

# ANNUAL REPORT 2016

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# 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 2016 fiscal year marks the close of the seventh year of operations of IVD Australia Ltd. Your industry association has achieved several major milestones within the last year as evidence of our growing profile

## Pathology Awareness

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, Peter Harman, our past CEO as the Company Secretary, our CEO Wendy-Jane on the PAAL Board, and our Executive Assistant Chami providing administrative support.

## A Revised Strategic Plan

In early 2016 the Board and the CEO set about reviewing our Strategic Plan for the next three years. From this session emerged the revised Strategic Plan with the overall objective being the "futureproofing 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.

## 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 2015-2016, we believe that we have made excellent progress on this objective, evidenced by the:

- Launch of the inaugural Australian Global Diagnostics Market Statistics (GDMS) Report, at no additional cost to members
- Excellent working relationship with the Therapeutic Goods Administration regarding the transition of in vitro diagnostics to the new regulatory framework and with the Department of Agriculture regarding the quarantine conditions covering the importation of IVDs.
- Successful nomination of our immediate past Board Member, Paul Cray to the Pathology Business Group of the MSAC and the MBS Review
- Industry-led MSAC trial submission project
- Standards Australia Committee Membership for the Vendor Credentialing Standard; and the revision of the Australian Standard for Detection of Drugs in Oral Fluids (AS4760)
- Contribution to the CIE Health Economics Report

## Changing of the Guard

Two long-standing Directors namely Bruce Evans (Abacus-ALS) and Patrick Cook (Macarthur Cook Group) retired in February. I would like to acknowledge and congratulate these two individuals for their outstanding contribution to IVD Australia; and especially for their role in the formation of a stand-alone IVD focused industry association.

## Vote of Thanks

Finally, I would like to acknowledge the contribution of my fellow Board Members – Bernadette Snopek (Perkin Elmer), John Crothers (Abbott Diagnostics), Jim Kakaflikas (QIAGEN Australia), Tristan Duggan (Diagnostic Solutions), David Basseal (Becton Dickinson), Ted Maione (Werfen Australia), Rayden Rivett (Cepheid), Vito Trifilo (Tecan Australia). I would also like to acknowledge the contribution of Mark Laubscher to the Finance, Audit & Risk Management Committee, our secretariat (Wendy-Jane and Chami), plus the many committee members who do important work in their areas of expertise.

In the coming twelve months we will see significant activity around the funding of pathology; activation of the Code of Conduct Certification Program; innovation and market development; and branding of the association.

In vitro diagnostic companies have played a significant role as suppliers and enablers in achieving efficiencies, savings and greater quality through the provision of highly automated pathology solutions coupled with world best practice in after-sales support. It is time to capitalise on the innovative capacity of the IVD Industry.

Sebastian D'Angelo  
Chairman, IVD Australia



## 2016 A LOOK AT WHAT WE'VE ACHIEVED

Every year, IVD Australia looks to add value by achieving things as an organisation that our Members cannot achieve on their own, and this past year, we have improved the business conditions for IVD businesses, increased the advocacy power of the industry and have commenced projects that will improve market access. This year we reviewed our Strategic Plan to ensure IVD Australia is working on the right issues that matter most to you. We need to make sure that all our Members are able to have input into our advocacy and other focussed activities we undertake. In this regard, 2016 saw the first of our roadshows that allow for in-depth interaction with industry peers; and where discussions delve into participant-directed topics of immediate concern.

# CEO'S REPORT

### The Planning Process

They say we live in interesting times, and IVD Australia is leading the discussion on changes in our environment. In March this year, IVD Australia asked all members to complete a survey to direct our 2015 - 2018 Strategic Plan Review, and workshopped for over eight hours to come to an overview of our progress, best achievements, gaps and weaknesses and the importance of each pillar of our strategy. We emerged with the vision of the ideal environment

### IVD Australia's Vision

The IVD industry in Australia is recognised as an integral component of a sustainable healthcare system

- All the major industry parties in or contributing to IVD Australia because they are experiencing the value
- Overall - increase in reimbursement
- Continual inclusion (proactively sought for opinion) on major committees and working groups - funding, reimbursement, policy

### What we need to do to get to our Vision of the ideal environment

In the short to medium term IVD Australia will facilitate the delivery of high quality healthcare to all Australians through the provision of high quality pathology testing; and the two strategic pillars that will help us realise our vision through our purpose statement are:

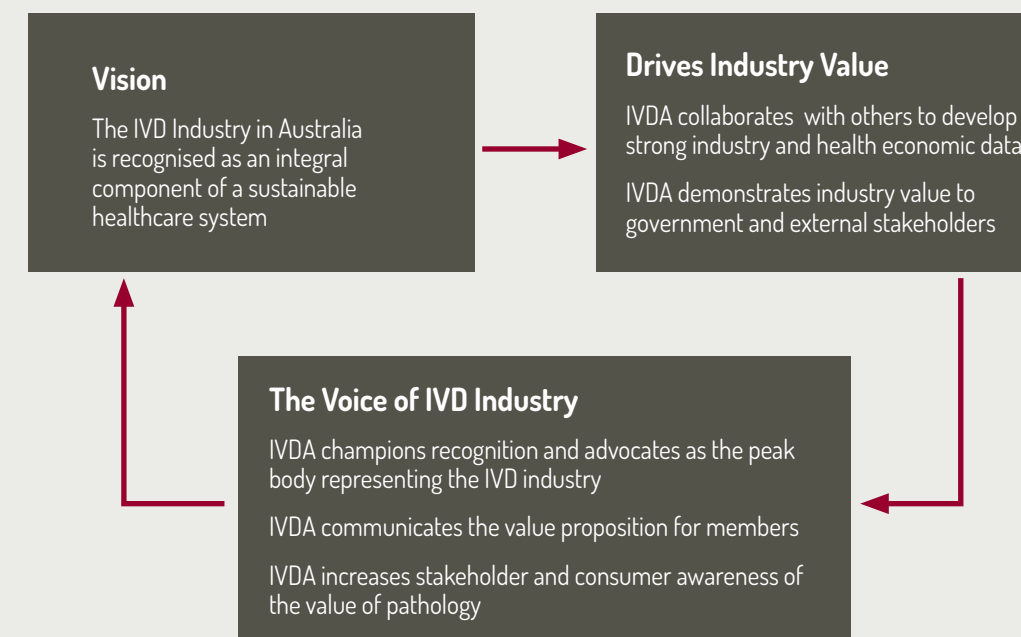
- Being the Voice of Industry and
- Driving industry value

