA-Industry supported 'Sponsor Training and Information Day'. In a first for the medical devices sector each session on the day was presented by both TGA and industry in a joint effort to present both sides of the regulations. The day was sold out in record time and TARSC hopes that members gained valuable insights from the day. Professor John Skerritt (National Manager TGA) spoke at length about his vision for the future of the TGA. Presentations will be available on both the TGA and the IVD Australia websites.

The industry continues to be well represented on a number of crucial committees, notably the Department of Agriculture Biologicals Consultative Group (BCG) where IVD Australia continually strives to ensure the customs import process for IVDs is commensurate with the minimal risk they pose.

TARSC said farewell to Peter Harman as CEO after the August TARSC meeting acknowledging the major contribution he made in supporting TARSC over the last 5 years during this crucial period for the industry. TARSC welcomes Wendy-Jane Morrow to the 'team' and looks forward to an equally productive future.

## COMMITTEE MEMBERSHIP THE TECHNICAL AND REGULATORY STANDING COMMITTEE

**Sally Jennings** - Chair  
Abbott Australasia P/L

**George Koumantakis**  
Roche Diagnostics  
Australia P/L

**Walter Shepherd**  
Immuno P/L

**Karen McLeod**  
MP Biomedicals

**Lilies Chen**  
BioRad Laboratories P/L

**Hiram Chipperfield**  
Alere Australia P/L

**Hoon Koh**  
Siemens Healthcare

**Peter Lowe**  
GenProbe/Hologic Inc

**Peter Traynor**  
ThermoFisher Scientific  
ANZ P/L

**Susan Alder**  
Minerva Medica P/L

# IVD AUSTRALIA MARKET DEVELOPMENT WORKING GROUP (MDWG)

## IVD Australia Market Development Working Group (MDWG) held its inaugural meeting on 31st January 2104.

The goal of this Working Group is to assist in the ongoing development of the market for *in vitro* diagnostic products in Australia. To this end the Working Group will participate in the development of policies that assist in the growth of the overall market for human pathology testing. IVDs in this context include point-of-care products as well as those whose intended use is within the professional laboratory environment.

Activities for this group include:

1. Monitoring and reviewing changes to the market conditions pertaining to IVDs in Australia.
2. Proactively anticipating and responding to changes to government legislation and decisions that may affect the availability and or / reimbursement of pathology testing in Australia or limit the access of IVD Australia member companies to the market.
3. Providing assistance and guidance to IVD Australia members and the Board regarding participation in the Value of Pathology Campaign promoted by Pathology Awareness Australia.
4. Providing assistance and guidance to IVD Australia members and the Board regarding participation in the market statistics program promoted by European Diagnostics Manufacturers Association and CIP .
5. Providing assistance and guidance to members and the Board regarding the National Product Catalogue (NPC) and related initiatives.

6. Providing coordinated expert responses and commentary to government white papers, consultations etc. related to IVDs and pathology testing.
7. Interacting with other stakeholders including Department of Health, RCPA, AACB, NATA, ACRRM etc. in respect to the development of pathology testing market.
8. Ensuring that the IVD Australia Code of Conduct is promoted to all members participating in the Australian pathology testing market.
9. Communicating MDWG activities to the IVD Australia Board and IVD Australia membership

The Market Development Working Group is comprised of 7 nominated representatives from member companies and is supported by the IVD Australia Secretariat.

John Emmerson, from London Agency, together with John Crothers, Chairman of the PPA, have provided much feedback on the Know Pathology: Know Healthcare campaign. The first major activity is for this group is the involvement in International Pathology Day 5th November.

### COMMITTEE MEMBERSHIP IVD AUSTRALIA MARKET DEVELOPMENT WORKING GROUP

**John Crothers**  
Abbott Diagnostics  
(Board Member)

**Holly Simmonds**  
Hologic (Board  
Member)

**Simon Pratt**  
BioRad (Board  
Member) / replaced  
by Brooke Troth

**Christine Johnson**  
Abacus ALS

**Angus Hastie**  
Cepheid

**Jennifer Carson**  
Siemens

**Kathryn Humphries**  
Alere

# THE POINT OF CARE WORKING GROUP

Point of Care Testing (PoCT) is undoubtedly an important and growing area of Pathology testing and patient care.

In Australia however, there are some obstacles that still need to be overcome to allow PoCT to thrive. These include Regulatory "Road-blocks" as well as education and understanding of PoCT technology amongst Healthcare professionals, and the correct usage and Quality Checks. The IVD Australia POC Working Party was set up in 2012 to help promote PoCT amongst Healthcare Professionals and to improve education, training and networking.

