PATHOLOGY
TECHNOLOGY
AUSTRALIA

# ANNUAL REPORT 2019

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THE POWER OF OUR TECHNOLOGIES, DIAGNOSTIC TESTS, AND OUR INDUSTRY ARE THE DRIVERS OF INNOVATIVE HEALTHCARE STRATEGIES AND OUTCOMES.

OUR SOLUTIONS ARE MOST OFTEN FOUND IN PUBLIC AND PRIVATE PATHOLOGY LABORATORIES ACROSS AUSTRALIA, AND INCREASINGLY AT THE POINT-OF-CARE, FOR HIV, DIABETES AND HOME PREGNANCY TESTS.

# CHAIR'S REPORT

I AM VERY PLEASED TO BE PROVIDING MY REPORT IN THIS TENTH ANNIVERSARY YEAR OF OUR ORGANISATION. WHILE I REFLECT WITH APPRECIATION ON THE FORESIGHT OR OUR FOUNDERS, I FIND MYSELF FOCUSSING FAR MORE ON THE GREAT OPPORTUNITIES AHEAD OF US TO TAKE A LEADERSHIP POSITION IN OUR INDUSTRY.

This year was one of great change. We changed our name and logo; Pathology Technology Australia strongly states who we are and what we do. We farewelled our previous CEO Dr. Wendy-Jane Morrow and thanked her for her contributions over the past 5 years. We welcomed a new CEO, Dean Whiting, and have seen a re-focussing of our organisation into stronger advocacy, collaboration and change management activities. The Board, and I believe the membership, has appreciated these changes and the focussed direction we are taking.

We also had the federal election and the surprise return of the Liberal Coalition government. There are both threats and opportunities for us on this front. While there is the threat of funding cuts to services, there is also talk of reducing business complexity and red tape. We must push where-ever we can to uncover benefits from the later. With Minister Greg Hunt back in charge of Health I expect steady progress on his stated aims of better funding for certain conditions, including cancer; for a stronger focus on genomic technologies; and a focus on fighting multiple drug resistant organisms.

I am very proud of the achievements our organisation made in 2019. We continued to be a trusted consultant to the TGA, providing advice on Clinical Evidence Guidelines, Medical Device Cyber Security, Software as a Medical Device, UDI and more. We successfully had the Department of Agriculture relax rules around Biological imports as they relate to IVD Kits. We were the only non-medical body invited to the Department of Health review on assessment of gene-based testing for rare somatic cancers. We again strongly supported the Know Pathology Know Healthcare campaign which has now facilitated well in excess of 100 politician visits to pathology Labs, has achieved over $4 million in gratis TV airtime and is achieving industry leading conversion of hits on the website.

I now challenge our organisation to leverage these achievements into a stronger leadership position in our industry. It is now time for us to clearly articulate the important position we hold in the healthcare economy and to gain our rightful place at the key advocacy tables. Even more than this, it is time for us to take greater control of promoting our products and services, and to lead the changes required to take advantage of the new technologies that we offer.

In closing I want to recognise the team at Pathology Technology Australia; the contribution of my fellow Board Members – Antoinette Violo (Perkin Elmer), John Crothers (Abbott Diagnostics), David Basseal (Roche Australia), Tony Feneziani (Merck Group), Karen Macleod (MP Biomedicals), Sally Hickman (Werfen Australia), Rayden Rivett (Cepheid), and Vito Trifilo (Tecan Australia). Their dedication to our organisation 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 Jenny Zhao (Tecan Australia) to the Finance, Audit & Risk Management Committee, our Secretariat (Dean Whiting and Chami Gunasinghe) and we continue to have the best people on committees that care deeply about improving our business. It is this passionate commitment that ensures we can continue our successes.

To our Members, I thank you for your ongoing support and loyalty, and I look forward to growing the value we offer you today and in the future.

Sebastian D'Angelo
Chairman, Pathology Technology Australia



# CEO'S REPORT

Dear Members

Welcome to our first annual report as Pathology Technology Australia. By the time this report is published I will be 6 months into my tenure as CEO of this organisation. Pathology has been my calling and it has occupied my entire working life. I am passionate about what our technology delivers to patient outcomes and to the healthcare economy. But before I move on, I want to thank Dr. Wendy-Jane Morrow for her contribution to our organisation as CEO and for facilitating a smooth transition to the role for me.

This is our 10th year as an organisation dedicated to the IVD technology sector. I can recall back when Peter Harmon, Bruce Evans and a few other intrepid leaders first suggested the need for an organisation such as ours. 10 years ago, we were facing constant funding cuts, increased regulation and pressure to drive efficiency. As an organisation we rose to the challenge; driving laboratory efficiency, working consultatively with TGA on regulations and successfully preventing fee cuts for most of the past 10 years. We have contributed strongly to the success of the Know Pathology Know Healthcare initiative; unique in the world, and so effective. Much to be proud of.

I am very grateful for the support I have had from the standing committees. Our FARM and TARSC teams are particularly strong and constantly set our organisation on the path to success. Our Marketing Development Committee and Marketing Communications Committee are now well supported and have very clear projects linked to our vision and 3-year plan. While membership of our committees offers a great development opportunity, it also requires dedication and some hard work. I very much appreciate the fine work they do.

There is still much to do for our members, and on behalf of our customers, our patients and for the healthcare economy in Australia. We are taking a stronger leadership position to demonstrate more clearly the importance of our products and services to delivering high quality, accessible and affordable healthcare in Australia. The next 10 years will be so critical for our sector; with the aging population and increases in disease chronicity driving ever higher demand on healthcare services. I firmly believe that the innovations being delivered by our members will be a major contributor to an effective healthcare economy. And it is around this point that I have been focussing the attention of key healthcare stakeholders.

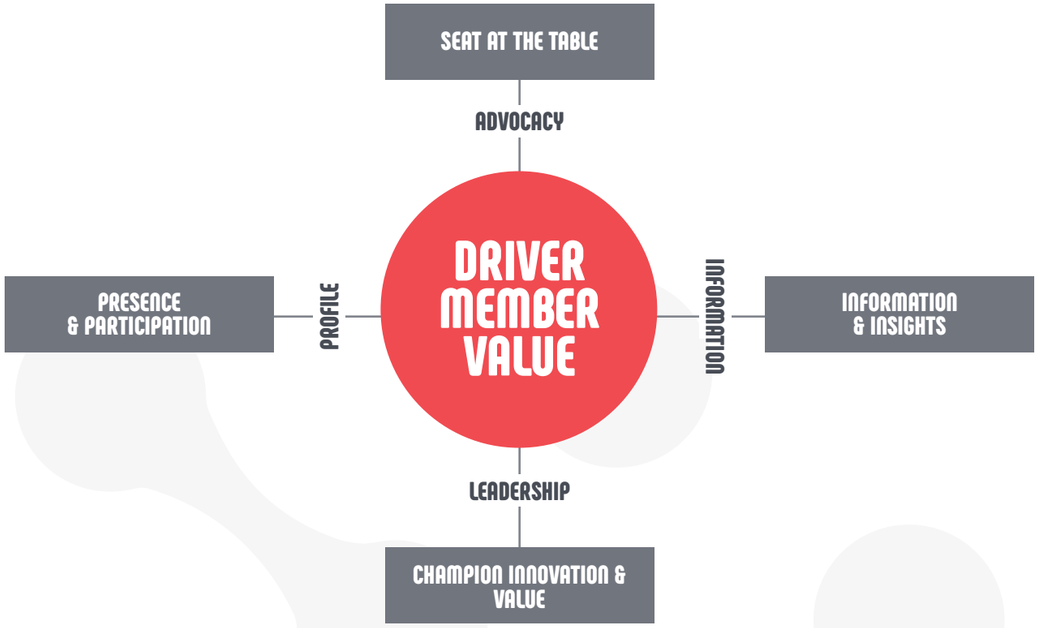
Many of the processes and policies for assessing the clinical utility and the value of our products to the healthcare economy, are no longer fit for purpose. There is no easy way to evaluate the end to end benefit our products deliver to patient outcome and to total healthcare cost. Many things must change. I am currently collaborating with a group of like-minded stakeholders to address the most critical of these. You, our members, have a role in this and many of you have already been involved. Contribution at Board level, membership of our committees and expert panels; and by retaining your membership, you support this effort.