### IVD Australia's Purpose Statement

#### The Voice of the IVD Industry

To facilitate the delivery of high quality healthcare to all Australians through the provision of high quality pathology testing.

#### Driving Industry Value



### When we open these strategic pillars ...

We can see how we will achieve our Vision of the IVD Industry in Australia being recognised as an integral component of a sustainable healthcare system.

#### The Voice of IVD the Industry

- Actively participate in Pathology Awareness Australia (PAA)
- Redevelop and actively communicate with to share our value proposition
- Identify and address critical industry needs and issues
- Build representation on external committees and working groups

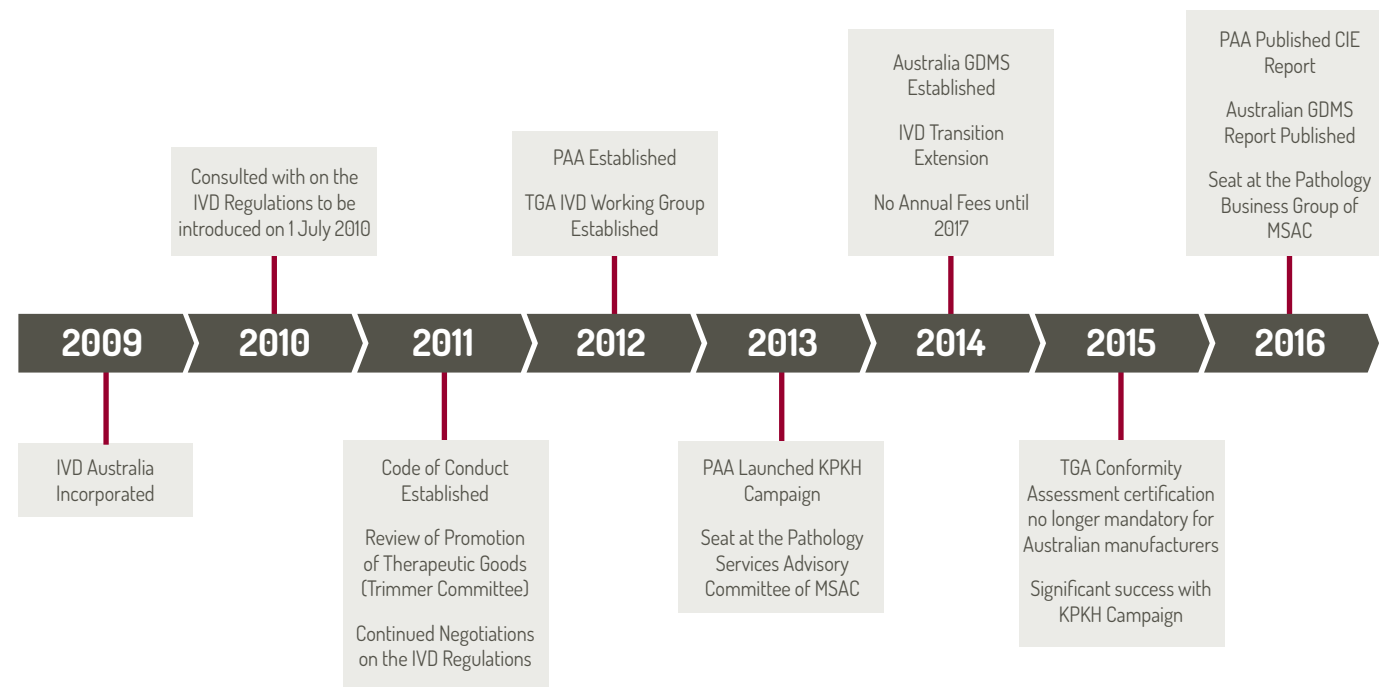
#### Drives Industry Value

- Grow the value and credibility of Australian Industry Data (GDMS)
- Drive collaboration to increase availability of strong national and international health economic data
- Develop targeted advocacy
- Utilise data to communicate industry value



## A LOOK BACK AT OUR ACHIEVEMENTS

For such a young industry association, IVD Australia is punching well above its weight. The IVD Regulations were a significant focus over the transition and we negotiated solid outcomes with the TGA to ensure industry would not be over-burdened by the introduction of the legislation.



### Pathology Awareness Australia

A special vote of thanks needs to go to Peter Harman and John Crothers for their tireless efforts to establish and grow the Know Pathology Know Healthcare Campaign, which maintains a key focus in the improve awareness and understanding of the pathology sector among the decision makers – politicians and consumers.