In October 2014 IVD Australia was invited to hold a 2 hour POC workshop at the ACRRM annual Congress in Sydney. This followed on from the successful Congresses at Fremantle and Cairns where we hosted hands-on training and lectures covering aspects of PoCT including Infectious Disease testing, INR, Glucose/Ketones, HbA1c, Cardiac Markers, etc. Eight members companies of the POC WP were represented at ACRRM, and the response from GP's was very encouraging.

Raising the profile of PoCT with the Department of Health and Ageing, State Pathology services and the general community is one goal of the POC WP. Working as part of IVD Australia, the group has had input to various documents and responses to NPAAC and NATA PoCT Guidelines. Whilst the argument for full reimbursement of PoCT may continue for some time yet, we are making slow headway with getting PoCT guidelines and documents structured in a way that they are useful to non-laboratory trained Healthcare professionals wishing to use PoCT correctly. A GP operating in a rural or remote area will not be able

to achieve full NATA accreditation, but he should be able to perform PoCT competently and use all the resources available to him to ensure the right result, at the right time for the right patient.

"Self Testing" Infectious Disease tests (e.g. HIV) started to appear a few years ago and helped increase the spotlight on PoCT. The rekindled debate continues over reimbursement, the benefits to the community of various "Self testing" or rapid test methods (not just HIV) and ensuring accurate results are recorded.

PoCT has to be seen as a main stay of effective healthcare delivery in Australia. The goal now is to extend the availability of PoCT and its reimbursement to other tests such as INR, HbA1c and to establish a quality assurance and training framework for PoCT in conjunction with other stakeholders.

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

## **Martin Roccliffe M I Biol**

Chair, Point-of-Care Working Group  
AMSL POC Division Manager.

## **COMMITTEE MEMBERSHIP** THE PoCT COMMITTEE

**Martin Roccliffe** - Chair  
AMSL LTD

**Judy Ward**  
Alere Australia P/L

**Adrienne Ripley**  
Roche Diagnostics P/L

**Barry Wilson**  
Abbott Australasia P/L

**Helen Persano**  
bioMerieux Australia P/L

**Daniela Symons-Troy**  
Cepheid





# VALUE OF PATHOLOGY

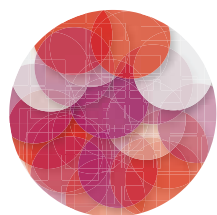
## The last 12 months have been an exciting period for Pathology Awareness Australia (PAA).

Since incorporating PAA, the company board has been busy preparing for the official launch of the campaign - KNOW PATHOLOGY KNOW HEALTHCARE.

That preparation involved meeting with as many individual laboratories across Australia, making them aware of the campaign and requesting their support through engaging their phlebotomists in signing up patients to support the on-line campaign.

On June 16th at Parliament House, Canberra, PAA officially launched KNOW PATHOLOGY KNOW HEALTHCARE. The launch involved inviting MP's to have a HbA1c test as a means of determining their likelihood of diabetes. We were well supported by Ms Cathy Freeman as our Ambassador. Cathy was genuinely interested in helping raise the awareness of the value of pathology after spending several hours visiting one of the major labs in Melbourne the week before. The launch was concluded with a cocktail event at parliament house.

The campaign now shifts to building both the supporter base and the engagement of politicians and other key stakeholders in the understanding of the VALUE that Pathology delivers to Healthcare.



know **pathology**  
know **healthcare**

The key focus on the supporter base is targeting those people that are in a greatest position to care. These people are those attending collection centres or clinics in hospitals across Australia. In the last 12 months there have been over 12 million pathology

collections. It is these people that we are looking to engage in understanding why pathology is important and why they should consider supporting pathology by providing their details on our website. Our initial testing showed that 20% of patients would be willing to commit their support. We are now bringing on board collection centres across Australia from nearly all the providers in the country. It is a gradual role out of 5 collection sites per organisation per quarter. Once we know we can support them and the sites are ready we will increase this momentum. For those supporters we have providing a monthly newsletter that provides a patient story, a lab story and where appropriate ties in a healthcare consumer organisation (HCO).

