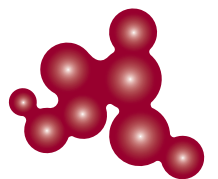




Annual Report

2017

IVD  
AUSTRALIA



# The Value of being an IVD Australia member in 2016-2017

Each year, the IVD Australia Board asks the question about the value of being a member of IVD Australia, and the answer is clear.

Being part of IVD Australia pertains to having a seat at the table to gain access to those within our environment that influence our business. Through such access, we are able to exert greater influence as a collective industry body compared to what an individual organisation can achieve.

Below are some examples to date:

- IVD Australia has been a key player in protecting the industry from budget cuts. IVD Australia is a co-founder and key driver of Pathology Awareness Australia (PAA), a company that was established to raise the awareness of the value of pathology. Through the Know Pathology Know Healthcare initiative we have been successful elevating the value of pathology to government. An example of this success was the impact of the Don't Kill Bulk Bill campaign. This campaign activated the general public and resulted in the government not implementing cuts of \$400M to the pathology budget. This was acknowledged by the Federal Health Minister Hon Greg Hunt MP in a recent conversation with John Crothers, IVD Australia Board Director.
- The collective representation of the industry with the TGA continues to save considerable time and money for members – the first fees will be due to be paid from 1 July 2017 compared to the 1 July 2015 original requirement. This has saved the industry significant expenditure.
- The code of conduct is important and through our seat at the table we will be able to ensure this organisation continues to drive compliance of members to a higher ethical standard.
- The Pathology Business Group is a sub-committee formed to advise government as part of the MBS Review. IVD Australia has representation on this important committee. The board via its nominated representative has direct influence on this committee.

The IVD Australia Board also answered the question “what would be missed if IVD Australia was to dissolve?” Whilst the items above were cited, it is also the potential of what the association can achieve that was highlighted as the answer. In particular, IVD Australia aims to ensure that pathology is valued as a key component of the healthcare system and in turn making it easy for member companies like yours to operate. Efforts that are already under way include:

1. Increasing the involvement of IVD companies in the MSAC process: We are working on streamlining the MSAC submission process. IVD Australia is working directly with the RCPA to achieve this.
2. Representing the industry to ensure business requirements are equitable: IVD Australia represents the industry and engages the public health system and GS1 to reduce the burden and cost of the requirements to comply with NPC and RecallNet.
3. Increasing the appreciation of pathology through better understanding the economic value. IVD Australia is working with its members to quantify the total amount of tests performed in Australia. By quantifying the number of tests sold by IVD companies to public and private pathology institutions, IVD Australia will be able to provide critical information to government regarding the true number of tests performed in Australia. Today this information is limited given the coming of tests through the MBS and the large number of tests performed in public institutions and funded directly by the state. Such information can enable a better conversation on evidence based pathology and our collective impact on the well-being of Australians. Such information will provide the industry more relevance and an important seat at the table when negotiating with government and advocating on the industry's behalf.

IVD Australia is the peak body advocating for the best interests of its members and protecting the business environment in which we operate. Our membership, and more importantly, our active participation, ensures all our members have a voice and input in all the endeavours mentioned above.



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# Report



## CHAIRMAN'S

The end of the 2017 fiscal year marks the close of the eighth 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.

### Value for Members

On the inside front cover of this Annual Report, you will read about the Board's Strategic Planning Day outcomes, during which we scrutinised the value of being a member of IVD Australia; and what would be missed if IVD Australia was to dissolve.

### 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; and Standards Australia. Being part of IVD Australia pertains to having a seat at the table to gain access to those within our environment that influence our business. Through such access, we are able to exert greater influence as a collective industry body compared to what an individual organisation can achieve.

### 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), and Vito Trifilo (Tecan Australia). Their dedication to IVD Australia and our Industry has enabled us to drive the strategic agenda at an ever increasing pace.

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.

I would like to close by thanking all member companies and their staff for their ongoing commitment to IVD Australia. 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 rebranding 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



# Report



CEO's

2016-2017 was the year for “getting it done”. Our continued focus on delivering results on member issues saw the organisation drive strong growth in new strategic initiatives in FY17. We are strongly positioned for continued growth in FY18.

## Lifting Brand Awareness

This year we established our Marketing & Communications Committee to continuously improve our Member and Stakeholder communications, renew our brand and redevelop our website. More than Words, the Value of our Industry: In March this year, PAA hosted the Diabetes Parliamentary Group and provided Parliamentarians with HbA1c tests. The event highlighted pathology's critical role in diagnosis and management of Diabetes. There have been 52 pathology lab tours by politicians, including Malcolm Turnbull, Bill Shorten, Greg Hunt, Catherine King and other very familiar names. As pathology remains largely hidden, it is important that decision makers understand its integral role in order to make informed policy choices. Politicians are given a look behind the laboratory doors to learn how pathology underpins diagnosis, effective treatment and preventative healthcare.

## Investing in Strategic Projects for Critical Industry Needs & Issues

Market access is the lifeblood of our industry. Even incremental improvements in market access arrangements can make major gains for industry. This year IVD Australia has worked on two key projects in this area, a trial generic MSAC submission that will provide the foundation for more industry-led submissions; and we have worked closely with the Department of Agriculture and Water Resources (through the BCG, previously AQIS) to improve import conditions for large and small companies. The work of the Technical & Regulatory Committee is never-ending as we work alongside the TGA to improve guidance for IVD sponsors.