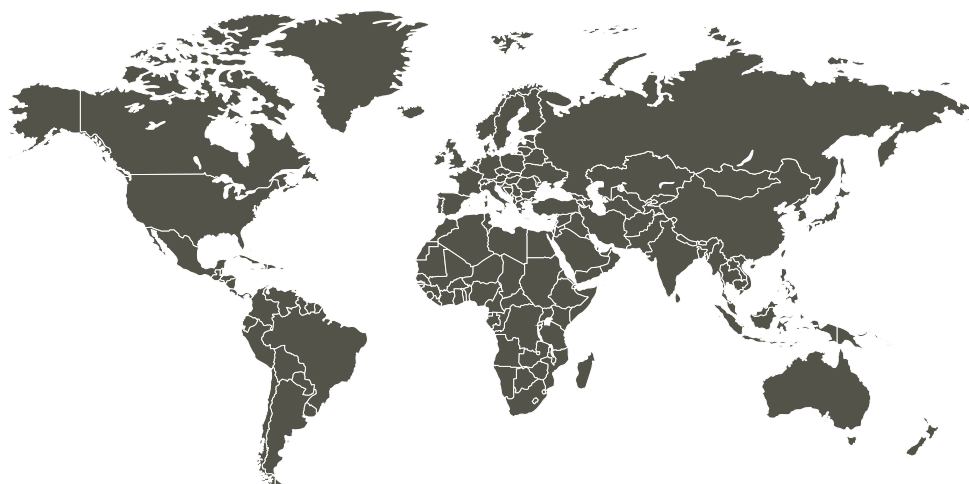
### Australian Diagnostic Market Statistics

The first Australian Edition of the Global Diagnostic Market Statistics program (GDMS) was published in 2015 and this milestone was the first step in improving the position of our industry in the Pathology sector. As more data is received, and more companies join the program, we will see trends and issues arise that will inform long-term growth strategies for our members.

IVD Australia is committed to this project and no fees are paid by members to contribute.

## Contribution of the IVD Industry to Healthcare

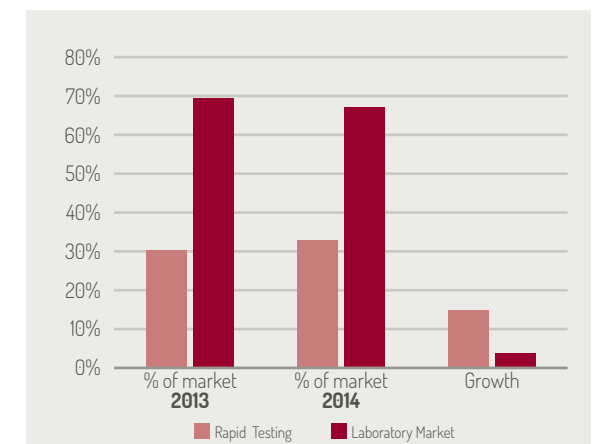
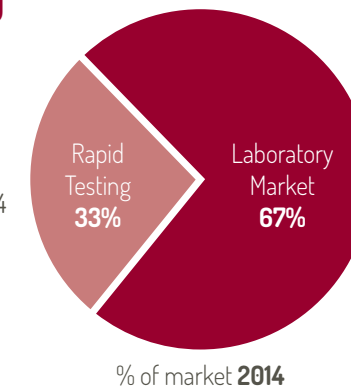
- **Companies** report directly to an independent, non-profit organisation, their product-level national net invoiced sale.
- **Frequency:** quarterly
- **Reporting** is made at controlled parameter levels in Australian Dollars
- **Cost** to Members: Free



## Contribution of the IVD Industry to Healthcare CONTINUED

### Percentage of Growth of the:

- Whole Australian market from 2013 to 2104  
• **+7.2%**
- Laboratory Market  
• **+4.2%**
- Rapid Testing including PoCT  
• **+14.0%**



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

With over 3,000 employees across 60+ companies, IVD companies are an integral component of the **Pathology Value Chain**

### Having a Seat at the Table

IVD Australia is acutely aware that without a role in discussions of key importance to our industry will result in unintended consequences for our industry, this year we have participated in the following: Pathology Business Group of MSAC (MBS Review); Pathology Awareness Australia (KPKH Campaign); TGA IVD Working Group; TGA RegTech Forum; Department of Agriculture Biological Consultative Group; Protocol Advisory Sub-Committee of MSAC; Standards Australia and the National Pathology Accreditation Advisory Council.

### MBS Review

The Australian government's review of the medical benefits schedule is looking at the 'clinical evidence' to support items on the list, which could soften growth in pathology services. This in turn could have a devastating or beneficial impact on our industry and IVD representation in the review was imperative. IVD Australia has an important role in the MBS review, with a position on the Pathology Business Group.

### Collaborative Training: Medical Devices Industry & TGA

This important training event is organised by members of the Regulatory and Technical Consultative Forum (RegTech Forum) to help all sponsors and manufacturers better understand the regulation of medical technology. The RegTech Forum is established as a consultative forum to facilitate consultation between the Therapeutic Goods Administration (TGA) and the medical devices industry.

The members of the working group for the event are: IVD Australia; Australian Dental Industry Association; Medical Technology Association of Australia; AusBiotech; and the Therapeutic Goods Administration. These events give our companies unprecedented access to the expertise of the TGA.

### Industry Positioning Activities

- Member of the Pathology Business Group in the MBS Review
- Engagement with Politicians in Industry and Health
- Engagement with Stakeholders
- Member of the TGA Devices Secretariat RegTech Forum
- Membership of MSAC's Pathology Business Group
- Membership of PASC
- Advocacy Agenda
- Several Position Statements
- Membership of NPAAC Point of Care Drafting Committee
- Code of Conduct Certification
- Pre-Budget Submission
- Innovative Cancer Drugs Senate Inquiry
- TGA – IVD Working Group

# 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:

**Mr Sebastian D'Angelo (Chair)**

General Manager, Laboratory Diagnostics Division, Siemens Healthcare – Australia & New Zealand.