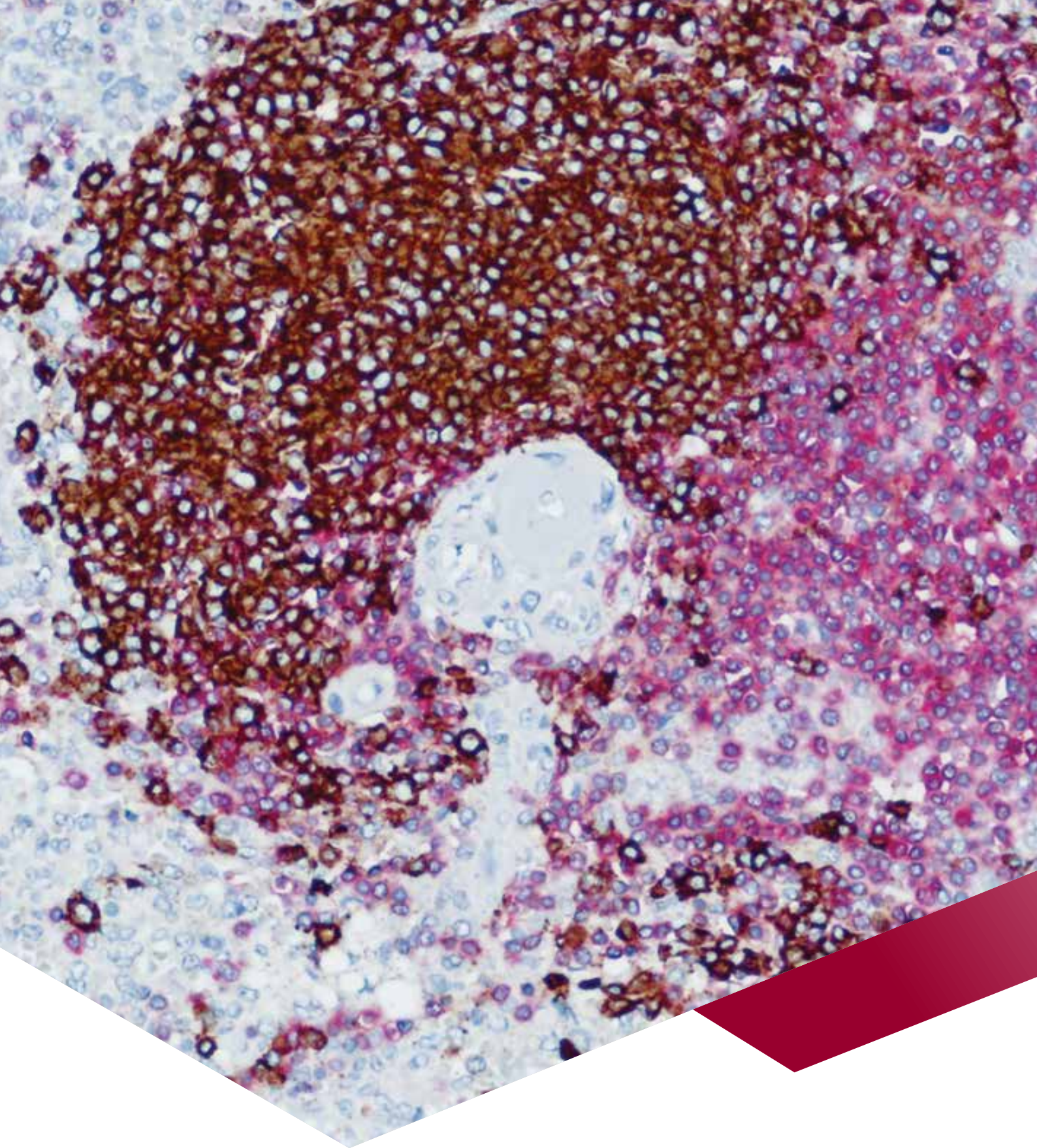
In addition, supporters are able to access LabTests Online (LTO) through the KPKH website, providing RCPA and AACB approved, government sponsored information on pathology tests.

In addition, we have commitment from 20 politicians to form a Pathology Friendship Group. This group will commit their time 2-3 times per year to meet and discuss relevant topics that are impacting the industry or are relevant for them to understand the critical role pathology plays in healthcare across Australia.