Some of the projects we have undertaken, or commenced this year, including Drug & Alcohol Workplace Testing Standard, MSAC – RCPA Project, National Product Catalogue, Vendor Credentialing, MBS Review, Genomics, Choosing Wisely, Funding, Code Of Conduct, Eu Legislation, Antimicrobial Resistance, Import / Export, GS1 Recallnet, Bulk Billing Incentive.

Another solid year with a return to a small profit, FY17 will allow us to focus, even more, on pursuing strategic issues.

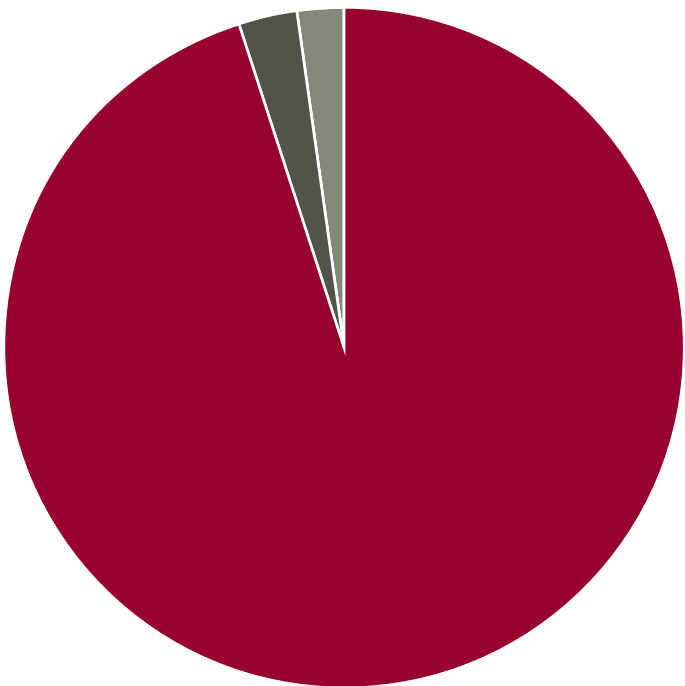


# TREASURER'S Report

I would like to present the IVD Australia accounts for the financial year ending June 30, 2017. The accounts, audited by Nexia Australia, are included in this Annual Report and are available to those who wish to have a copy.

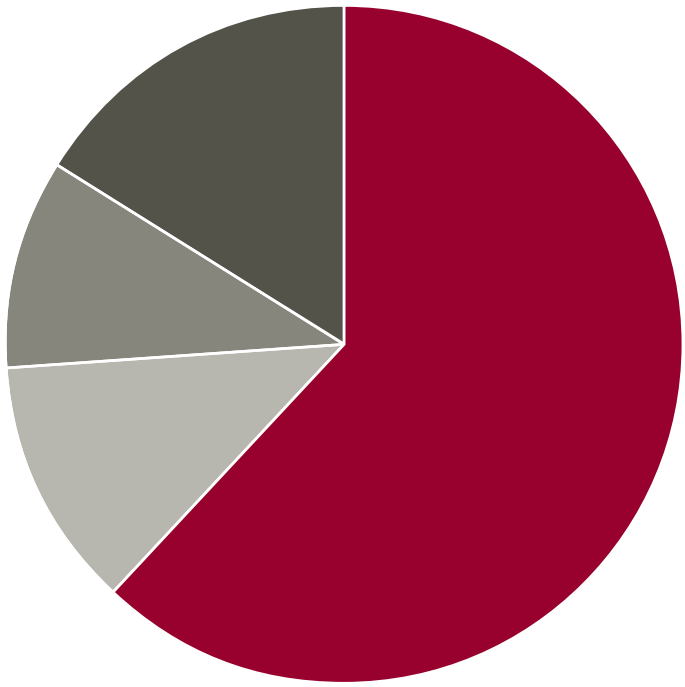
Against a backdrop of a number of years where financial reserves were depleted, I am pleased to report that, through careful control of costs, we have ended the year with a positive balance. Whilst a small amount of that surplus is committed to cover costs in the 2017-2018 financial year, we continue to ensure the financial stability and security of the organisation; and invest in strategic projects to support our members.

Our income for the year was approximately \$473,807 from a combination of membership, training, events and interest. This income is an increase of approximately \$75,176 on last year's income.



## IVD Australia Income

Our expenditure for the year was \$439,708. The majority of this expenditure was for employment costs, administration, events and training. Special Projects accounted for \$69,414, including the Code of Conduct, Pathology Awareness Australia, the Australian GDMS and Health Economics. Full details of both the income and expenditure can be found in the accounts.



## IVD Australia Expenditure

In summary, I am pleased to report a successful year with the financial position of IVD Australia being stronger as we leave the year than when we entered it.  
Tristan Duggan



# IVD AUSTRALIA Board

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

## **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 David Basseal (Deputy Chair)**

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 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 John Crothers**

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 Jim Kakaflikas**

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

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 bioMérieux 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).