We have a clear vision and 3-year plan. Achieving this plan will put our organisation front and centre at the policy, regulatory and funding tables; having our say and being heard. I am very pleased to say that we are very much on track with our plan.

There are many ways in which we can take a stronger leadership position. Not only by collaborating to change the system, but also by taking a stronger role in how we represent our products and services. Within the next 12 months we will hold a technology day in Canberra. We will be taking a stronger role in opening market access for products at the point of care; to compliment the many laboratory-based products we sell. We will have optimised our process for MSAC applications. And, we will be more engaged in social media activities to drive recognition of the benefits of our technology.

I look forward to your continued support, feedback and ideas as we lead this change and deliver the products and services so vital to high quality, accessible and affordable healthcare in Australia.

# PATHOLOGY TECHNOLOGY AUSTRALIA
# STRATEGIC PLAN




## Our Vision

Is of a healthier Australia that values our members as the driver of innovative technologies; integral to the highest quality, accessible and affordable healthcare system.

## Our Mission

Is as the Industry peak body, we will advocate for our members and influence key stakeholders to foster an environment for success.

## Our Values

**INNOVATION -** by driving innovation, our members are critical to quality, accessible and affordable healthcare in Australia

**COMMITMENT -** we are passionate about the technology our members deliver to the healthcare economy and will advocate to the fullest on their behalf.

**RESPONSIVENESS -** listening and acting in a timely manner to further the interests of members.

**COLLABORATION -** we seek to build successful partnerships in pursuit of common goals.



# OUR
# 3 YEAR PLAN

# MEMBER VALUE
## MARKET ACCESS AND FUNDING

| BENEFITS | VOTING MEMBERS | LIFE MEMBERS | ASSOCIATE MEMBERS |
|---|---|---|---|
| **Eligible to hold office and Eligible to vote**<br>Influence the direction and work of Pathology Technology Australia | ✓ | | |
| Eligible to attend General Meetings | | | |
| Be informed about the work of Pathology Technology Australia | ✓ | ✓ | ✓ |
| Opportunity to Participate in the Code of Conduct | | | |
| Participate in Industry Self-Regulation | ✓ | ✓ | ✓ |
| Invitation to Member Networking Events | | | |
| Providing consultation and networking amongst key industry players | ✓ | ✓ | ✓ |
| Opportunity to participate in Pathology Technology Australia Committees | | | |
| Lead the industry in shaping the regulatory framework, and lobbying government | ✓ | ✓ | ✓ |
| **Consultation on Industry Issues**<br>Assist in shaping the regulatory framework | ✓ | ✓ | ✓ |
| **Use of Pathology Technology Australia Logo**<br>Differentiating Pathology Technology Australia Members and other affiliated organisations | ✓ | ✓ | ✓ |
| **Participate in Strategic Planning**<br>Influence the direction and work of Pathology Technology Australia | ✓ | ✓ | ✓ |
| Access to Industry Members | ✓ | ✓ | ✓ |

| SERVICES | VOTING MEMBERS | LIFE MEMBERS | ASSOCIATE MEMBERS |
|---|---|---|---|
| **Pathology Technology Australia Website**<br>Login and password to access member-only services | ✓ | ✓ | ✓ |
| **Pathology Technology Australia Updates**<br>Members only updates full of industry information and current issues and research | ✓ | ✓ | ✓ |
| Media Releases | | | |
| Keeps you abreast of all media issues being dealt with by your council | ✓ | ✓ | ✓ |
| Code of Conduct Certification | ✓ | ✓ | ✓ |
| **Pathology Technology Australia Events at Discounted Rates**<br>Ensuring you remain at the forefront of your industry | ✓ | ✓ | ✓ |
| **Pathology Technology Australia Member Directory**<br>Electronic | ✓ | | ✓ |

# TREASURER'S REPORT

I WOULD LIKE TO PRESENT THE PATHOLOGY TECHNOLOGY AUSTRALIA ACCOUNTS FOR THE FINANCIAL YEAR ENDING JUNE 30, 2019. THE ACCOUNTS, AUDITED BY NEXIA AUSTRALIA, ARE INCLUDED IN THIS ANNUAL REPORT AND ARE AVAILABLE TO THOSE WHO WISH TO OBTAIN A COPY.

The main work of the Finance, Audit & Risk Management (FARM) Committee has been in financial stewardship and ensuring that our members are experiencing value for money. Through change, a strong focus on new members and associates, diligent risk management and cost control, we will continue to ensure the financial stability and security of the organisation. We plan on investing in strategic projects with a greater presence on social media to showcase how our technology delivers important healthcare outcomes.

Following a challenging year and a change in our CEO, I report that our income for the year was above budget at $436,463; from a combination of membership, training, events and interest. This total income decreased $4,538 on last year's income due to the consolidation of companies within our industry.

Our expenditure for the year was higher at $481,790. Expenses exceeded past year by $56,166. The majority of this increased expenditure was for employment costs (including once off payment of approximately $14,000 due to unbudgeted CEO change), administration and unbudgeted subscription fees of $14,000.

Business development expenses were also over budget due to increased travel expenses associated with CEO on boarding and marketing costs, offset by some underspend in Networking.

Project expenses accounted for $125,271, including Pathology Awareness Australia, the Australian GDMS, Re-branding, Social Media, Purchasing Contracts, and Health Economics.

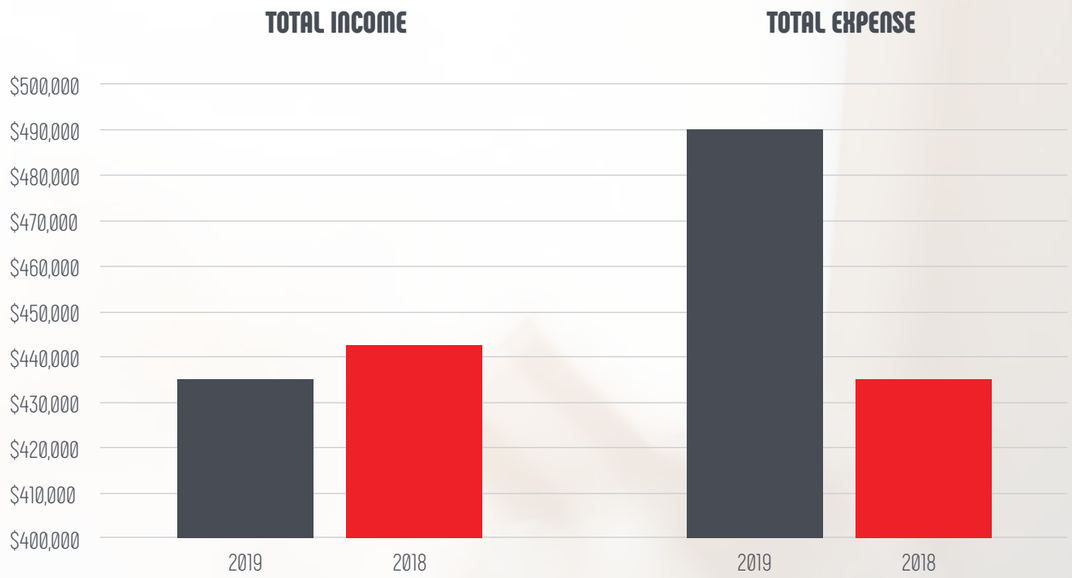
Full details of the income and expenditure (including Auditor adjustments) can be found in the accounts.