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 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 Tristan Duggan (Treasurer)**

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 David Basseal**

David is the Business Director, Australia & New Zealand, BD Diagnostics

David Basseal has over 20 years industry experience in Life Sciences with 10 years specifically in In-Vitro Diagnostics. David commenced his career as a scientific researcher in the field of proteomics. He entered the commercial arena with Bio-Rad Laboratories Australia/ New Zealand and held positions of increasing responsibility over a 7 year period.

Today David is the Business Director for Diagnostics for Australia/ New Zealand at Becton Dickinson (BD). This involves the management of two business segments within BD – Pre-Analytical Systems (PAS) and Diagnostics Systems (DS).

**Mr Jim Kakaflkas**

General Manager, QIAGEN

Jim is Director, Head of Commercial Operations at QIAGEN Pt Ltd and on the QIAGEN Leadership team for Asia Pacific. Prior to joining QIAGEN, Jim was the Enterprise Director at Abbott Diagnostics and was responsible for managing business development for Australia and New Zealand. At Abbott Diagnostics, Jim was also a Director for Global Accounts, working with key customer groups in Europe and the USA. Jim has over 25 years' experience in the In-vitro Diagnostics and healthcare markets, having also worked in a variety of senior marketing, sales and support roles at GlaxoSmithKline and Bayer Diagnostics. Jim started his career as a Medical Scientist in Haematology.

Jim holds a Masters of Business Administration (Australian Graduate School of Management | UNSW) and a Bachelor of Applied Science (MLS) degree from RMIT University.

**Mr Ted Maione**

General Manager, Werfen

Ted is the General Manager of Werfen in Australia, moving from the Boston area of United States three years ago.

Ted's career in the IVD industry has spanned the last thirty years, the first twenty of which were with Abbott Diagnostics and the last ten years have been with Werfen/IL. During the twenty years at Abbott he held eight positions of greater responsibility in five different cities throughout the United States. Ten years ago Ted was recruited by Werfen/IL to be the Director of Global Marketing, where his team are responsible for product development and marketing IL's critical care products throughout the world.

**Mr Rayden Rivett**

General Manager, Cepheid Holdings Pty Ltd

General Manager, Cepheid Holdings Pty Ltd Rayden has been continuously involved in the IVD Industry since 1979 working in sales, marketing and senior management. For 15 years he was Managing Director of bioMerieux in Australia and since 2006 has worked in the USA, Asia-Pacific and more recently in establishing Australian subsidiaries for overseas-based IVD companies. Rayden has represented the IVD sector in the past, being a Board member of MIAA (now MTAA) from 1999 to 2006 and its Vice-Chair (2003-2004), a member of their Diagnostic/IVD Standing Committee 1994-2001, member of the Market Development Committee (1997-2003) and its Chair (2000-2002).

**Ms Bernadette Snopek**

Senior Manager, PERKINELMER Australia.

Bernadette has worked in the healthcare industry for over 20 years. She started her career at the Ludwig Institute for Cancer Research in Parkville as an Assistant Laboratory Manager. Several commercial roles in the Life Sciences industry for a decade and the last ten years have been specific to the Diagnostics industry in South East Asia. She has run her own company manufacturing Australian made goods and self published a book relating to chronic fatigue syndrome/ myalgic encephalomyelitis/ fibromyalgia. The book is an aide for sufferers.

Her current corporate role specializes in Molecular Diagnostics and Nucleic Acid Products supporting the regional team. Bernadette has been involved with TGA and all regional company product registrations in various South East Asian countries in her role with PerkinElmer.

## IVD AUSTRALIA BOARD CONTINUED

**Mr Vito Trifilo**

General Manager, Tecan Australia

I have over 20 years' experience in the Life Science and in vitro diagnostic businesses in the Australian and New Zealand markets. I have had held business development and sales management roles for over 10 years and was an early company representative with AMRAD Pharmacia Biotech during the start-up phase. My

current role is General Manager at Tecan Australia (a position that I have held for over 2 years), with ANZ sales, marketing, legal and regulatory responsibilities. Tecan is a leading global provider of laboratory instruments and solutions (strongly automation focussed) in biopharmaceuticals, forensics and clinical diagnostics.

**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.

**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.

**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-forprofit 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.

**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.

**Director**

Mr Sebastian D'Angelo (Chair)

**Director**

Mr John Crothers (Deputy Chair)

Dated: 12 September 2016

# CODE ADMINISTRATION COMMITTEE

The Code Administration Committee is the body charged with ensuring that the Code continues to reflect community, industry and regulatory standards and values, that it is understood and respected by key stakeholders and that – above all – it is adhered to by our members. Committee members include a consumer representative, representatives of member companies and representatives of professional bodies in the IVD sector. Together they bring the advantage of many different perspectives as well as a wealth of experience to our administration of the Code.

We are required by the Code to conduct a review every three years, so it's time to do it again! Members will recall that in 2013 we undertook an extensive review, drawing on the first three years' experience with the Code and incorporating the recommendations of the Trimmer Committee, which had reviewed codes of practice across all therapeutic goods industry sectors. Without the impetus for significant change either from within industry or externally, it is unlikely that the next Code review will be as extensive as the last. However we will be focussing on the procedure for complaints review and will certainly be seeking input from our members and external stakeholders on this and any other aspect of the Code that is of concern. The Committee will review all comments and suggestions in order to ensure that the Code continues to reflect current standards.