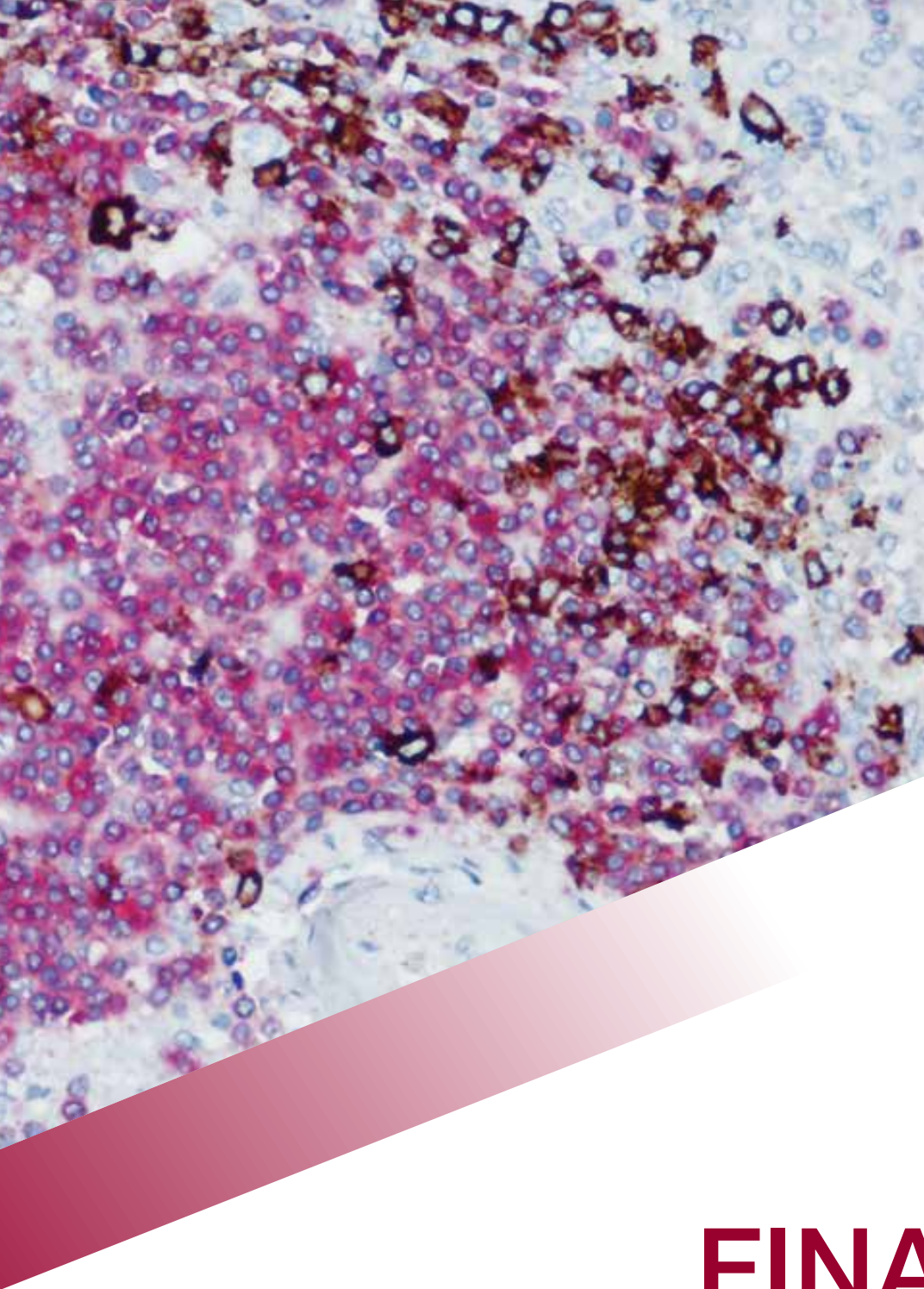
In closing, it is important to accept that we will not change perception overnight. Pathology has been the black-box of healthcare for a very long time. The ability to shed some light on the engine room of healthcare will require the concerted effort of all stakeholders and the associated 25,000 people 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 GENUINELY VALUE PATHOLOGY.

Thank you for your continued support through IVD Australia and I look forward to your continued participation in driving awareness of the VALUE of PATHOLOGY.









# FINANCIAL STATEMENTS

FOR THE PERIOD  
ENDED 30 JUNE 2014



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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 20 August 2014.  
The company has the power to amend and reissue the financial statements.

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# DIRECTORS' REPORT

30 June 2014

The directors present their report on the company for the financial year ended 30 June 2014.

## 1. General information

### (a) Directors

The names of the directors in office at any time during, or since 30 June 2014 are:

Names	Appointed/Resigned
Bruce William Evans (Chairperson)	8 July 2009 to present
Paul Simon Gray	8 July 2009 to present
Mark Stephen Volling	10 December 2009 to present
Patrick Ian Cook (Treasurer)	22 October 2010 to present
John Crothers (Deputy Chair)	14 October 2011 to present
Simon Hugh Pratt	17 October 2013 to present
Holly Simmonds	18 October 2012 to present
Sebastian D'Angelo	20 February 2014 to present
Kirk Martin Kimler	20 February 2014 to present
Anthony Acciarito	17 October 2013 to 3 February 2014

### (b) Company particulars

IVD Australia Limited was incorporated on the 8 July 2009. The Company is domiciled in Australia and is a public company limited by guarantee. The addresses of the registered office and principal place of business are listed below:

#### Registered Office

Lower Ground Suite 2  
55 Phillip Street  
PARRAMATTA NSW 2150

#### Principal Place of Business

Lower Ground Suite 2  
55 Phillip Street  
PARRAMATTA NSW 2150

### (c) Company secretary

Peter Harman has held the position of company secretary since the company was incorporated on 8 July 2009 to 1 July 2014. Wendy-Jane Morrow was appointed as company secretary on 1 July 2014.