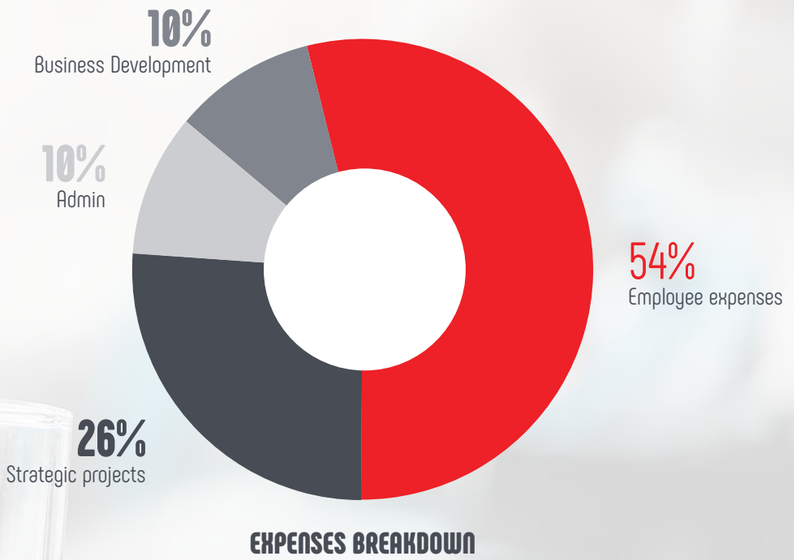
I would like to thank the FARM committee; Wendy-Jane Morrow (previous CEO), Dean Whiting (CEO) Sebastian D'Angelo, Rayden Rivett, Jenny Zhao (CPA) and Chami Gunasinghe for all the time and effort put into helping us to strive for financial stability and diligent risk management.

In summary, as a not for profit organisation, I am pleased to report a successful year albeit a challenging one with the financial position of Pathology Technology Australia being stable but with considerably higher expenditure.

Thank you and best regards,

Vito Trifilo



# PATHOLOGY TECHNOLOGY AUSTRALIA BOARD

**Mr Sebastian D'Angelo (Chair)**
GENERAL MANAGER, LABORATORY DIAGNOSTICS DIVISION, SIEMENS HEALTHINEERS – 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 Healthineers 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.

**Ms Karen Macleod (Deputy Chair)**
DIRECTOR AND COUNTRY MANAGER, MP BIOMEDICALS

Karen's 30-year career in the in-vitro diagnostics and pharmaceuticals industries began as a medical scientist in public pathology and includes varied sales and management roles with Australian based global companies such as BioMerieux, Boehringer Mannheim (now Roche) and GSK. Currently Director and Country Manager at MP Biomedicals, she is responsible for all sales, management, and regulatory functions. Karen has a Bachelor of Applied Science and Graduate Diploma in Marketing from UTS, Sydney and has been a member of the Pathology Technology Australia Technical and Regulatory Standing Committee since 2011.

**Mr Vito Trifilo (Treasurer)**
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 6 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 David Basseal**
ROCHE DIAGNOSTICS, BUSINESS AREA MANAGER PATHOLOGY

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).

# PATHOLOGY TECHNOLOGY AUSTRALIA
## BOARD (CONTINUE)

### Mr John Crothers
REGIONAL DIRECTOR, ABBOTT 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 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).

### Mr Tony Feneziani
HEAD OF RESEARCH SOLUTIONS ANZ, MERCK GROUP

Tony has over 25 years commercial experience in the in vitro diagnostic and life sciences industries. During this time, Tony has undertaken a range of leadership roles including commercial operations, sales and marketing and business development.

Tony's current role at Merck also includes Country Leadership Team membership of the Merck Life Sciences operation in ANZ.

### Ms Sally Hickman
GENERAL MANAGER, WERFEN AUSTRALIA & NZ

Sally has over 12 years experience in the Australian IVD industry having undertaken key roles in the areas of strategic marketing and customer account management. In 2012, Sally joined Werfen Australia and assumed key management responsibilities at a time when company took direct operations of key business units in Oceania.

Sally has a passion for diagnostics having trained and worked in public pathology laboratories for more than 5 years in the UK.

Sally holds a Bachelor of Science degree in Biomedical Sciences from The University of Bradford, UK and a Master of Science in Biomedical Sciences degree (specialising in Haematology) from The University of Ulster, UK.

### Ms Antionette Violo
REGIONAL SALES DIRECTOR, DIAGNOSTICS, PERKINELMER

My association with the life sciences, human health and diagnostics industries has extended for over 25 years across the commercial and academic sectors. I am currently the Regional Sales Director for PerkinElmer's diagnostic's business in the Applied Genomics division.

My commercial career commenced when I was approached to start the Life Sciences Division of PerkinElmer in Australia. I have been fortunate to progress within the organisation and have managed divisions and many staff across Australia, New Zealand and Asia for over 15 years. A significant achievement I am very proud of has been to partner PerkinElmer in the commercialisation of an Australian developed immunoassay kit (TGR Biosciences).

I was approached to join the Diagnostics Division twelve months ago to develop the Applied Genomics division within the Asia Pacific region. This has been an exciting challenge and a personal interest of mine in observing the impact that translational medicine has on human health outcomes.

# FINANCE, AUDIT & RISK MANAGEMENT REPORT

THE MAIN FOCUS OF THE FINANCE, AUDIT & RISK MANAGEMENT (FARM) COMMITTEE HAS BEEN IN FINANCIAL STEWARDSHIP AND ENSURING THAT OUR MEMBERS ARE EXPERIENCING VALUE FOR MONEY.

As a not for profit industry organisation we have limited financial resources. Our primary responsibility is to our members. As recipients of member funding we also have a responsibility to use our resources wisely. These factors mean that the board's attitude to risk is generally cautious. It is also the responsibility of the Board, delegated to the FARM Committee with the assistance of the CEO, to carry out risk management analyses of the organisation, and to take appropriate measures.

Therefore, the FARM Committee ensures that:

- a CEO for the organisation is nominated;
- effective risk management procedures are in place, applicable to all relevant areas;
- risk management procedures are reviewed regularly;
- recommendations arising out of the risk management process are evaluated and, if necessary, implemented; and
- employees are aware of all applicable risks and familiar with the organisation's risk management procedures.

Members of the current committee are Dean Whiting (CEO) Sebastian D'Angelo, Rayden Rivett, Jenny Zhao (CPA), Chami Gunasinghe (Executive Support) and myself as chair. We meet every six weeks to discuss the current financial and risk position of our organisation with the goal of financial stability and diligent risk management.

Given our challenging 2018-2019 year due to increased expenditure, our goals for 2019-2020 are to sustain and grow our business by gaining new members; this has been challenging based on industry mergers and take overs. Secondly, we want to control our costs by maintaining our strict approval process for expenditure whilst continually focussing on member value and needs. Lastly, our risk register and assessment tool has been revamped and will be utilised more actively by the committee and the board to stratify and mitigate our risks.

Thank you & best regards,

Vito Trifilo

**Finance Audit and Risk Committee**

Vito Trifilo (Chair)
Chami Gunasinghe
Dean Whiting
Jenny Zhao
Rayden Rivett
Sebastian D'Angelo



# TECHNICAL & REGULATORY STANDING COMMITTEE

THE TECHNICAL AND REGULATORY STANDING COMMITTEE FOCUS ON THE REGULATORY ISSUES THAT AFFECT THE IVD INDUSTRY.

In late 2018 TARSC committee members advocated for various cross departmental discussions between the Therapeutic Goods Administration (TGA), the Department of Agriculture and Water Resources (DAWR) and other branches of the Department of Health impacting our member products; we see meetings of this nature now aligning with the Government's stance towards better efficiencies. This will flow over to FY20 as our hard work in raising concerns is paying off with meeting invites.

One of the most significant changes in relation to IVD's as Therapeutic Goods in FY19 was the end of the use of Health Canada's ISO 13485 CMDCAS in support of a majority of our Manufacturing Conformity Assessment Evidence Certifications and the introduction of the more global Medical Devices Single Audit Programme (MDSAP). Equally the publication of the Guidance on the Use of Evidence from Comparable Overseas Regulations can not go unmentioned, this was a game changer in the Australian Medical Device (inclusive of our In Vitro Diagnostics) industries. Our TARSC members will continue to watch and support all our members as the use of new Certifications gains experience.