At the 2015 AGM, we introduced our Code Certification Program with the intention of actively promoting it to all member companies. The promotion of the Program was put on hold while the Board considered the development of a Vendor Credentialing initiative, of which the Code Certification Program would have been part. The recent decision not to proceed with that initiative has put the Code Certification Program back on the Agenda, and members can expect to receive information about the Program very shortly. Code Certification is a means by which members can confirm that their company complies with the Code and has established mechanisms for ensuring compliance. A distinctive logo will serve as a visible symbol of Code compliant companies.

We have a busy year ahead... by the next AGM, we aim to have completed the next review of the Code and to report that 100% of members have completed their Code certification.

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 AND REGULATORY STANDING COMMITTEE REPORT

Vendor credentialing has been a key focus for TARSC in 2016 as the IVD and medical device industries seek to manage customer expectations with respect to tenders, supplier evaluations and WHS requirements. As shown in other countries like the USA, allowing third party vendors to take control on behalf of our customers could lead to very costly overheads for IVD sponsors and manufacturers.

TGA consultations have switched to focus on post-market requirements like changes to ARTG entries and, after considerable negotiation by the industry associations, guidance should soon be published on the TGA website. The same is expected of the much-anticipated guidance on changes to Conformity Assessment Certificates. We await the outcome of a public consultation on Clinical Evidence requirements which was disappointing in its lack of consideration of IVDs. Whilst still relevant in terms of concepts to be considered, the IVD Australia position is that a separate guidance is required for IVDs.

IVD Australia has actively participated in a pilot of the new TGA e-business Conformity Assessment application form which is being developed as part of the TGA Business Improvement Program. I'm happy to say it's a vast improvement on the old form and should be launched by year end.

2017 will see the end of the transition period for laboratories manufacturing in-house IVDs to comply with the regulations. Members are reminded this means as of the 1st July 2017 annual fees will apply for all ARTG entries for IVDs.

The next phase for TARSC will be to continue to consult with Government on the recommendations of the Review of Medical Device and Medicines Reforms, particularly in relation to areas such as third party conformity assessment. We will be following the progress of the imminent European Regulations and ensuring their better alignment to the Australian regulations is of benefit to Australian sponsors.

## COMMITTEE MEMBERSHIP THE TECHNICAL AND REGULATORY STANDING COMMITTEE

**Sally Jennings** - Chair  
Abbott Australasia 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**  
SJ Alder

**Fouzia Calder**  
Siemens

**Brett Kennedy**  
Illumina

**Kasey Kime**  
ThermoFisher NZ

**Libby McDermott**  
ESL Bio Science

**Paul Cohen**  
Roche

**Karen McLeod**  
MP Biomedicals

**Dario Pedulla**  
ThermoFisher

**Suellen Blackaby**  
Blackaby Diagnostics

# POINT OF CARE TESTING (PoCT) REPORT

Over the past few years that I have been involved with the IVD-Australia Point Of Care Working Group, there appears to have been growing acceptance of the validity of PoCT by Hospital Pathology Departments and Healthcare professionals.

Some Hospital Laboratories have viewed PoC as a poorly controlled element of Healthcare with associated problems of clinical management of patients.

In a few cases this criticism was valid due to poor PoC training, weak products performance and irregular Quality Control testing. However, in many instances it was unfair criticism borne out of lack of involvement and a sense of the labs competing for the same business as PoC.

The PoCT community had felt that sometimes its path forward was being unnecessarily blocked by bodies such as NATA and Hospital Pathology Services.

On more than one occasion, PoCT advocates have been heard to say "it's like getting Turkeys to vote for Christmas !" (perhaps a slightly more Pommy expression than Australian).

I'm pleased to say that as companies like those represented within the PoC WP, have improved their products, training and support, the acceptance of PoCT by mainline Hospital laboratories has blossomed.

More and more Pathology networks are appointing dedicated PoC Managers, and also embracing the advantages that PoCT Connectivity can bring to improving patient outcomes and cost control.

Being able to monitor PoCT devices remotely and also downloading results into the patient's electronic records is now a reality.

And more of our member companies are now seeing an increase in sales of high quality PoCT in the community. The prevalence of PoCT at Health Centres, Walk-in Centres and High Street Pharmacies is now greater as they are offer well managed PoCT for a wide range of medical conditions.

IVD Australia is proud to report that the PoCT WP once again it will be supporting the Australian College of Rural and Remote Medicine (ACRRM) annual Congress in Canberra.

GP's 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. IVD-Australia will also be displaying at the AACB PoC SES meeting in Adelaide on 11th November.

Internationally, Australia's PoCT community continues to have a healthy involvement. An example of this is the IFCC Working Party which is developing guidelines for PoC Blood Glucose testing in the ICU. There are no less than three Australians on this committee.