### (d) 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.

## DIRECTORS' REPORT continued

### (e) Short term objectives

The Company's short term objectives are to:

- To retain members and have 60 members by June 2015
- To maintain a Reserve Fund of \$250,000.
- To present TGA Regulatory Training to members as required in 2014/15
- To ensure regular ongoing meetings with Members to determine their sector issues
- To work with Pathology Awareness Australia and other stakeholders to maintain the 'Know Pathology Know Healthcare' program.

### (f) Long term objectives

The Company's long term objectives are to:

- To grow 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 implement and operate a Code of Conduct that is representative of the IVD and wider community
- To provide an equitable and transparent complaints process
- To demonstrate strong corporate governance of the sector
- To influence direct regulatory policy to the benefit of members

### (g) 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 AAPP 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
- Work with regulatory agencies and participate in government committees, taskforces and working groups
- 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
- Ensure that IVD Australia is recognised by the TGA as the peak body regarding supply of *in vitro* diagnostics in Australia and ensure regular, robust and continuing dialogue with TGA via forums, committees and one-on-one meetings
- Develop an understanding of IVD benefits within the Consumer Health Forum and other consumer groups
- 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

### (h) 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 deficit of the Company for the financial year ended 30 June 2014 amounted to \$44,699 (2013: net deficit of \$32,609)

#### (ii) Dividends

The Constitution of the Company does not permit the payment of dividends.



**(i) Significant changes in state of affairs**

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

**(j) 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.

**(k) 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.

**(l) Environmental regulations**

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

**(m) 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 2014. Such insurance contracts insure against certain liability (subject to specific exclusions) persons who are or have been directors or executive officers of the Company.

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.

**(n) 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).

**(o) Information on directors**

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

Bruce William Evans (Chairperson)

Bachelor of Applied Science (Medical Laboratory Science)  
Master of Business Administration (MBA)  
Fellow of Australian Institute of Company Directors (FAICD)  
IVD industry CEO experience  
Executive Director, Non-Executive Director and Chairperson experience in both for profit and not-for-profit sectors

Paul Simon Cray

BSc Hons, University College of Wales  
Post Graduate Certificate of Marketing, University of NSW  
Post Graduate residential courses at IMD, Switzerland  
Managing Director  
Experience in the IVD industry: 30 Years in 6 Countries

## DIRECTORS' REPORT continued

Mark Stephen Volling	<p>Masters in Technology Management (Biotech)  Grad Cert Management (International Bus)  B Bus (Accounting/Finance)  Associate Dip Clinical Lab Tech  Regional Managing Director  Experience in IVD industry: 31 Years (Commercial 20 years)</p>
Patrick Ian Cook (Treasurer)	<p>Bachelor of Applied Science (Biomed)  Graduate Diploma in Marketing  FAICD  Certificate IV in Training and Assessment  Managing Director  Experience in IVD Sector: 34 years</p>
John Crothers (Deputy Chair)	<p>BAppSc (MLS), Grad Dip Bus Admin  Regional Director, Australia for Abbott Australasia  Experience in the IVD industry 18 years across ANZ, USA and Asia</p>
Simon Hugh Pratt	<p>Registered as a medical scientist in NZ  Post graduate qualifications in business and human resources  Experience in business development and sales management roles within Europe  Company representative with BIVDA during the start-up phase  Diagnostics Divisional Manager at Bio-Rad Laboratories, with ANZ sales and marketing responsibilities 5 years</p>
Holly Simmonds	<p>Gynae-oncology clinical nurse specialist  (Equivalent to Bachelor of Nursing)  Current Company Directorships include: Hologic (Australia) Pty Ltd,  Simmonds Holdings, Sydney  Training and Conference Centre, IVD Australia  Registered nurse for 12 years  Sales and Marketing 25 years in medical device industry overall  6 years MD of IVD company and 5 years MD of Conceptus (Australia) Pty Ltd  Medical Device Company</p>
Sebastian D'Angelo	<p>Vice President, Diagnostics Division,  Healthcare Sector, Siemens Ltd, Pacific Region  Bachelor of Applied Science (MLS) degree from RMIT University  Master of Marketing degree from the Melbourne Business School  Member of the Australian Institute of Company Directors  30 years' experience within the Australian IVD industry</p>
Kirk Martin Kimler	<p>President, ANZ and Korea for Thermo Fisher  Scientific Bachelor degree from the University of Notre Dame and a MBA from the University of Chicago  Over 25 years of diagnostic industry experience  Holds several diagnostic patents and served on several not-for-profit Boards</p>
Anthony Acciarito	<p>Bachelor of Science degree; Diploma of Laboratory Technology;  Chartered Chemist member of AIM.  Over 23 years of experience and a proven track record within the Diagnostic and broader Scientific sector  Director &amp; General Manager Thermo Fisher Scientific Pty Ltd</p>