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## **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.

## **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.



# Strategic Plan

## REPORT

### Acronyms

<b>AdvaMedDx</b>	American Diagnostics arm of AdvaMed (association)
<b>BCG</b>	Biological Consultative Group (DoAWR)
<b>CAC(WG)</b>	Code Administration Committee (Working Group)
<b>DAT (WG)</b>	Drug & Alcohol Testing (Working Group)
<b>DoAW</b>	Department of Agriculture & Water Resources
<b>GDA</b>	Global Diagnostic Alliance
<b>GDMS (WG)</b>	Global Diagnostic Market Statistics (Working Group)
<b>GMTA</b>	Global Medical Technology Alliance
<b>GS1</b>	GS1 Australia (company)
<b>IAMR</b>	International Antimicrobial Resistance Project - AdvaMedDx
<b>KPKH</b>	Know Pathology Know Healthcare Initiative
<b>M&amp;CC</b>	Marketing & Communication Committee
<b>MBS</b>	Medicare Benefits Schedule
<b>MDC</b>	Market Development Committee
<b>NPC (WG)</b>	National Product Catalogue (Working Group)
<b>PBG</b>	Pathology Business Group
<b>PoC</b>	Policy Committee
<b>PoCT (WG)</b>	Point of Care Testing (Working Group)
<b>RCPA</b>	Royal College of Pathologists of Australasia
<b>RTF</b>	RegTech Forum (TGA & Devices Industry)
<b>TARSC</b>	Technical & Regulatory Standing Committee
<b>TCC</b>	TGA Consultative Committee (TGA & Therapeutic Goods Industry)
<b>TICC</b>	TGA Industry Consultative Committee (TGA, Therapeutic Goods Industry, Consumers)

### 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.

### Vision

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

### Drives Industry Value

IVDA collaborates with others to develop strong industry and health economic data  
IVDA demonstrates industry value to government and external stakeholders

### The Voice of IVD Industry

IVDA champions recognition and advocates as the peak body representing the IVD industry  
IVDA communicates the value proposition for members  
IVDA increases stakeholder and consumer awareness of the value of pathology

### 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

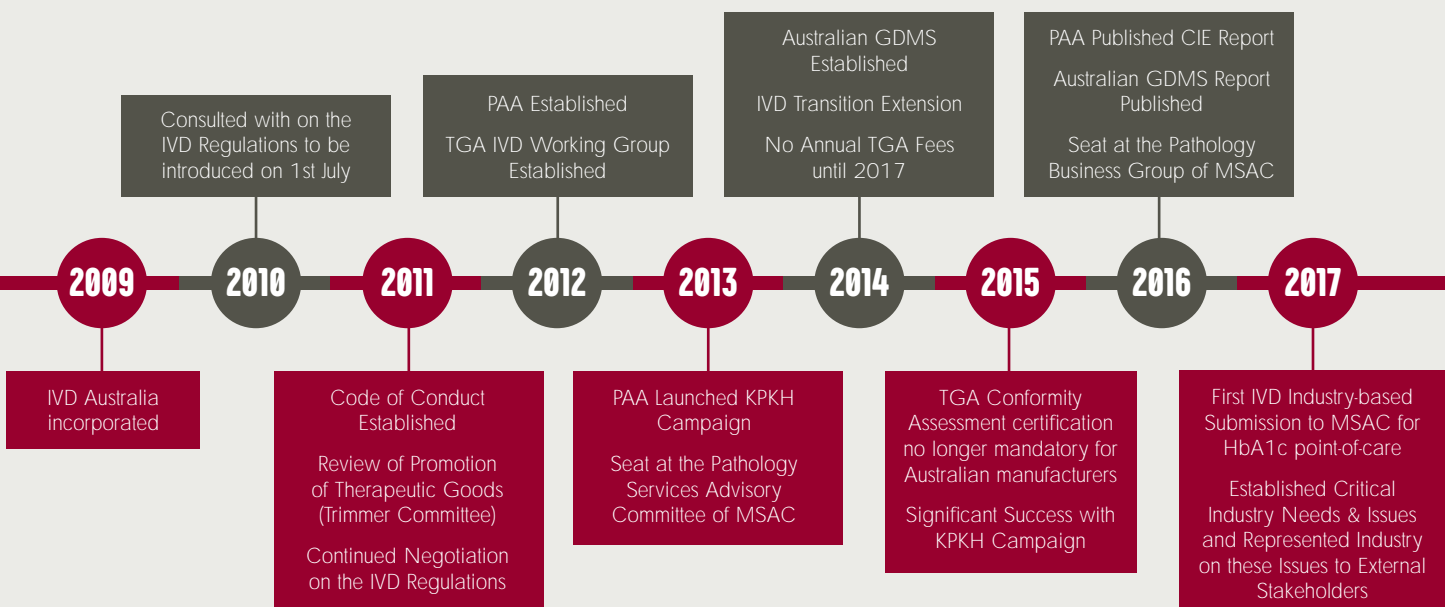
Actively participate in Pathology Awareness Australia (PAA)  
Redevelop and actively communicate with to share our value proposition  
Identify and address critical industry needs and issues  
Build representation on external committees and working groups