On the ground level delegates of TARSC have attended TGA RegTech Forum and DAWR Biological Consultative Group meetings and in these have had successes in clarifying requirements, reviewing guidance documents, along with monitoring and raising awareness of impending Regulation change impacts, as seen in several of the CEO Newsletters this last year. In particular, we have discussed both internally and externally a number of topics to clarify the understanding of conditions in relation to:

- Diagnostic Kits permit conditions with successful future changes;
- Consultations on Culture Media and Enzymes in relation to biological import review conditions;
- Annual reporting for Antibiotic Licences as they pertain to IVDs;
- Clinical Evidence for IVDs (ongoing); Opened Adverse Event discussions & applicability to IVDs
- Changes affecting TGA issued CA Certificates; Clarity around Varying details of ARTGs
- Consulted on a significant regulations change regarding IVD's as Companion Diagnostics;

**Technical and Regulatory Committee**

Melissa Robins (Chair)
Alex Leung
Chami Gunasinghe
David McLean
Dean Whiting
Erica Loh
Hoon Koh
Karen Macleod
Kasey Kime
Lazarela Vucinic
Libby McDermott
Lillies Chen
Merrilyn Colussi
Michael Gunter
Peter Lower
Peter Traynor

# MARKETING & COMMUNICATIONS COMMITTEE

THE MARKET COMMUNICATION COMMITTEE (MCC) IS A COMMUNICATION PLATFORM, FOR OUR MEMBERS AND KEY STAKE HOLDERS.

The Market Communication Committee (MCC) is a communication platform, for our members and key stake holders. The role of the committee is to provide strategic advice on the delivery of promotional campaigns and events designed to increase awareness of Pathology Technology Australia, our brand and positioning, including the retention and attraction of Pathology Australia members.

I am pleased to report that we have recruited 3 new members to the Marketing Communication Committee; I welcome them and look forward to their contribution to our team.

**Over the past 12 months this committee has;**

- Organized a number of networking events focused on key topics relevant to our members.
- Changed our name from IVD Australia to Pathology Technology Australia. The name change reflecting more accurately the value and who we represent in our industry. The MCC participated in the rebranding activities, providing input and guidance.
- Increased awareness through the use of social media through an increased focus on Twitter and Linked In. We have also started a Pathology Technology Australia YouTube station.

**The MCC is currently engaged in;**

- Releasing a series of Podcasts. Currently we are releasing a series titled "Its in our Blood", with subject matter relevant to our members and our industry. We have released 4 podcasts to date, with a total of 12 episodes planned as a pilot.
- Celebrating 10 years of PTA. Pathology Technology Australia celebrates 10 years in October. The milestone will be marked by a networking event, focused on celebrating the last 10 years of our industry and looking forward to the challenges that lay ahead in the next 10 years. The event will take the form of a panel discussion with well know experts covering topics such as regulation, technology and health economics.
- Adding additional value to our members. The MCC is looking to run an Industry Expo every two years with a focus on showcasing emerging and disruptive technologies. This event will most likely be run in Canberra.

**Over the next 12 months the MCC is working towards;**

- Increasing our communication via our social platforms, direct communication and more events.
- Reviewing our website to enhance the landing page and continually updating the content.
- Celebrating PTA 10 year Milestone by hosting a "10:10 Disruptive Pathology Technology of the Future" event
- An Industry Expo to showcase emerging technologies.

We expect to make inroads in these areas over the course of remaining 2019.

**Market Communication Committee**

Antoniette Violo (Chair)
Aida Mulabecirovic
Chami Gunasinghe
Dean Whiting
John Emmerson
Mark Dupal
Michael Wawrzyniak
Sam Spanswick



# MARKETING DEVELOPMENT COMMITTEE

THE MARKET DEVELOPMENT COMMITTEE (MDC) IS FOCUSSED ON FINDING WAYS TO INCREASE MARKET GROWTH AND TECHNOLOGY ACCESS FOR PATHOLOGY TECHNOLOGY AUSTRALIA MEMBERS. IT PROVIDES STRATEGIC ANALYSIS AND ADVICE - SUPPORTING OUR ROLE IN PROVIDING A HIGH QUALITY, AFFORDABLE AND ACCESSIBLE HEALTHCARE SYSTEM.

OVER THE COURSE OF 2018-19 THE MDC MET ON 5 OCCASIONS.

**The MDC is working to;**

- create opportunities for joint supplier funding submissions to MSAC
- leverage our industries combined knowledge and experience
- provide industry specialty comments and position statements to influence outcomes in policy, regulatory and funding decisions
- analyse and comment on testing technology trends and on market conditions

**As a result, the MDC is driving to;**

- **Coordinate the power of PTA Members in MSAC submissions.** Currently we are investigating the viability of a Procalcitonin (PCT) submission. With the support of a number of PTA members we have engaged Health Technology Analysts (HTA) to investigate the Health economic evidence of PCT and advise us on the likelihood of a submission to MSAC being successful. Once we have the findings and recommendation a decision will be made to pursue a funding submission, with the support of interested member organisations. Once this project is on its way the MDC will then explore other submission options through PTA members.
- **Provide industry expertise.** The MDC is in the process of creating a panel of Subject Matter Experts to provide specialty commentary and input to position papers, as required. We are in the process of finalising specialty areas and have begun recruiting specialists from our member organisations. We have already had a number of individuals accept invitations to join this panel and will be recruiting actively from our member organisations.
- **Provide Market Development of Innovation.** The MDC is investigating providing market development support in areas of innovative technologies for Australian companies performing R&D which they are seeking to commercialise. We have reached out to PTA and non-PTA organisations who have developed innovative technologies and require support to develop market access. Although we are early in this process, it is clear that companies with market-ready innovations struggle to find access to the Australian market, and a result look to international markets for their products. There is an opportunity for the MDC to work with such organisations to provide them Australian market expertise and help them utilise existing industry resources to gain market access. At the same time, this has the potential to grow and strengthen our PTA membership.
- **Provide Market Data and Insight.** Until recently, PTA has provided Australian market data to members through a global data source. While this data was useful, it did not cover all areas our members need to better understand testing trends and market dynamics. The MDC is currently investigating alternate partners to provide market stats that meet the specific needs of PTA members. Such market data will also provide PTA the required insight to have more meaningful discussions with healthcare policy makers.

We expect to make inroads in these areas over the course of remaining 2019.

**Market Development Committee**

Jim Kakaflikas (Chair)
Brooke Troth
Chami Gunasinghe
Daniel Legovich
Dean Whiting
Jenny Carson
John Emmerson
Karen Macleod
Mark Volling
Nicolas Latouche

# CODE ADMINISTRATION COMMITTEE

THERE HAVE BEEN NO CODE OF PRACTICE VIOLATIONS REPORTED DURING 2018/19 FISCAL YEAR.

OUR CODE OF PRACTICE IS AN IMPORTANT WAY WE COMMUNICATE OUR MEMBERS' COMMITMENT TO FAIR, ETHICAL AND COMPLIANT BUSINESS PRACTICES. ALL MEMBER COMPANIES AGREE TO ABIDE BY OUR CODE WHEN THEY JOIN OR WHEN THEY RENEW THEIR MEMBERSHIP ANNUALLY.

Our Code of Practice was a main pillar of this organisation when we first launched, 10 years ago. Since then, many of our member companies have instituted extensive codes of their own – with mandatory training, audit and certification processes. Many of these now meet or exceed the requirements set out in our Code.

During this past year, Pam Davis, Chair of the Code Administration Committee, met with Dean Whiting to review our Code and to determine what changes might be required to stay ahead of changing needs. We believe the Code of Practice remains an important service our organisation provides to members and remains critical to our position as the peak body, representing our sector. On the 10th Anniversary of our organization – and of our Code – it is timely to review how the Code is continuing to meet the needs of members and our organization. To do this, we will be surveying our members to understand better what codes they have in place and what processes they have for training, audit and certification. With this information we will be well positioned to draft any necessary amendments to ensure our own Code remains appropriate to the current business environment.