## 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
Bruce William Evans (Chairperson)	7	6
Paul Simon Cray	7	7
Mark Stephen Volling	7	6
Patrick Ian Cook (Treasurer)	7	6
John Crothers (Deputy Chair)	7	7
Simon Hugh Pratt	6	5
Holly Simmonds	7	7
Sebastian D'Angelo	4	2
Kirk Martin Kimler	4	1
Anthony Acciarito	2	2

## 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 2014 has been received and can be found on page 7 of the financial report,

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



Bruce William Evans



Patrick Ian Cook

Dated 20 August 2014

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

Dear Board Members

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

In accordance with section 307C of the Corporations Act 2001, I am 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 2013, I declare that, to the best of my knowledge and belief, 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



Ian Stone  
Partner

Dated: 20 August 2014

Sydney

**Sydney Office**

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**Independent Audit Report to the members of IVD Australia Limited**

**the next solution**

**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 2014, 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 and fair presentation of the financial report and have determined that the accounting policies described in note 1 to the financial statements, which form part of the financial report, are appropriate to meet the requirements of the Corporations Act 2001 and are appropriate to meet the needs of the members. The directors' responsibility also includes establishing and maintaining internal controls relevant to the preparation and fair presentation of the financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

**Auditor's Responsibility**

Our responsibility is to express an opinion on the financial report based on our audit. No opinion is expressed as to whether the accounting policies used, as described in note 1, are appropriate to meet the needs of the members. We conducted our audit in accordance with Australian Auditing Standards. These 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.

The financial report has been prepared for distribution to the members for the purpose of fulfilling the directors' financial reporting requirements under the Corporations Act 2001. We disclaim any assumption of responsibility for any reliance on this report or on the financial report to which it relates to any person other than the members, or for any purpose other than that for which it was prepared.

Our procedures include reading the other information in the Annual Report to determine whether it contains any material inconsistencies with the financial report.

Our audit did not involve an analysis of the prudence of business decisions made by directors or management.

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 2014 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.



Nexia Court & Co  
Chartered Accountants

Sydney

Dated: 20 August 2014



Ian Stone  
Partner

# DIRECTORS' DECLARATION

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

1. The financial statements and notes, as set out on pages 27 to 34, are in accordance with the *Corporations Act 2001*
  - 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 2014 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,  
John Crothers (Deputy Chair)

Dated 20 August 2014

# STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the Year Ended 30 June 2014

	Note	2014 \$	2013 \$
Revenue	2	394,739	384,480
<b>Total income</b>		<b>394,739</b>	<b>384,480</b>
Employee benefits expense	3(a)	(253,595)	(232,537)
Depreciation expense	3(b)	(3,118)	(3,709)
Administration expense		(149,644)	(139,401)
Travel expenses		(33,081)	(41,442)
<b>Total expenses</b>		<b>(439,438)</b>	<b>(417,089)</b>
<b>(Deficit)/Surplus for the year</b>		<b>(44,699)</b>	<b>(32,609)</b>
Other comprehensive income		-	-
<b>Total comprehensive income for the year</b>		<b>(44,699)</b>	<b>(32,609)</b>

# STATEMENT OF FINANCIAL POSITION

As At 30 June 2014

	Note	2014 \$	2013 \$
<b>ASSETS</b>			
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	4	277,971	298,122
Trade and other receivables	6	38,224	20,857
Other assets	5	18,000	19,897
Current tax receivable		-	837
<b>TOTAL CURRENT ASSETS</b>		<b>334,195</b>	<b>339,713</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment	7	4,386	5,347
<b>TOTAL NON-CURRENT ASSETS</b>		<b>4,386</b>	<b>5,347</b>
<b>TOTAL ASSETS</b>		<b>338,581</b>	<b>345,060</b>
<b>LIABILITIES</b>			
<b>CURRENT LIABILITIES</b>			
Trade and other payables	8	68,755	32,739
Employee benefits	9	10,015	10,171
Other liabilities	10	47,372	45,012
<b>TOTAL CURRENT LIABILITIES</b>		<b>126,142</b>	<b>87,922</b>
<b>NET ASSETS</b>		<b>212,439</b>	<b>257,138</b>
<b>EQUITY</b>			
Retained earnings		212,439	257,138
<b>TOTAL EQUITY</b>		<b>212,439</b>	<b>257,138</b>



# STATEMENT OF CHANGES IN EQUITY

For the Year Ended 30 June 2014

<b>2014</b>	<b>Retained Earnings \$</b>	<b>Total \$</b>
Balance at 1 July 2013	257,138	257,138
Loss for the year	(44,699)	(44,699)
<b>Balance at 30 June 2014</b>	<b>212,439</b>	<b>212,439</b>