### 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.





# Activities

IVD AUSTRALIA  
2017-2018

## Pathology

### Awareness - KPKH

Lab Tours; Parliamentary Events  
Consumer engagement - NGOs  
Company Secretary & Chair  
**MDC**

## Representation

PBG - MBS Review  
Vendor Credentialing  
Dept of Ag - BCG  
GDA, GMTA  
Workplace DAT  
**NPC, PoC, MDC, TARSC, Board, DATWG, NPCWG**

## Advocacy

Stakeholder Engagement - Meeting & Engaging  
Funding of Genomics Proposal  
**PoC**

## Health Economics

Data Generation - RCPA Proposal  
**MDC**

## 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

## Value Proposition

Code Certification  
Code Review  
MSAC Submissions, RCPA Collaboration - MSAC  
Networking & Events  
Website - Redevelopment  
Rebranding IVD Australia  
**CAC, CACWG, MDC, M&CC**

## Critical Industry Needs & Issues

NPC and GS1  
Regulatory - Participation in RTF, TICC, TGAC, BCG  
Vendor Credentialing  
IAMR Project  
Point of Care Testing  
**MDC, TARSC, MDC, PoC, PocTWG**

## 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

## GDMS

Data Reports & Trends  
GDMS WG  
**MDC**

## Utilising the Data

Value-based Funding Event  
Policy Committee developing genomic funding model paper  
**MDC, Poc**





# IVD AUSTRALIA Events

## IVD Australia Networking & Events

Organising Costs, No Income

### AGM

- September w AACB
- Innovation focus

### Updated

- February w Path Update
- Regulatory focus

### Roadshows

- Mid-Year
- IVD Australia focus



## Supported

Organising Costs, No Income

### PAA

- Parliamentary Attendance
- Lab Tour - Ambassadors

### AACB Conference

- Sponsorship
- IVD Event

### ACRRM Conference

- Host an IVD session, w "round-robin"
- Sponsorship

### AACB PoCT SES Day

- IVD Australia "round-robin" Session

### RCPA Path Update

- IVD Australia Event



## Co-Hosted Events

Potential Profit/Loss

### TGA Devices Sponsor Information Day

- ADIA, AMMDA, IVD Australia, MTAA, AusBiotech

### Disruption in Healthcare: Pathology Leadership & Innovation Conference

- AACB, AIMS, IVD Australia, Dark Report



# Marketing & Communications

## COMMITTEE REPORT

The M&CC Marketing & Communications Committee was formed as a new Committee of IVD Australia in 2016. Its purpose was to aid in the review of strategy for external marketing and communications to the broader IVD membership community of our industry organisation.

### The Key Activities the MC&C conducted in FY1617 were:

1. Review of Value of IVD Australia – overall plan & including communication letter to member CEOs
2. Branding review of IVD Australia – general – do we need to update our name?
3. Tagline options for IVD Australia website presented to the Board
4. Website content review – what's good and what could be improved
5. Afternoon Member Roadshows in Melbourne, Sydney & Brisbane May 2017
6. Networking event at AACB Brisbane Sept 2016

### The Goals noted and agreed by committee members in FY1617 were:

1. To improve the perception of the value of IVD Australia to Member Companies
2. Improve branding and perception of our organisation

The Future Goals and Activities for the new FY 1718 are to continue strengthening our external messaging and identity and continue with the work commenced and ongoing in the current year.

The MC&C Committee Members including Jim Kakaflikas, Ted Maione, David Basseal, John Emmerson, Vito Trifilo, Wendy-Jane Morrow [CEO], Chami Gunasinghe [EA] and myself, wish to thank the participating member companies and staff of London Agency and for their involvement and participation in IVD Australia events during the FY1617. The member feedback and requested insights have been beneficial to the IVD Australia Board and Committee in planning future events to consolidate our industry based messaging for the benefit of all IVD Diagnostics companies that we represent into the new financial year and beyond.

### Committee Membership

#### Marketing & Communications Committee

#### John Emmerson

London Agency

#### Bernadette Snopek

PerkinElmer (Chair)

#### Ted Maione

Werfen

#### Jim Kakaflikas

Qiagen

#### David Basseal

Beckman Dickinson

#### Vito Trifilo

Tecan

#### Cassandra Anderson

ThermoFisher

# Market Development

## COMMITTEE REPORT

In 2017, the Market Development Committee is working in two main areas.

- i) Engagement in the MBS inclusion and funding process
- ii) The better use of Invitro Diagnostic local market statistics

### Engagement in the MBS inclusion and funding process

The MBS inclusion and appropriate funding of new and innovative diagnostic tests has been a challenge for our industry for many years. The Market Development Committee has investigated ways that IVD suppliers can better engage stakeholders and contribute to this effort.

As IVD suppliers, we are the R&D of Pathology and such, we play an important role to play in this process. Our ability to communicate the availability of new tests ahead of launch, the release of new testing technologies and the value they will provide in lab efficiencies and health economic impacts, is vital to changing the landscape of funding decisions.

Key for us will be our ability as an industry to provide health economic data to justify listings and appropriate funding that is aligned with the value that they bring to our health ecosystem. Vital in changing the paradigm from cost to value.