The aim is to maintain high standards in our Code of Practice while at the same time minimise duplication for companies with comparable codes. The benefit for other members remains that our Code gives very clear guidance as to the business conduct expected for our sector.

**Code of Conduct**

Pam Davis (Chair)
Dean Whiting
Chami Gunasinghe
George Koumantakis
Helen Mikolaj
Kevin Carpentar

# KNOW PATHOLOGY KNOW HEALTHCARE REPORT

## Value of Pathology

2019 IS PROVING TO BE A YEAR OF MILESTONES. AS PATHOLOGY TECHNOLOGY AUSTRALIA REACHES ITS TENTH ANNIVERSARY, WE CAN BE PROUD THAT THE PROFILE OF PATHOLOGY AMONG THE PUBLIC AND POLICYMAKERS HAS NEVER BEEN HIGHER. THERE REMAINS SIGNIFICANT WORK TO BE DONE BEFORE PUBLIC RECOGNITION OF OUR SECTOR MATCHES THE TRUE VALUE OF ITS CONTRIBUTION IN HEALTHCARE DELIVERY, BUT THE LAST 12 MONTHS HAVE SEEN SIGNIFICANT STRIDES TOWARDS OUR GOAL.

Pathology Awareness Australia (PAA) conducted its 100th Know Pathology Know Healthcare politician laboratory tour when Federal Member for Wentworth, Dave Sharma, visited a laboratory in his electorate, five years after the first tour of its kind in Seymour, Victoria, with Rob Mitchell MP. These tours are an effective way to showcase to decision makers the sophistication of innovative pathology technology and the highly skilled professionals working in laboratories.

PAA also brings the laboratory to parliament, with regular educational events held at Australian Parliament House, including providing politicians with PSA tests in conjunction with The Prostate Cancer Foundation of Australia as part of The Big Aussie Barbie. This is now a familiar event in the parliamentary calendar in September each year. In 2018 more than 200 parliamentarians and staff were bled during the course of the day, including Health Minister Greg Hunt among those who opted to be tested. Jason Clare MP, co-Chair of the Parliamentary Friends of Prostate Cancer, has spoken in Parliament House on the importance of pathology.

These activations are appreciated by parliamentarians and contribute to better understanding and engagement with pathology, as evidenced by International Pathology Day in November 2018 when more than 30 parliamentarians provided messages of support, including a resolution in the Senate on the value of pathology!

It is crucial to maintain these engagements as politics can throw up surprises – none more so than the 2019 Federal election. In this context, the need to continue to showcase the value of pathology is vital to our sector's continued sustainability.

With innovative pathology technology challenging some of healthcare's most complex and wicked problems, funding pressures remain, so the need for meaningful and trusted engagement with Government and policymakers has never been greater.

I am pleased to say that many parliamentarians have acknowledged PAA's contribution in providing impartial information on the role of pathology and as a representative voice for the entire profession. The annual CIE report The Economic Value of Pathology forms an important part of this continued engagement.

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More broadly Know Pathology Know Healthcare continues to build awareness of the value of pathology with those who rely on it most – consumers. Education initiatives with health consumer organisations including Diabetes Australia, Prostate Cancer Foundation of Australia, Cancer Council Australia and the Australian Cervical Cancer Foundation tell the story of diagnosis and diagnostics to those who are heavily invested in the information that pathology provides.

Know Pathology Know Healthcare's partnership with Lab Tests Online is a centrepiece to build health literacy and understanding of the value of pathology. Consumer curiosity and interest in their tests is likely to increase further with the adoption of My Health Record – an electronic record that will inevitably be filled with information relating to pathology. Knowpathology.com.au now appears at the top of most online searches relating to pathology – providing a trusted source of Australian information for questions about medical tests.

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

# FINANCIAL STATEMENTS

FOR THE YEAR ENDED 30 JUNE 2019



**General information**

The financial statements cover Pathology Technology Australia Limited as an individual entity. The financial statements are presented in Australian dollars, which is Pathology Technology Australia Limited's functional and presentation currency.

Pathology Technology Australia Limited is a not-for-profit unlisted public company limited by guarantee.

The financial statements were authorised for issue, in accordance with a resolution of directors, on 29 August 2019.

# DIRECTOR'S REPORT

THE DIRECTORS PRESENT THEIR REPORT, TOGETHER WITH THE FINANCIAL STATEMENTS, ON THE COMPANY FOR THE YEAR ENDED 30 JUNE 2019.

## 1. GENERAL INFORMATION

### (a) Directors

The following persons were directors of the company during the whole of the financial year and up to the date of this report, unless otherwise stated:

| | |
|---|---|
| Mr Sebastian D'Angelo (Chair) | Appointed 20 February 2014 to present |
| Mr Vito Trifilo (Treasurer) | Appointed 17 September 2015 to present |
| Mr John Crothers | Appointed 14 October 2011 to present |
| Mr David Basseal | Appointed 26 February 2019 to present |
| Ms Sally Hickman | Appointed 21 February 2018 to present |
| Ms Antionette Violo | Appointed 28 February 2018 to present |
| Ms Karen Macleod | Appointed 28 February 2018 to present |
| Mr Tony Feneziani | Appointed 28 February 2018 to present |
| Mr Rayden Rivett | Appointed 17 September 2015 to present |
| Mr Paul Cray | Appointed 11 September to January |

### (b) Company secretary

Wendy-Jane Morrow was appointed as company secretary on 1 July 2014 and held the position of company secretary until 29 February 2019. Dean Whiting was appointed as the new company secretary from 18 March 2019 and the rest of the year.

### (c) Principal activities

The principal activity of Pathology Technology Australia Limited during the financial year during the financial year involved facilitating the growth and development of the in-vitro diagnostics industry in Australia.

The company has changed its name on 25 September 2018 from IVD Australia Limited to Pathology Technology Australia Limited (PTA) as a result of the rebranding project.

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 2019
- To maintain a Reserve Fund of $240,000
- To present TGA Regulatory Training to members as required in 2018-19
- To ensure regular ongoing meetings with Members to determine 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 PTA 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 PTA 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 PTA is recognised as a key stakeholder in the pathology industry
- Develop relevant publications on topics that can demonstrate PTA's benefits to the community such as POCT, the role of diagnostics in prevention and treatment of chronic disease and the PTA 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 and promote a range of policies that support the IVD Sector including POCT, Chronic Disease, Pharmacogenomics and reimbursement
- Develop links with and enhance knowledge of the benefits of IVDs within the Health and Insurance sectors.