<b>2013</b>	<b>Retained Earnings \$</b>	<b>Total \$</b>
Balance at 1 July 2012	289,747	289,747
Loss for the year	(32,609)	(32,609)
<b>Balance at 30 June 2013</b>	<b>257,138</b>	<b>257,138</b>

# STATEMENT OF CASH FLOWS

For the Year Ended 30 June 2014

	Note	2014 \$	2013 \$
<b>CASH FROM OPERATING ACTIVITIES:</b>			
Receipts from customers		422,950	450,134
Payments to suppliers and employees		(453,325)	(454,895)
Interest received		12,381	16,910
		(17,994)	12,149
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property, plant and equipment		(2,157)	(3,385)
		(2,157)	(3,385)
<b>CASH FLOWS FINANCING ACTIVITIES ACTIVITIES:</b>			
Net cash increase (decreases) in cash and cash equivalents		(20,151)	8,764
Cash and cash equivalents at beginning of year		298,122	289,358
Cash and cash equivalents at end of year	4	277,971	298,122

# NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 30 June 2014

## 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 address of the Company's registered office is Lower Ground Suite 2, 55 Phillip Street, Parramatta NSW 2150. 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.

### (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

	2014 \$	2013 \$
Member subscriptions	374,206	354,572
Training income	7,934	13,510
Interest revenue	12,599	16,398
	<b>394,739</b>	<b>384,480</b>

## 3 Expenses

### (a) Employee benefits expense

Wages and salaries	211,935	191,478
Other associated personnel expenses	21,835	22,714
Superannuation	19,825	18,345
	<b>253,595</b>	<b>232,537</b>



**(b) Depreciation expense**

	2014 \$	2013 \$
Depreciation - computer equipment	2,404	3,098
Depreciation - furniture and fixtures	714	611
	<b>3,118</b>	3,709

**4 Cash and Cash Equivalents**

Cash at bank	37,971	98,122
Term deposits	240,000	200,000
	<b>277,971</b>	298,122

**5 Other Assets**

Prepaid expenses	-	1,897
Lease guarantee	18,000	18,000
	<b>18,000</b>	19,897

**6 Trade and other receivables**

Trade receivables	3,922	3,704
GST paid	34,302	17,153
	<b>38,224</b>	20,857

**7 Plant and equipment**

Furniture, fixture and fittings - At cost	3,589	3,589
Accumulated depreciation	(1,422)	(708)
	<b>2,167</b>	2,881
Computer equipment - At cost	12,204	10,047
Accumulated depreciation	(9,985)	(7,581)
	<b>2,219</b>	2,466
Total property, plant and equipment	<b>4,386</b>	5,347

**(a) Movements in Carrying Amounts**

Movement in the carrying amounts for each class of property, 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 2014			
Balance at the beginning of year	2,881	2,466	5,347
Additions	-	2,157	2,157
Depreciation expense	(714)	(2,404)	(3,118)
<b>Balance at the end of the year</b>	<b>2,167</b>	<b>2,219</b>	<b>4,386</b>

## NOTES TO THE FINANCIAL STATEMENTS continued

### 8 Trade and other payables

	2014 \$	2013 \$
Accrued expenses	24,450	15,712
GST Collected	40,046	12,954
PAYG Payable	4,259	4,073
	<b>68,755</b>	<b>32,739</b>

### 9 Employee Benefits

Provision for annual leave	<b>10,015</b>	10,171
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### 10 Other liabilities

Income in advance	<b>47,372</b>	45,012
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### 11 Auditors' Remuneration

Payable to the auditors of the company -  
Nexia Court & Co

- Audit services	<b>9,000</b>	8,250
- Non-audit services	<b>5,200</b>	3,073
	<b>14,200</b>	<b>11,323</b>

### 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, Peter Harman. 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: \$ 202,676 (2013: \$188,370). 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 organisation in which the Directors are employed.

### 14 Contingent Liabilities

#### Operating lease commitments subsequent to year end

	2014 \$	2013 \$
Payable - minimum lease payments		
- not later than one year	6,240	39,600
- between one year and five years	-	6,600
	<b>6,240</b>	<b>46,200</b>