In 2017, we engaged with The Royal College of Pathologists of Australasia (RCPA) to collaborate with their efforts to drive MBS inclusions. Although in the early stages, by working together, we hope to leverage our aligned strengths around key new tests and technologies where possible.

The RCPA have already shared with us the test areas they will focus on, while we are currently collecting from IVD Australia members the areas of highest priority.

### The better use of Invitro Diagnostic local market statistics

In 2013, IVD Australia began its support of The Global Diagnostic Market Statistics (GDMS) project which is focused on determining a substantiated figure on the size of the Australian market. The IVD Industry in Australia needs this figure to underpin our approach to government to gain improved access that then enables our ability to position our value proposition that ultimately ensures the sustainability of our respective businesses by ensuring appropriate reimbursement of the innovative solutions that our sector provides healthcare in this country.

The GDMS reports are available to IVD Australia members as part of their membership. In 2017 and leading into 2018, we are working to provide members more comprehensive training in the use and interpretation of these reports.

Thanks to the MDC Committee Members and IVD Australia Board Members for their support and guidance.

### Committee Membership

#### Marketing Development Committee

#### Jim Kakaflikas

Chair

#### Brooke Troth

Bio-Rad

#### Vito Trifilo

Tecan Australia

#### John Crothers

Abbott

#### John Emmerson

London Agency

#### Jennifer Carson

Siemens



# Technical & Regulatory Standing

## REPORT

1st July 2017 saw the absolute end of the transition period for compliance with the Therapeutic Goods (Medical Devices) Regulations 2002. Laboratories manufacturing in-house IVDs must now be compliant with the regulations along with commercial manufacturers. With this, of course, has come annual fees for all ARTG entries for commercial IVDs.

Below is a snapshot of some of the key activities that IVD Australia has either been involved in or provided input to in 2016-17.

Several TGA guidance documents relevant to IVDs have been published in the last 12 months, with more to follow in the coming year. Those published include:

- Substantial changes affecting a TGA conformity assessment certificate and Transfers of certificates,
- Varying entries in the ARTG - medical devices and IVDs,
- Clinical Evidence Requirements.

The Clinical Evidence Requirements guidance is generally applicable to IVDs but TGA has acknowledged further work is required for IVDs. IVD Australia's position is still that a separate guidance is required for IVDs.

In addition to the work on consultation papers, IVD Australia has continued to participate in the pilot of the new TGA e-business

Conformity Assessment application form which is being developed as part of the TGA Business Improvement Program. This is being actively used by those on the pilot now and TGA indicates it will launch soon.

The Medical Device Single Audit Program (MDSAP) has moved out of the pilot phase. With Health Canada phasing out CMDCAS in favour of MDSAP certification, IVD Australia sought clarification from TGA on their acceptance of MDSAP audit reports. TGA has indicated it will accept MDSAP reports in support of applications. However, a confidence building period is required before these can be accepted in lieu of TGA assessment.

TARSC continues to be actively involved in several industry related meetings, for example, the TGA Tech and Reg Forum and the Biological Consultative Group. IVD Australia will again participate in the TGA Sponsor Information Day for 2017. A workshop on non-TGA related requirements for IVDs has also been proposed but will be dependent on the willingness of the relevant authorities to participate.

As always, TARSC welcomes your involvement and any issues you would like addressed or raised. Feel free to contact us for further details on our activities.

### 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**  
SI 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)

www.ivd.org.au

## REPORT

Over the past two years there seems to have been a noticeable change in mind-set and acceptance of Point of Care Testing (POCT) from many areas of mainstream Pathology.

POCT has been described as Pathology's 'poor cousin' or an 'irritating competitor stealing revenue'. And POCT advocates have unfairly described getting mainstream Pathology acceptance of POC as "like getting Turkeys to vote for Christmas".

But now many Hospital Labs and Health Authorities are now investing in high quality POC systems. This includes IT Solutions for Connectivity, giving far greater control and support capabilities. Also, there has been a gradual realisation that with this comes the ability to stabilise revenue from testing done at the Point of Care, rather than the bench.

Until recently, Australia's acceptance of POC devices seemed to begin and end with Blood Gas Analysers. However, now it is more and more common to see included

in the discussion Coag meters/INR, Urine analysers, Cardiac markers, portable HbA1c meters and even 'good old Glucose' meters.

The POCT WVP of IVD Australia is planning to hold its "Speed Dating " at the ACRRM annual Congress in Melbourne, October 2017. GP's from the Australia College of Rural and Remote Rural will hear from POC experts and have the opportunity to get hands on experience with a variety of PoCT devices. These will include Infectious Disease testing, INR, Glucose/Ketones, HbA1c, Cardiac Markers, etc.

Australia continues to develop a meaningful presence in the worldwide POC community. For example the IFCC committee for "Glucose meters in Critical Care" is Chaired by an Australian with two others on the WP.

With new genetic based POC Technologies on the horizon, things are getting more and more interesting.

### 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



# CODE ADMINISTRATION Committee

The intense media scrutiny recently focussed on the marketing practices of the pharmaceutical industry has highlighted the importance of industry adherence to a Code of Conduct that reflects current ethical standards. The IVD Australia Code was developed for that purpose, and continues to provide a benchmark for ethical marketing practices for our industry sector.