Once again my thanks to members of the IVD-Australia PoC WP and the IVD Secretariat for the support and efforts in this important area Healthcare in Australia

## COMMITTEE MEMBERSHIP THE PoCT COMMITTEE

**Martin Roccliffe**  
AMSL (Chair)

**Peter Merrilees**  
PoCD

**Adrienne Ripley**  
Roche

**Daniela Symons-Troy**  
Cepheid

**Danielle Brown**  
HemoCue

**Tim Hinrichs**  
Abbott

**Robyn Smith**  
Alere

**Mark Volling**  
Alere

**Voula Henry**  
BioMérieux

**Helen Persano**  
BioMérieux

**Barry Wilson**  
Abbott

**Adam Barrett**  
HemoCue

**Rachel Coxon**  
Abbott



# VALUE OF PATHOLOGY

In the last 12 months Pathology Awareness Australia has continued to work on the objects of its constitution, namely:

- (1) establish and fund the Program;
- (2) improve awareness and understanding of the pathology sector among the wider community;
- (3) improve awareness and understanding of the pathology sector among the medical community, including medical practitioners and other health care practitioners;
- (4) improve awareness and understanding of the pathology sector among patient and relevant advocacy organisations and to work with them to promote the economic and social value that modern pathology provides to the wider community; and
- (5) undertake, and publicise the results of health economic outcome research (HEOR) relating to the pathology sector

IVD Australia has maintained a strong commitment and leadership on the board of PAA. The united force of PAA is one of the key attributes of our success and we feel that the recent tight federal election as well as the negotiated position for ACC's in Australia with Pathology Australia was part due to the inroads we have made in raising public awareness of the value of pathology.

Pathology Awareness Australia has continued to create a platform of understanding how important pathology is to our healthcare in this country. No doubt there is still much to do and the journey continues.

One of our major achievements has been the Economic Value of Pathology report commissioned by the Centre of International Economics. It has given us a starting point in our need to develop better economic evidence demonstrating the impact we have on the economy in Australia. The report focused on diabetes, heart disease and cancer, highlighting the measurable value pathology contributes supporting these disease states and ultimately healthcare in Australia.

PAA is continuing to improve consumer awareness through the interaction of patients and collectors as well as the next initiative, patient and HCP. A current pilot of GP's administering the business card model is providing positive feedback on its benefit to GP's as well as patients with a focus on health literacy. This will be a significant investment in 2016/17 along with renewed political engagements, social media and special events that all work towards the organisations objectives

IVD Australia members continue to be an important contributor to the value story. We are the R&D of pathology and we have incredible stories to tell on how we impact value. Your active participation in the know pathology know healthcare initiative continues to be critical as we look to engage and enable the 35000 people that work in the pathology industry. Most of these people have the passion for impacting patient's well-being through what we do. A concerted effort is the only way we will achieve the goal of PEOPLE GENUALLY VALUING PATHOLOGY.





# FINANCIAL STATEMENTS

FOR THE PERIOD ENDED  
30 JUNE 2016

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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 12 September 2016.  
The company has the power to amend and reissue the financial statements.

# 30 JUNE 2016 DIRECTORS' REPORT

The directors present their report on the company for the financial year ended 30 June 2016.

The directors present their report on the company for the financial year ended 30 June 2016.

## 1. GENERAL INFORMATION

### (a) Directors

The names of the directors in office at any time during, or since 30 June 2016 are:

Names	Appointed/Resigned
Mr Sebastian D'Angelo (Chair)	20 February 2014 to present
Mr John Crothers (Deputy Chair)	14 October 2011 to present
Mr Tristan Duggan (Treasurer)	15 October 2014 to present
Mr David Basseal	25 February 2016 to present
Mr Jim Kakaflikas	17 September 2015 to present
Mr Ted Maione	17 September 2015 to present
Mr Rayden Rivett	17 September 2015 to present
Ms Bernadette Snopek	17 September 2015 to present
Mr Vito Trifilo	17 September 2015 to present
Mr Patrick Ian Cook	22 October 2010 to 25 February 2016
Mr Bruce William Evans	8 July 2009 to 25 February 2016
Mr Paul Cray	8 July 2009 to 17 September 2015
Mr Mark Veiling	10 December 2009 to 17 September 2015
Mr Simon Pratt	17 October 2013 to 10 July 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 2016-17
- 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 direct 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 deficit of the Company for the financial year ended 30 June 2016 amounted to \$60,473 (2015: net surplus of \$15,932).

#### (ii) Dividends

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



DIRECTOR’S 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 2016. 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.

(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).

(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 is a director at the date of this report are:

Mr Sebastian D’Angelo  
(Chair)

General Manager, Laboratory Diagnostics Division, Siemens Healthcare – Australia & New Zealand.

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 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 Tristan Duggan  
(Treasurer)

Managing Director, Diagnostic Solutions Ply 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 David Basseal

David is the Business Director, Australia & New Zealand, BD Diagnostics

David Basseal has over 20 years industry experience in Life Sciences with 10 years specifically in In-Vitro Diagnostics. David commenced his career as a scientific researcher in the field of proteomics. He entered the commercial arena with Bio-Rad Laboratories Australia/New Zealand and held positions of increasing responsibility over a 7 year period.

Today David is the Business Director for Diagnostics for Australia/New Zealand at Becton Dickinson (BD). This involves the management of two business segments within BD – Pre-Analytical Systems (PAS) and Diagnostics Systems (DS).

Mr Jim Kakaflkas

General Manager, QIAGEN

Jim is Director, Head of Commercial Operations at QIAGEN Pt Ltd and on the QIAGEN Leadership team for Asia Pacific. Prior to joining QIAGEN, Jim was the Enterprise Director at Abbott Diagnostics and was responsible for managing business development for Australia and New Zealand. At Abbott Diagnostics., Jim was also a Director for Global Accounts, working with key customer groups in Europe and the USA. Jim has over 25 years’ experience in the In-vitro Diagnostics and healthcare markets, having also worked in a variety of senior marketing, sales and support roles at GlaxoSmithKline and Bayer Diagnostics. Jim started his career as a Medical Scientist in Haematology.

Jim holds a Masters of Business Administration (Australian Graduate School of Management | UNSW) and a Bachelor of Applied Science (MLS) degree from RMIT University.

Mr Ted Maione

General Manager, Werfen

Ted is the General Manager of Werfen in Australia, moving from the Boston area of United States three years ago.