### 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.

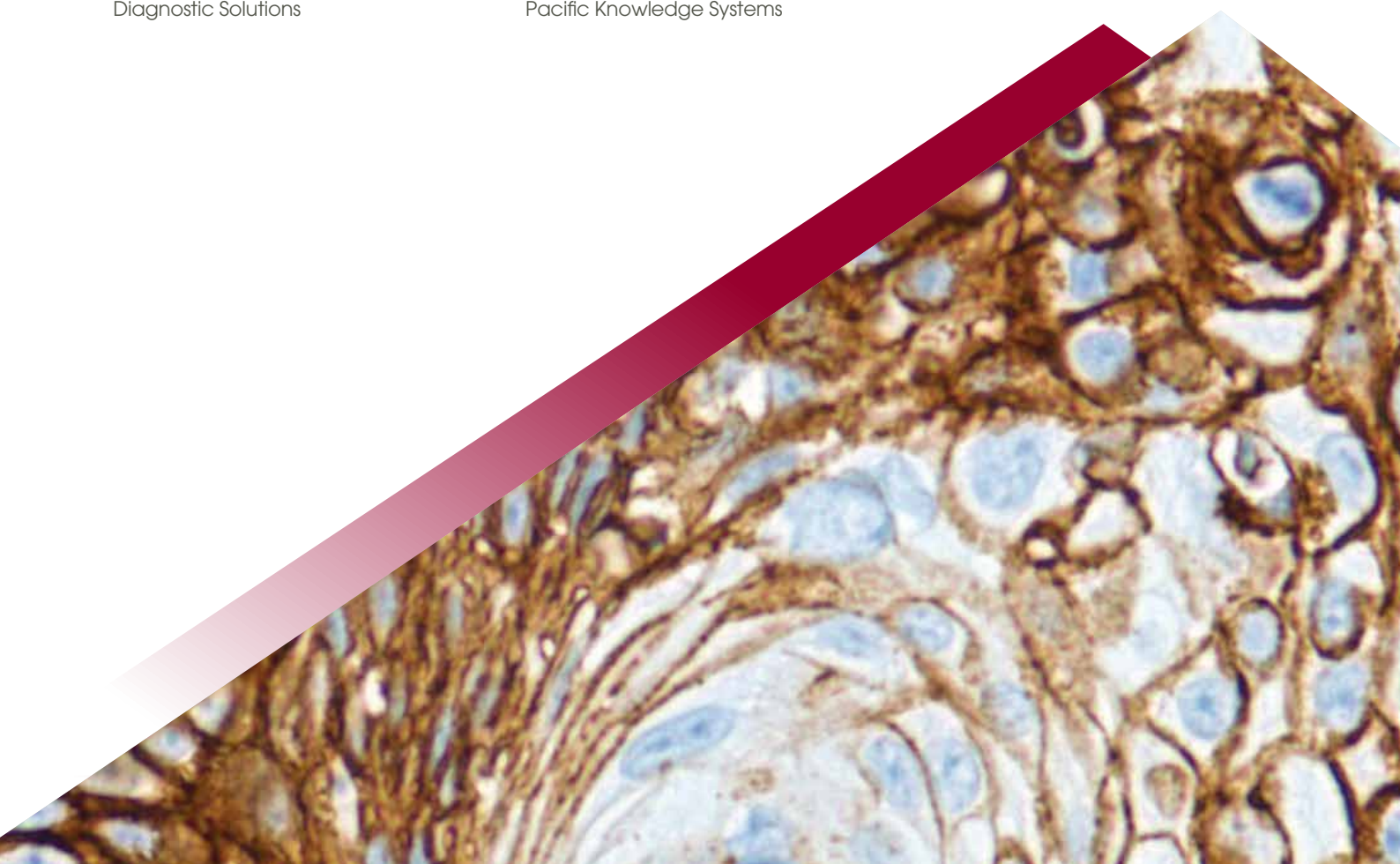
# IVD MEMBERS

at 30 June 2014

Abacus ALS  
Abbott Diagnostics  
Acrapack  
Agilent Technologies  
Alere  
Archer Emery and Associates  
Astral Scientific  
AsureQuality  
AusDiagnostics  
Australasian Medical and Scientific  
bioMerieux  
Bio-Rad Laboratories  
Biospecifix  
Blackaby Diagnostics  
Brandwood Biomedical  
Cepheid  
Clinical Genomics  
Diagnostic Technology  
Diagnostic Solutions

Diagnostica Stago  
Dutec Diagnostics  
Elitech Group  
ESL Biosciences  
Grifols Australia  
Health World  
Helena Laboratories  
Hemocue Australia  
Hologic  
Illumina  
Immuno  
Integrated Sciences  
Life Bioscience  
Macarthur Cook Group  
Merck Australia  
Minerva Medica  
MP Biomedicals  
Novartis Vaccines and Diagnostics  
Pacific Knowledge Systems

Paragon Therapeutic Technologies  
PerkinElmer  
Point of Care Diagnostics  
Prohealth Asia Pacific  
Qiagen  
R-Biopharm  
Randox  
Roche Diagnostics  
Sequenom  
Siemens Healthcare Diagnostics  
Southern Cross Diagnostics  
Sysmex Asia Pacific  
ThermoFisher Clinical Diagnostics  
Universal Biosensors  
Vela Diagnostics  
Werfen Australia





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