It was with the aim of demonstrating our industry's adherence to the Code that the Code Administration Committee (CAC) developed the Code Certification Program. Over the past year, the Program has been promoted to members as a means by which they can demonstrate their commitment to the Code. Companies that successfully complete the program receive a Certificate and are encouraged to prominently display the Code logo - for example, at the company's trade display booths. It is hoped that all member companies will seek to display this visible indicator of Code compliance.

Some companies, particularly larger multinational companies, have internal Codes which may have provisions that are stricter than the IVD Australia Code. Those companies will have no difficulties meeting the requirements of the Program. For companies with an internal code that is less stringent than the IVD Australia Code, the latter Code will apply.

The Code Certification Program is available via the IVD Australia website at: [www.ivd.org.au/about-us/code-of-conduct/code-certification/](http://www.ivd.org.au/about-us/code-of-conduct/code-certification/)

Over the next year, the CAC will undertake its periodic review of our Code, concentrating primarily on the complaints mechanisms and ensuring that the Code aligns with those of comparable overseas organisations - the MedTech Europe Code of Ethical Business Practice and the Code of Ethics of the Asia Pacific Medical Technology Industry Association (APAC Med). Compatibility with these Codes is of particular importance to companies who conduct business outside Australia.

The CAC consists of representatives of key stakeholder bodies, including Royal College of Pathology Australia (RCPA), The Australasian Association of Clinical Biochemists (AACB), Royal Women's hospital and member representatives from Roche and Siemens as well as consumer representative.

The CAC invites input from all those who have questions or comments about the administration of the Code, and particularly from those with suggestions for its further development.

Pam Davis  
Chair, 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



[www.ivd.org.au](http://www.ivd.org.au)

# Pathology

VALUE OF



It would be an understatement to say that the last 12 months has seen considerable change! On a global, local and individual level, the ever-present dynamics of fast transformation means the imperative on the pathology sector to demonstrate its value in healthcare delivery is as constant as ever before.

I am pleased to say that the Know Pathology Know Healthcare education initiative has continued to make great advances in building recognition of the value of pathology.

The 2016/17 financial year began with a Federal Election. A returned Government, many new faces in Parliament, and yet the continued scrutiny on healthcare spending persists. A key component of educating parliamentarians on the role of pathology in healthcare is via laboratory tours in their electorates. We have now hosted laboratory tours with more than sixty Federal politicians across the country - it is an unrivalled mechanism to showcase the to considerable contribution of the sector.

Pathology was brought to Australian Parliament House in March, with Pathology Awareness Australia co-hosting an event with Diabetes Australia and the Parliamentary Friends of Diabetes. As part of the event parliamentarians and staff were offered an HbA1c test to learn about their diabetes status. More than ninety people took up the opportunity. The success of this event has seen Pathology Awareness Australia invited to participate in a similar event with The Prostate Cancer Foundation of Australia in September this year. Working with Health Consumer Organisations and Parliamentary Friendship Groups is an effective way to demonstrate the vast array of ways that pathology intersects in all of healthcare.

Building consumer awareness of the value of pathology remains a key pillar of the initiative. A redeveloped [knowpathology.com.au](http://knowpathology.com.au) website was launched on International Pathology Day in November 2016. The new site has seen increased engagement and closer integration with Lab Tests Online - a highly effective way to build health literacy among the public. Consumers are signposted to the website via prompts in collection centres. This model has recently been trialed in General Practices in New South Wales and Queensland, where dwell times have greatly increased - demonstrating the curiosity from many patients to learn more about their tests and the engine room of healthcare.

Mainstream media is frequently reporting the multitude of ways in which pathology is central to healthcare as part of the initiative. You may have also seen the Know Pathology Know Healthcare TV advert. Released as a Community Service Announcement it has received significant airplay since January - an effective way to peek interest from the public on what is involved in finding their medical answers.

IVD Australia remains an active and committed member of Pathology Awareness Australia, and as members your support and input is welcomed and appreciated.



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# FINANCIAL Statements

FOR THE PERIOD ENDED 30 JUNE 2017

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 30 August 2017. The company has the power to amend and reissue the financial statements.



# Report

30 JUNE 2017  
DIRECTORS'

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

## 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 David Basseal (Deputy Chair)	25 February 2016 to present
Mr Tristan Duggan (Treasurer)	15 October 2014 to present
Mr John Crothers	14 October 2011 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

### (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.

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.

### (d) 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

### (e) 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, PPA 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

### (f) Business Review

#### (i) Operating results

The Company continued to engage in its principal activity, the results of which are disclosed in the attached financial statements. The net surplus of the Company for the financial year ended 30 June 2017 amounted to \$35,788 (2016: net deficit of \$60,473).

#### (ii) Dividends

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

### (g) Significant changes in state of affairs

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



DIRECTOR'S REPORT CONTINUED

(h) 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.

(i) 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.

(j) Environmental regulations

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

(k) 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 2017. 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.

(l) 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) 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 David Basseal (Deputy Chair)

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 Kakaflikas

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

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 bioMérieux 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**

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.