## (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 2019 amounted to $45,327 (2018:$15,377 net surplus).

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

## (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.

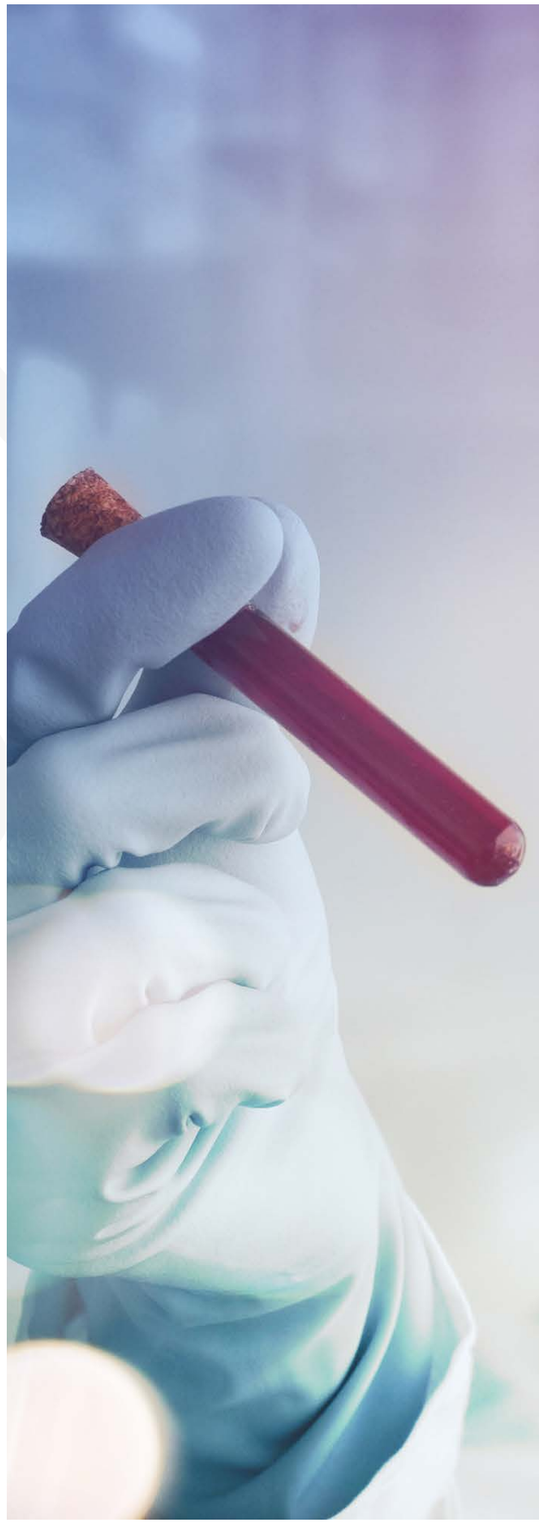
## (l) Indemnification and insurance of officers and auditors

(i) 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 2019. 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.

(ii) 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 dollar ($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 Healthineers – 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 Healthineers 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 Paul Cray**

**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.

**Mr Tony Feneziani**

**Head of Research Solutions ANZ, Merck Group**

Tony has over 25 years commercial experience in the in vitro diagnostic and life sciences industries. During this time, Tony has undertaken a range of leadership roles including commercial operations, sales and marketing and business development.

Tony's current role at Merck also includes Country Leadership Team membership of the Merck Life Sciences operation in ANZ.

**Sally Hickman**

**General Manager, Werfen Australia & NZ**

Sally has over 12 years experience in the Australian IVD industry having undertaken key roles in the areas of strategic marketing and customer account management. in 2012, Sally joined Werfen Australia and assumed key management responsibilities at a time when company took direct operations of key business units in Oceania.

Sally has a passion for diagnostics having trained and worked in public pathology laboratories for more than 5 years in the UK.

Sally holds a Bachelor of Science degree in Biomedical Sciences from The University of Bradford, UK and a Master of Science in Biomedical Sciences degree (specialising in Haematology) from The University of Ulster, UK.



**Karen Macleod**

**Director and Country Manager, MP Biomedicals**

Karen's 30-year career in the in-vitro diagnostics and pharmaceuticals industries began as a medical scientist in public pathology and includes varied sales and management roles with Australian based global companies such as BioMerieux, Boehringer Mannheim (now Roche) and GSK. Currently Director and Country Manager at MP Biomedicals, she is responsible for all sales, management, and regulatory functions. Karen has a Bachelor of Applied Science and Graduate Diploma in Marketing from UTS, Sydney and has been a member of the Pathology Technology Australia Technical and Regulatory Standing Committee since 2011.

**Antionette Violo**

**Regional Sales Director, Diagnostics, PerkinElmer**

My association with the life sciences, human health and diagnostics industries has extended for over 25 years across the commercial and academic sectors. I am currently the Regional Sales Director for PerkinElmer's diagnostic's business in the Applied Genomics division.

My commercial career commenced when I was approached to start the Life Sciences Division of PerkinElmer in Australia. I have been fortunate to progress within the organisation and have managed divisions and many staff across Australia, New Zealand and Asia for over 15 years. A significant achievement I am very proud of has been to partner PerkinElmer in the commercialisation of an Australian developed immunoassay kit (TGR Biosciences).

I was approached to join the Diagnostics Division twelve months ago to develop the Applied Genomics division within the Asia Pacific region. This has been an exciting challenge and a personal interest of mine in observing the impact that translational medicine has on human health outcomes.

**Mr Vito Trifilo (Treasurer)**

**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 6 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.

**John Crothers**

**Chair, Pathology Awareness Australia Regional Director, Abbott Diagnostics Pty Ltd**

John Crothers is the Regional Director for Australia and New Zealand. Prior to the role in Australia, John was the Commercial Director for Asia Pacific and has also had several years in US Marketing. With over 25 years' experience in the pathology industry in both the laboratory and IVD, the appreciation of the value of the industry in healthcare is a passion that John continues to pursue. John has a BSc(MLS) from RMIT and a Graduate Diploma in Business Administration from Swinburne University.

**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).

**Mr David Basseal**

**Business Area Manager, Pathology at Roche Diagnostics Australia**

David Basseal has over 20 years industry experience in Life Sciences with 12 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. David then spent 9 years with Becton Dickinson (BD) leading numerous businesses within the diagnostics area. David final role at BD was the Business Director for Diagnostics for Australia/New Zealand at Becton Dickinson. Today David is with Roche Diagnostics Australia and holds the position of Business Area Manager for Pathology.



## 2. MEETINGS OF DIRECTORS

The number of meetings of the company's Board of Directors ('the Board') held during the year ended 30 June 2019, and the number of meetings attended by each director were:

| | FULL BOARD | |
|---|---|---|
| | ATTENDED | HELD |
| Mr Sebastian D'Angelo (Chair) | 5 | 6 |
| Mr Vito Trifilo (Treasurer) | 6 | 6 |
| Mr John Crothers | 6 | 6 |
| Mr Rayden Rivett | 4 | 6 |
| Mr Paul Cray | 2 | 3 |
| Ms Karen Macleod | 6 | 6 |
| Ms Antoniette Violo | 3 | 6 |
| Ms Sally Hickman | 2 | 6 |
| Mr Tony Feneziani | 5 | 6 |
| Mr David Basseal | 3 | 3 |

Held: represents the number of meetings held during the time the director held office.

## 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 2019 has been received and can be found on page 8 of the financial report.

This report is made in accordance with a resolution of directors, pursuant to section 298(2)(a) of the Corporations Act 2001.

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

**Chair**
Mr Sebastian D'Angelo

**Treasurer**
Mr Vito Trifilo

Dated: 6th September 2019

Nexia Australia

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

As audit partner for the audit of the financial statements of Pathology Technology Australia Limited for the financial year ended 30 June 2019, 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.

Nexia

**Nexia Sydney Partnership**

**Mark Boyle**
Partner
Sydney

Dated: 6 September 2019

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# STATEMENT OF PROFIT OR LOSS & OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2019

| | NOTE | 2019 $ | 2018 $ |
|---|---|---|---|
| Revenue | 4 | **429,805** | 433,881 |
| Interest income | | **6,658** | 7,120 |
| **TOTAL INCOME** | | **436,463** | 441,001 |
| Employee benefits expense | 5 | **(257,561)** | (254,332) |
| Depreciation expense | 5 | **(824)** | (400) |
| Administrative expenses | | **(223,405)** | (170,892) |
| **TOTAL EXPENSES** | | **(481,790)** | (425,624) |
| **SURPLUS/(DEFICIT) FOR THE YEAR** | | **(45,327)** | 15,377 |
| Other comprehensive income | | - | - |
| **TOTAL COMPREHENSIVE INCOME FOR THE YEAR** | | **(45,327)** | 15,377 |