Ted’s career in the IVD industry has spanned the last thirty years, the first twenty of which were with Abbott Diagnostics and the last ten years have been with Werfen/IL. During the twenty years at Abbott he held eight positions of greater responsibility in five different cities throughout the United States. Ten years ago Ted was recruited by Werfen/IL to be the Director of Global Marketing, where his team are responsible for product development and marketing IL’s critical care products throughout the world.

Mr Rayden Rivett

General Manager, Cepheid Holdings Pty Ltd

General Manager, Cepheid Holdings Pty Ltd Rayden has been continuously involved in the IVD Industry since 1979 working in sales, marketing and senior management. For 15 years he was Managing Director of bioMerieux in Australia and since 2006 has worked in the USA, Asia-Pacific and more recently in establishing Australian subsidiaries for overseas-based IVD companies. Rayden has represented the IVD sector in the past, being a Board member of MIAA (now MTAA) from 1999 to 2006 and its Vice-Chair (2003-2004), a member of their Diagnostic/IVD Standing Committee 1994-2001, member of the Market Development Committee (1997-2003) and its Chair (2000-2002).

DIRECTOR’S REPORT CONTINUED

Ms Bernadette Snopek	<p>Senior Manager, PERKINELMER Australia.</p> <p>Bernadette has worked in the healthcare industry for over 20 years. She started her career at the Ludwig Institute for Cancer Research in Parkville as an Assistant Laboratory Manager. Several commercial roles in the Life Sciences industry for a decade and the last ten years have been specific to the Diagnostics industry in South East Asia. She has run her own company manufacturing Australian made goods and self published a book relating to chronic fatigue syndrome/myalgic encephalomyelitis/fibromyalgia. The book is an aide for sufferers.</p> <p>Her current corporate role specializes in Molecular Diagnostics and Nucleic Acid Products supporting the regional team. Bernadette has been involved with TGA and all regional company product registrations in various South East Asian countries in her role with PerkinElmer.</p>
Mr Vito Trifilo	<p>General Manager, Tecan Australia</p> <p>I have over 20 years’ experience in the Life Science and in vitro diagnostic businesses in the Australian and New Zealand markets. I have had held business development and sales management roles for over 10 years and was an early company representative with AMRAD Pharmacia Biotech during the start-up phase. My current role is General Manager at Tecan Australia (a position that I have held for over 2 years), with ANZ sales, marketing, legal and regulatory responsibilities. Tecan is a leading global provider of laboratory instruments and solutions (strongly automation focussed) in biopharmaceuticals, forensics and clinical diagnostics.</p>
Mr Mark Volling	<p>Regional Managing Director, Alere Pty Ltd.</p> <p>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).</p> <p>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).</p>
Mr Simon Pratt	<p>Division Manager, Clinical Diagnostic group – Pacific Region, Bio-Rad Laboratories.</p> <p>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.</p> <p>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.</p>
Mr Bruce Evans	<p>Non-Executive Director, Abacus Pty Ltd.</p> <p>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</p>
Mr Patrick Cook	<p>Director, Macarthur Cook Group Pty Ltd.</p> <p>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.</p> <p>Patrick worked as a medical scientist for both public and private laboratories and previously held sales &amp; senior marketing positions at Abbott Diagnostics, Roche Diagnostics and Agen Ltd (an Australian publically listed biotechnology manufacturer and exporter).</p> <p>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.</p>
Mr Paul Cray	<p>Managing Director, Roche Diagnostics Australia Pty Ltd.</p> <p>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.</p> <p>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.</p> <p>Paul is a Member of the Australian Institute of Company Directors.</p>

2. MEETING OF DIRECTORS

During the financial year, 6 meetings of directors (including committees of directors) were held. Attendances by each director during the year were as follows:

	DIRECTOR’S MEETINGS	
	NUMBER ELIGIBLE TO ATTEND	NUMBER ATTENDED
Mr Sebastian D’Angelo (Chair)	6	6
Mr John Crothers (Deputy Chair)	6	5
Mr Tristan Duggan (Treasurer)	6	4
Mr David Basseal	3	2
Mr Ted Maione	5	4
Mr Vito Trifilo	4	3
Ms Bernadette Snopek	5	4
Mr Rayden Rivett	5	4
Mr Jim Kakaflikas	5	4
Mr Paul Cray	2	1
Mr Mark Volling	2	2
Mr Simon Pratt	1	1
Mr Patrick Ian Cook	4	3
Mr Bruce William Evans	4	4

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 2016 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  
Mr Sebastian D;Angelo (Chair)

Dated: 12 September 2016

  
Director  
Mr John Crothers (Deputy Chair)

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

Date: 12 September 2016

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 2016, I declare that, to the best of our 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

Sydney



**Joseph Santangelo**  
Partner

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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 2016, 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 2016 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.