**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.

**2. MEETINGS OF DIRECTORS**

During the financial year, 5 meetings of directors (including committees of directors) were held. Attendances by each director during the year were as follows:

DIRECTORS' MEETING		
	NUMBER ELIGIBLE TO ATTEND	NUMBER ATTENDED
Mr Sebastian D'Angelo (Chair)	5	5
Mr John Crothers (Deputy Chair)	5	4
Mr Tristan Duggan (Treasurer)	5	3
Mr David Basseal	5	5
Mr Ted Maione	5	3
Mr Vito Trifilo	5	4
Ms Bernadette Snopek	5	5
Mr Rayden Rivett	5	5
Mr Jim Kakafilikas	5	3

**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 2017 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: 30 August 2017



**Director**  
Mr David Basseal (Deputy Chair)



The Board of Directors  
IVD Australia Limited  
PO Box 298

Parramatta CBD BC NSW 2124

Date: 30 August 2017

Dear Board Members

#### Auditor's Independence Declaration under section 307C of the Corporations Act 2001

As lead audit partner for the audit of the financial statements of IVD Australia Limited for the financial year ended 30 June 2017, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- (a) the auditor independence requirements of the Corporations Act 2001 in relation to the audit; and
- (b) any applicable code of professional conduct in relation to the audit.

Yours sincerely



**Nexia Court & Co**  
Chartered Accountants

Sydney



**Joseph Santangelo**  
Partner

#### Sydney Office

Level 16, 1 Market Street  
Sydney NSW 2000  
PO Box H195  
Australia Square NSW 1215

**p** +61 2 9251 4600  
**f** +61 2 9251 7138  
**e** [info@nxiacourt.com.au](mailto:info@nxiacourt.com.au)  
**w** [www.nexia.com.au](http://www.nexia.com.au)

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## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF IVD AUSTRALIA LIMITED

### Opinion

We have audited the financial report of IVD Australia Limited (the Company), which comprises the statement of financial position as at 30 June 2017, the statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion, the accompanying financial report of ABC Company Ltd is in accordance with the Corporations Act 2001, including:

- (i) giving a true and fair view of the Company's financial position as at 30 June 2017 and of its financial performance for the year then ended; and
- (ii) complying with Australian Accounting Standards – Reduced Disclosure Requirements and the Corporations Regulations 2001.

### Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Report section of our report. We are independent of the Company in accordance with the auditor independence requirements of the Corporations Act 2001 and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the Corporations Act 2001, which has been given to the directors of the Company, would be in the same terms if given to the directors as at the time of this auditor's report.

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

### 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 – Reduced Disclosure Requirements 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.

In preparing the financial report, the directors are responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Company or to cease operations, or have no realistic alternative but to do so.



## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF IVD AUSTRALIA LIMITED CONTINUED

### Auditor's responsibility for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit 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.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial report or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial report, including the disclosures, and whether the financial report represents the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Nexia Sydney Partnership



**Joseph Santangelo**  
Partner

Sydney  
Dated: 30 August 2017

# DIRECTORS' Declaration

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

1. The financial statements and notes, as set out on pages 18 to 22, 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 2017 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)

Dated: 30 August 2017



**Director**  
Mr David Basseal (Deputy Chair)



# Income

STATEMENT OF PROFIT OR LOSS  
AND OTHER COMPREHENSIVE

FOR THE YEAR ENDED 30 JUNE 2017

		2017	2016
	NOTE	\$	\$
Revenue	2	466,365	388,717
Interest income		7,442	9,914
<b>TOTAL INCOME</b>		<b>473,807</b>	398,631
Employee benefits expense	3(a)	(268,993)	(253,158)
Depreciation expense	3(b)	(1,150)	(2,100)
Administrative expenses		(167,877)	(203,846)
<b>TOTAL EXPENSES</b>		<b>(438,020)</b>	(459,104)
<b>SURPLUS/(DEFICIT) FOR THE YEAR</b>		<b>35,787</b>	(60,473)
<b>Other comprehensive income</b>			
Other comprehensive income			
<b>TOTAL COMPREHENSIVE INCOME FOR THE YEAR</b>		<b>35,787</b>	(60,473)

# Position

STATEMENT OF  
FINANCIAL

AS AT 30 JUNE 2017

		2017	2016
	NOTE	\$	\$
<b>ASSETS</b>			
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	4	373,284	9,914
Trade and other receivables	5	6,800	4,294
<b>TOTAL CURRENT ASSETS</b>		<b>380,084</b>	278,909
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment	6	261	1,411
<b>TOTAL NON-CURRENT ASSETS</b>		<b>261</b>	1,411
<b>TOTAL ASSETS</b>		<b>380,345</b>	280,320
<b>LIABILITIES</b>			
<b>CURRENT LIABILITIES</b>			
Trade and other payables	7	46,526	22,091
Employee benefits	8	14,017	(2,100)
Income received in advance	9	104,099	63,839
<b>TOTAL CURRENT LIABILITIES</b>		<b>164,642</b>	112,422
Employee benefits		12,018	
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>12,018</b>	
<b>TOTAL LIABILITIES</b>		<b>176,660</b>	112,422
<b>NET ASSETS</b>		<b>203,685</b>	167,898
<b>EQUITY</b>			
Retained earnings		203,685	167,898
<b>TOTAL EQUITY</b>		<b>203,685</b>	167,898