# STATEMENT OF FINANCIAL POSITION

AS AT 30 JUNE 2019

| | NOTE | 2019 $ | 2018 $ |
|---|---|---|---|
| **ASSETS** | | | |
| **CURRENT ASSETS** | | | |
| Cash and cash equivalents | 6 | **374,074** | 291,679 |
| Trade and other receivables | 7 | **10,667** | 2,247 |
| Other | 8 | **1,276** | - |
| **TOTAL CURRENT ASSETS** | | **386,017** | 293,926 |
| **NON-CURRENT ASSETS** | | | |
| Plant and equipment | 9 | **2,065** | 2,214 |
| **TOTAL NON-CURRENT ASSETS** | | **2,065** | 2,214 |
| **TOTAL ASSETS** | | **388,082** | 296,140 |
| **LIABILITIES** | | | |
| **CURRENT LIABILITIES** | | | |
| Trade and other payables | 10 | **51,501** | 41,052 |
| Employee benefits | 11 | **10,058** | 9,475 |
| Other | 12 | **149,652** | 14,533 |
| **TOTAL CURRENT LIABILITIES** | | **211,211** | 65,060 |
| Employee benefits | 13 | **3,136** | 12,018 |
| **TOTAL NON-CURRENT LIABILITIES** | | **3,136** | 12,018 |
| **TOTAL LIABILITIES** | | **214,347** | 77,078 |
| **NET ASSETS** | | **173,735** | 219,062 |
| **EQUITY** | | | |
| Retained surpluses | | **173,735** | 219,062 |
| **TOTAL EQUITY** | | **173,735** | 219,062 |



# STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 30 JUNE 2019

| | RETAINED SURPLUSES $ | TOTAL EQUITY $ |
|---|---|---|
| **Balance at 1 July 2017** | **203,685** | **203,685** |
| Other comprehensive income for the year | 15,377 | 15,377 |
| Total comprehensive income for the year | - | - |
| **Balance at 30 June 2018** | **219,062** | **219,062** |
| **Balance at 1 July 2018** | **219,062** | **219,062** |
| Deficit for the year | (45,327) | (45,327) |
| Other comprehensive income for the year | - | - |
| Total comprehensive income for the year | (45,327) | (45,327) |
| **Balance at 30 June 2019** | **173,735** | **173,735** |

# STATEMENT OF CASH FLOWS

FOR THE YEAR ENDED 30 JUNE 2019

| | NOTE | 2019 $ | 2018 $ |
|---|---|---|---|
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | | |
| Receipts from customers (inclusive of GST) | | **612,154** | 381,772 |
| Payments to suppliers and employees (inclusive of GST) | | **(535,742)** | (468,226) |
| | | **76,412** | (86,454) |
| Interest received | | **6,658** | 7,202 |
| **NET CASH FROM/(USED IN) OPERATING ACTIVITIES** | | **83,070** | (79,252) |
| **CASH FLOWS FROM INVESTING ACTIVITIES** | | | |
| Payments for plant and equipment | 9 | **(675)** | (2,353) |
| **NET CASH USED IN INVESTING ACTIVITIES** | | **(675)** | (2,353) |
| **CASH FLOWS FROM FINANCING ACTIVITIES** | | | |
| **NET CASH FROM FINANCING ACTIVITIES** | | **-** | - |
| Net increase/(decrease) in cash and cash equivalents | | **82,395** | (81,605) |
| Cash and cash equivalents at the beginning of the financial year | | **291,679** | 373,284 |
| **CASH AND CASH EQUIVALENTS AT THE END OF THE FINANCIAL YEAR** | 6 | **374,074** | 291,679 |



# NOTES TO THE FINANCIAL STATEMENTS

## 1. GENERAL INFORMATION

The financial report covers Pathology Technology Australia Limited as an individual entity. Pathology Technology 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.

## 2. SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies adopted in the preparation of the financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

### (i) New or amended Accounting Standards and Interpretations adopted

The company has adopted all of the new or amended Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period.

Any new or amended Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

The adoption of these Accounting Standards and Interpretations did not have any significant impact on the financial performance or position of the company.

The following Accounting Standards and Interpretations are most relevant to the company:

**AASB 9 Financial Instruments**

The company has adopted AASB 9 from 1 July 2018. The standard introduced new classification and measurement models for financial assets. A financial asset shall be measured at amortised cost if it is held within a business model whose objective is to hold assets in order to collect contractual cash flows which arise on specified dates and that are solely principal and interest. A debt investment shall be measured at fair value through other comprehensive income if it is held within a business model whose objective is to both hold assets in order to collect contractual cash flows which arise on specified dates that are solely principal and interest as well as selling the asset on the basis of its fair value. All other financial assets are classified and measured at fair value through profit or loss unless the entity makes an irrevocable election on initial recognition to present gains and losses on equity instruments (that are not held-for-trading or contingent consideration recognised in a business combination) in other comprehensive income ('OCI'). Despite these requirements, a financial asset may be irrevocably designated as measured at fair value through profit or loss to reduce the effect of, or eliminate, an accounting mismatch.
For financial liabilities designated at fair value through profit or loss, the standard requires the portion of the change in fair value that relates to the entity's own credit risk to be presented in OCI (unless it would create an accounting mismatch).
New simpler hedge accounting requirements are intended to more closely align the accounting treatment with the risk management activities of the entity. New impairment requirements use an 'expected credit loss' ('ECL') model to recognise an allowance. Impairment is measured using a 12-month ECL method unless the credit risk on a financial instrument has increased significantly since initial recognition in which case the lifetime ECL method is adopted. For receivables, a simplified approach to measuring expected credit losses using a lifetime expected loss allowance is available.

### (ii) Basis of preparation

These general purpose financial statements have been prepared in accordance with Australian Accounting Standards - Reduced Disclosure Requirements and Interpretations issued by the Australian Accounting Standards Board ('AASB') and the Corporations Act 2001, as appropriate for not-for profit oriented entities.

**Historical cost convention**

The financial statements have been prepared under the historical cost convention, except for, where applicable, the revaluation of financial assets and liabilities at fair value through profit or loss, financial assets at fair value through other comprehensive income, investment properties, certain classes of property, plant and equipment and derivative financial instruments.

**Critical accounting estimates**

The preparation of the financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the company's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed in note 3.

**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**

Interest revenue is recognised as interest accrues using the effective interest method. This is a method of calculating the amortised cost of a financial asset and allocating the interest income over the relevant period using the effective interest rate, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

### (iii) 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.

### (iv) Current and non-current classification

Assets and liabilities are presented in the statement of financial position based on current and non-current classification.

An asset is classified as current when: it is either expected to be realised or intended to be sold or consumed in the company's normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is classified as current when: it is either expected to be settled in the company's normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current.

### (vi) Cash and cash equivalents

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.



### (vii) Trade and other receivables

Trade receivables are initially recognised at fair value and subsequently measured at amortised cost using the effective interest method, less any allowance for expected credit losses. Trade receivables are generally due for settlement within 30 days.

The company has applied the simplified approach to measuring expected credit losses, which uses a lifetime expected loss allowance. To measure the expected credit losses, trade receivables have been grouped based on days overdue.

Other receivables are recognised at amortised cost, less any allowance for expected credit losses.

### (viii) Plant and equipment

Plant and equipment is stated at historical cost less accumulated depreciation and impairment. 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 is calculated on a straight-line basis to write off the net cost of each item of property, plant and equipment (excluding land) over their expected useful lives as follows:

- Furniture, fixtures and fittings 3 - 5 years
- Computer equipment 3 years

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each reporting date.

Leasehold improvements and plant and equipment under lease are depreciated over the unexpired period of the lease or the estimated useful life of the assets, whichever is shorter.

An item of plant and equipment is derecognised upon disposal or when there is no future economic benefit to the company. Gains and losses between the carrying amount and the disposal proceeds are taken to profit or loss. Any revaluation surplus reserve relating to the item disposed of is transferred directly to retained profits.

### (ix) Trade and other payables

These amounts represent liabilities for goods and services provided to the company prior to the end of the financial year and which are unpaid. Due to their short-term nature they are measured at amortised cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

### (x) Employee benefits

**Short-term employee benefits**

Liabilities for wages and salaries, including non-monetary benefits, annual leave and long service leave expected to be settled wholly within 12 months of the reporting date are measured at the amounts expected to be paid when the liabilities are settled.