Yours sincerely



**Nexia Court & Co**  
Chartered Accountants

Sydney

Dated: 12 September 2016



**Joseph Santangelo**  
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 13 to 21, 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 2016 and of the performance for the year ended on that date of the Company.
2. There are reasonable 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**  
Mr Sebastian D'Angelo (Chair)



**Director**  
Mr Tristan Duggan (Treasurer)

Dated: 12 September 2016

# STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the Year  
Ended 30 June 2016

		2016	2015
	Note	\$	\$
Revenue	2	388,717	418,788
Interest Income		9,914	6,278
<b>TOTAL INCOME</b>		<b>398,631</b>	<b>425,066</b>
Employee benefits expense	3 (a)	(253,158)	(252,551)
Depreciation expense	3 (b)	(2,100)	(1,678)
Administrative expenses		(203,846)	(154,303)
Loss on sale of non-current asset			(602)
<b>TOTAL EXPENSES</b>		<b>(459,104)</b>	<b>(409,134)</b>
<b>(DEFICIT)/SURPLUS FOR THE YEAR</b>		<b>(60,473)</b>	<b>15,932</b>
<b>OTHER COMPREHENSIVE INCOME</b>			
Other comprehensive income			
<b>TOTAL COMPREHENSIVE INCOME FOR THE YEAR</b>		<b>(60,473)</b>	<b>15,932</b>

# STATEMENT OF FINANCIAL POSITION

As At 30 June 2016

	Note	2016 \$	2015 \$
<b>ASSETS</b>			
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	4	274,615	364,699
Trade and other receivables	5	4,294	15,684
<b>TOTAL CURRENT ASSETS</b>		<b>278,909</b>	<b>380,383</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment	6	1,411	3,511
<b>TOTAL NON-CURRENT ASSETS</b>		<b>1,411</b>	<b>3,511</b>
<b>TOTAL ASSETS</b>		<b>280,320</b>	<b>383,894</b>
<b>LIABILITIES</b>			
<b>CURRENT LIABILITIES</b>			
Trade and other payables	7	22,091	45,704
Employee benefits	8	26,492	10,015
Income received in advance	9	63,839	99,804
<b>TOTAL CURRENT LIABILITIES</b>		<b>112,422</b>	<b>155,523</b>
<b>NET ASSETS</b>		<b>167,898</b>	<b>228,371</b>
<b>EQUITY</b>			
Retained earnings		167,898	228,371
<b>TOTAL EQUITY</b>		<b>167,898</b>	<b>228,371</b>

# STATEMENT OF CHANGES IN EQUITY

For the Year Ended 30 June 2016

2016	RETAINED EARNINGS \$	TOTAL \$
Balance at 1 July 2015	228,371	228,371
Loss for the year	(60,473)	(60,473)
<b>Balance at 30 June 2016</b>	<b>167,898</b>	<b>167,898</b>

2015	RETAINED EARNINGS \$	TOTAL \$
Balance at 1 July 2014	212,439	212,439
Profit for the year	15,932	15,932
<b>Balance at 30 June 2015</b>	<b>228,371</b>	<b>228,371</b>

# STATEMENT OF CASH FLOW

For the Year  
Ended 30 June 2016

	Note	2016 \$	2015 \$
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Receipts from customers		385,685	518,342
Payments to suppliers and employees		(485,683)	(440,583)
Interest received		9,914	10,200
		(90,084)	87,959
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchase of property, plant and equipment			(1,233)
			(1,233)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Net (decrease)/ increase in cash and cash equivalents		(90,084)	86,726
Cash and cash equivalents at beginning of year		364,699	277,973
Cash and cash equivalents at end of financial year	4	274,615	364,699

# NOTES TO THE FINANCIAL STATEMENT

For the Year  
Ended 30 June 2016

## 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 STATEMENT 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 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.

Deprecation 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

	2016	2015
	\$	\$
Member subscriptions	388,717	400,753
Associate member		14,250
Training Income		3,785
	388,717	418,788

## 3. EXPENSES

(A) EMPLOYEE BENEFITS EXPENSE		
Wages and salaries	232,379	230,294
Other associated personnel expenses		300
Superannuation	20,779	21,957
	253,158	252,551

(B) DEPRECIATION EXPENSE		
Depreciation - computer equipment	1,581	1,131
Depreciation - furniture and fixtures	519	547
	2,100	1,678

## 4. CASH AND CASH EQUIVALENTS

Cash at bank	74,615	124,699
Term deposits	200,000	240,000
	274,615	364,699

## 5. TRADE AND OTHER RECEIVABLES

Trade receivables	2,129	124,699
GST Paid	2,165	15,684
	4,294	15 684

## NOTES TO THE FINANCIAL STATEMENT CONTINUED

### 6. PLANT AND EQUIPMENT

	2016	2015
	\$	\$
Furniture, fixtures and fittings – at cost	2,589	2,589
Accumulated depreciation	(2,090)	(1,572)
	(1,572)	1,017
Computer equipment – at cost	9,254	10,377
Accumulated depreciation	(8,342)	(7,883)
	912	2,494
<b>Total property, plant and equipment</b>	<b>1,411</b>	<b>3,511</b>

#### (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, FIXTURE & FITTINGS	COMPUTER EQUIPMENTS	TOTAL
	\$	\$	\$
<b>YEAR ENDED 30 JUNE 2016</b>			
Balance at the beginning of year	1,018	2,493	3,511
Depreciation expense	(519)	(1,581)	(2,100)
<b>Balance at the end of the year</b>	<b>499</b>	<b>912</b>	<b>1,411</b>

### 7. TRADE AND OTHER PAYABLES

Accrued expenses	10,000	9,495
Other payables	12,091	36,209
	22,091	45,704

### 8. EMPLOYEE BENEFITS

Provision for annual leave	26,492	10,015
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### 9. OTHER LIABILITIES

	2016	2015
	\$	\$
Income in advance	63,839	99,804

### 10. AUDITORS REMUNERATION

<b>Payable to the auditors of the company – Nexia Court &amp; Co</b>		
Audit services	10,000	9,494
Non-audit services	760	
	10,760	9,494

### 11. SUPERANNUATION COMMITMENTS

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

### 12. 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: \$187,724 (2015: \$205,306). 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.

### 13. 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 AUSTRALIA MEMBERS

at 30 June 2016

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

# Associate members





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