# STATEMENT OF CHANGES IN Equity

FOR THE YEAR ENDED  
30 JUNE 2017

2017	RETAINED EARNINGS \$	TOTAL \$
Balance at 1 July 2016	167,898	167,898
Surplus for the year	35,787	35,787
Balance at 30 June 2017	203,685	203,685

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

# Cash

## STATEMENT OF Flow

FOR THE YEAR ENDED 30 JUNE 2017

	2017 \$	2016 \$
NOTE		
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Receipts from customers	<b>554,263</b>	385,685
Payments to suppliers and employees	<b>(462,835)</b>	(485,683)
Interest received	<b>7,241</b>	9,914
	<b>98,669</b>	(90,084)
Net increase/(decrease) in cash and cash equivalents	<b>98,669</b>	(90,084)
Cash and cash equivalents at beginning of year	<b>274,615</b>	364,699
<b>Cash and cash equivalents at end of financial year</b>	<b>373,284</b>	274,615



# Statements

## NOTES TO THE FINANCIAL

### 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.

#### (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.

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.



## NOTES TO THE FINANCIAL STATEMENT

### CONTINUED

#### 2. REVENUE

	2017	2016
	\$	\$
Member subscriptions	450,368	388,717
Other income	5,860	
Conference income	10,137	
	466,365	388,717

#### 3. EXPENSES

(A) EMPLOYEE BENEFITS EXPENSE		
Wages and salaries	246,753	232,379
Superannuation	22,240	20,779
	268,993	253,158

(B) DEPRECIATION EXPENSE		
Depreciation - computer equipment	730	1,581
Depreciation - furniture and fixtures	420	519
	1,150	253,158

#### 4. CASH AND CASH EQUIVALENTS

Cash at bank	133,284	74,615
Term deposits	240,000	200,000
	373,284	274,615

#### 5. TRADE AND OTHER RECEIVABLES

Trade receivables	2,750	2,129
GST paid	1,721	2,165
Accrued Interest	2,329	
	6,800	4,294

#### 6. PLANT AND EQUIPMENT

	2017	2016
	\$	\$
Furniture, fixtures and fittings - at cost	2,589	2,589
Accumulated depreciation	(2,510)	(2,090)
	79	499
Computer equipment - at cost	9,254	9,254
Accumulated depreciation	(9,072)	(8,342)
	182	912
Total property, plant and equipment	261	1,411

##### (a) Movements in carrying amounts of plant and equipment

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

	FURNITURE, FIXTURES AND FITTINGS	COMPUTER EQUIPMENT	TOTAL
	\$	\$	\$
YEAR ENDED 30 JUNE 2017			
Balance at the beginning of year	499	912	1,411
Depreciation expense	(420)	(730)	(1,150)
Balance at the end of the year	79	182	261

#### 7. TRADE AND OTHER PAYABLES

Other payables	25,876	12,091
Accrued expenses	20,650	10,000
	46,526	22,091

#### 8. EMPLOYEE BENEFITS

Provision for long service leave	12,018	
Provision for annual leave	14,017	26,492
	26,035	26,492



NOTES TO THE FINANCIAL STATEMENT  
CONTINUED

9. OTHER LIABILITIES

	2017	2016
	\$	\$
Income in advance	104,099	63,839

10. AUDITORS REMUNERATION

Payable to the auditors of the company - Nexia Sydney Partnership		
Audit services	10,400	10,000
Non-audit services	3,410	760
	13,810	10,760

11. CASH AND CASH EQUIVALENTS

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: \$227,943 (2016: \$187,724). 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 2017

- Abacus ALS
- Abbott Australasia
- Agena Biosciences (Asia Pacific)
- Alere
- Astral Scientific
- Atomo Diagnostics
- Australasian Medical and Scientific Ltd
- BD Life Sciences
- bioMérieux Australia
- Bio-Rad Laboratories
- Blackaby Diagnostics
- Brandwood Biomedical
- Cepheid Holdings
- Dako Australia
- Diagnostic Solutions
- ESL Biosciences Australia (2012) P/L
- Grifols Australia
- Hologic (Australia)
- Illumina Australia
- Immuno
- Integrated Sciences
- Macarthur Cook Group
- Merck Millipore Australia
- MP Biomedicals Australasia
- Paragon Therapeutic Technologies
- PerkinElmer
- Pro-Health Asia Pacific
- QIAGEN
- Randox (Australia)
- Roche Diagnostics Australia
- Siemens Healthineers
- SJ Alder
- Southern Cross Diagnostics
- Specialty Diagnostix
- Speedx
- ThermoFisher Scientific
- Tecan Australia
- Werfen Australia





PO BOX 298  
PARRAMATTA CBD BC  
NSW 2124, AUSTRALIA

PHONE +61 (02) 8007 6632  
EMAIL [INFO@IVD.ORG.AU](mailto:INFO@IVD.ORG.AU)

**[WWW.IVD.ORG.AU](http://WWW.IVD.ORG.AU)**