**Other long-term employee benefits**

The liability for annual leave and long service leave not expected to be settled within 12 months of the reporting date are measured at the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on national government bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

### (xi) Goods and Services Tax ('GST') and other similar taxes

Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the tax authority. In this case it is recognised as part of the cost of the acquisition of the asset or as part of the expense.

Receivables and payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the tax authority is included in other receivables or other payables in the statement of financial position.

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the tax authority, are presented as operating cash flows.

## 3. CRITICAL ACCOUNTING JUDGEMENTS, ESTIMATES AND ASSUMPTIONS

### (i) Estimation of useful lives of assets

The company determines the estimated useful lives and related depreciation and amortisation charges for its plant and equipment. The useful lives could change significantly as a result of technical innovations or some other event. The depreciation and amortisation charge will increase where the useful lives are less than previously estimated lives, or technically obsolete or non-strategic assets that have been abandoned or sold will be written off or written down.

### (ii) Employee benefits provision

As discussed in note 2, the liability for employee benefits expected to be settled more than 12 months from the reporting date are recognised and measured at the present value of the estimated future cash flows to be made in respect of all employees at the reporting date. In determining the present value of the liability, estimates of attrition rates and pay increases through promotion and inflation have been taken into account.

## 4. REVENUE

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Member subscriptions | **426,174** | 427,024 |
| Other revenue | **3,631** | - |
| Conference revenue | **-** | 6,857 |
| **REVENUE** | **429,805** | 433,881 |

## 5. EXPENSES

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| **EMPLOYEE BENEFITS EXPENSE** | | |
| Wages and salaries | **234,300** | 236,802 |
| Superannuation | **23,261** | 21,226 |
| | **257,561** | 258,028 |
| **DEPRECIATION EXPENSE** | | |
| Computer equipment | **824** | 321 |
| Office equipment | **-** | 79 |
| | **824** | 400 |

## 6. CURRENT ASSETS - CASH AND CASH EQUIVALENTS

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Cash at bank | **134,074** | 51,679 |
| Term deposit | **240,000** | 240,000 |
| **REVENUE** | **374,074** | 291,679 |

## 7. CURRENT ASSETS - TRADE AND OTHER RECEIVABLES

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Trade receivables | **8,552** | - |
| Interest receivable | **2,115** | 2,247 |
| **REVENUE** | **10,667** | 2,247 |

## 8. CURRENT ASSETS - OTHER

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Prepayments | **1,276** | - |

## 9. NON-CURRENT ASSETS - PLANT AND EQUIPMENT

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Computer equipment - at cost | **12,282** | 11,607 |
| Less: Accumulated depreciation | **(10,217)** | (9,393) |
| | **2,065** | 2,214 |
| Furniture, fixtures and fittings - at cost | **2,589** | 2,589 |
| Less: Accumulated depreciation | **(2,589)** | (2,589) |
| | **2,065** | 2,214 |

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:

| | COMPUTER EQUIPMENT | TOTAL |
|---|---|---|
| | $ | $ |
| Balance at 1 July 2018 | **2,214** | 2,214 |
| Additions | **675** | 675 |
| Depreciation expense | **(824)** | (824) |
| **BALANCE AT 30 JUNE 2019** | **2,065** | 2,065 |

## 10. CURRENT LIABILITIES - TRADE AND OTHER PAYABLES

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Other payables | **11,957** | 12,575 |
| GST collected | **11,851** | 5,864 |
| Accrued expenses | **27,693** | 22,613 |
| | **51,501** | 41,052 |



## 11. CURRENT LIABILITIES - EMPLOYEE BENEFITS

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Annual leave | **10,058** | 9,475 |

## 12. CURRENT LIABILITIES - OTHER

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Revenue received in advance | **149,652** | 14,533 |

## 13. NON-CURRENT LIABILITIES - EMPLOYEE BENEFITS

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| Long service leave | **3,136** | 12,018 |

## 14. AUDITOR'S REMUNERATION

| | 2019 | 2018 |
|---|---|---|
| | $ | $ |
| **PAYABLE TO THE AUDITORS OF THE COMPANY - NEXIA SYDNEY PARTNERSHIP** | | |
| Audit services | **11,000** | 10,800 |
| Non-audit services | **8,104** | 5,064 |
| | **19,104** | 15,864 |

## 15. SUPERANNUATION COMMITMENTS

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

## 16. RELATED PARTY TRANSACTIONS

### Transactions with key management personnel

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: $212,946 (2018: $201,775). No other benefits were received or provided.

### Transactions with related entities

Unless otherwise stated, none of the transactions incorporate special terms and conditions and no guarantees were given or received.

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

### Loans to/from related parties

There were no loans to or from related parties at the current and previous reporting date.

## 17. SUPERANNUATION COMMITMENTS

There are no contingent liabilities that have been incurred by the Company in relation to 2019 or 2018.

## 18. EVENTS AFTER THE REPORTING PERIOD

No matter or circumstance has arisen since 30 June 2019 that has significantly affected, or may significantly affect the company's operations, the results of those operations, or the company's state of affairs in future financial years.



# DIRECTOR'S DECLARATION

In the directors' opinion:

- the attached financial statements and notes comply with the Corporations Act 2001, the Australian Accounting Standards - Reduced Disclosure Requirements, the Corporations Regulations 2001 and other mandatory professional reporting requirements;
- the attached financial statements and notes give a true and fair view of the company's financial position as at 30 June 2019 and of its performance for the financial year ended on that date; and
- there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of directors made pursuant to section 295(5)(a) of the Corporations Act 2001.

**Chair**
Mr Sebastian D'Angelo

Dated: 6th September 2019

**Treasurer**
Mr Vito Trifilo

Nexia Australia

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

REPORT ON THE AUDIT OF THE FINANCIAL REPORT

## Opinion

We have audited the financial report of Pathology Technology Australia Limited (the Company), which comprises the statement of financial position as at 30 June 2019, 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, 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 the Company is in accordance with the Corporations Act 2001, including:

- giving a true and fair view of the Company's financial position as at 30 June 2019 and of its financial performance for the year then ended; and
- 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 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.

## Other information

The directors are responsible for the other information. The other information comprises the information in Pathology Technology Australia Limited's annual report for the year ended 30 June 2019, but does not include the financial report and the auditor's report thereon.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of the other information we are required to report that fact. We have nothing to report in this regard.

## 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.

## 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.

A further description of our responsibilities for the audit of the financial report is located at The Australian Auditing and Assurance Standards Board website at: www.auasb.gov.au/auditors_files/ar4.pdf. This description forms part of our auditor's report.

**Nexia Sydney Partnership**

**Mark Boyle**
Partner
Sydney
Dated: 6 September 2019



# PATHOLOGY TECHNOLOGY AUSTRALIA MEMBERS

Abbott Australasia Pty Ltd
Agilent Australia
Astral Scientific Pty Ltd
Atomo Diagnostics
Australasian Medical and Scientific Ltd
BD Diagnostics Australia New Zealand
bioMérieux Australia Pty Ltd
Bio-Rad Laboratories Pty Ltd
Blackaby Diagnostics
Cepheid Holdings Pty Ltd
Dako
ESL Biosciences Australia (2012) P/L
Grifols Australia Pty Ltd
Hologic
Illumina Australia Pty Ltd
Integrated Sciences Pty Ltd
KHQ lawyers
London Agency
Macarthur Cook
Merck Millipore Australia Pty Ltd
MP Biomedicals Australasia
Paragon Therapeutic Technologies Pty Ltd
PerkinElmer Pty Ltd
Pro-Health Asia Pacific Pty Ltd
QIAGEN PtyLtd
Roche Diagnostics Australia Pty Ltd
Siemens Healthineers
SJ Alder
SpeeDx Pty Ltd
Sysmex Australia Pty Ltd
Tecan Australia
ThermoFisher Scientific
Werfen Australia

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