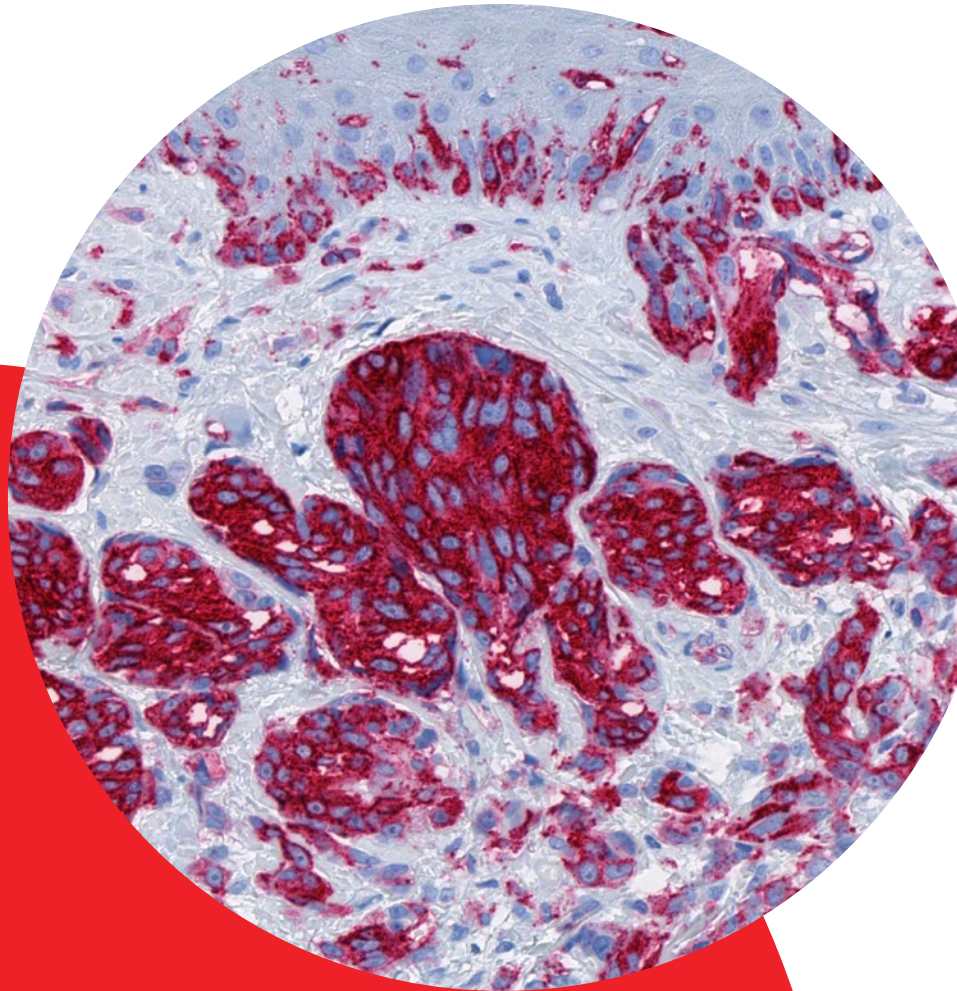




**PATHOLOGY
TECHNOLOGY
AUSTRALIA**



MEMBERSHIP INFORMATION PACKAGE

Maximising Member Value

Advocacy Leadership Profile Information

WELCOME LETTER FROM THE CEO

Dear Prospective Member,

In this, our 10th year, I invite you to join Pathology Technology Australia. As our industry grows and becomes more complex, Pathology Technology Australia is committed to represent the interests of technology developers, manufacturers and suppliers to the Australian pathology market.

I have been in the pathology industry all my working life; both as a customer and a supplier. I understand the industry from all perspectives, so I understand the complexities we face; from R&D to production, quality to regulatory and through to commercial success. I have experienced it all.

There has possibly never been a more important time for the pathology technology industry. There are significant changes occurring.

- Changes related to funding and reimbursements
- New and disruptive technologies
- IVD registration changes

These will affect all companies and we need to be together in our management of them. It is time we took more of a leadership role in managing the outcomes we want. Certainly, we must collaborate more widely with key partners, working together for a healthier Australia. At the same time, we must also ensure that our representations, as an industry body, are understood and accepted; in particular, our key messages - centred on the critical role we play in delivering the highest quality, affordable and accessible healthcare system.

In my role as CEO of Pathology Technology Australia I am here to represent your company and interests; to listen and respond; to improve

market access; to represent your views to the policymakers, regulators and funders; and to foster an environment for you to be successful. Most of all, I am here to maximise the value you get for your membership dollars.

We have a clear strategic plan in place, linked to our activities and outcomes. We have built trust with and have good access to key people at the Federal Department of Health, the TGA and the Department of Agriculture. Members now have a voice on the Reg Tech group and the Consultative Committee at the TGA. We have a seat at the Biologicals Consultative group at the Department of Agriculture. We are now invited to the Department of Health's Health Technology Assessment workshops and we sit on the MBS Pathology Business Group. I am pushing for participation in further policy and working groups; giving members a greater degree of influence over the factors that affect them.

We have been successful in advocating reduced TGA fees. We have recently had good success in speeding up biological import permits for members. We are actively addressing market access topics on behalf of members. And maybe best of all, we participate in the Pathology Awareness campaign "Know Pathology Know Healthcare". This globally unique program is having remarkable success; with social media conversion rates 5 times higher than the industry standard; more than \$4 million in gratis mainstream media coverage; completing 97 politician laboratory visits. This project is instrumental in focussing unprecedented attention on healthcare at the federal political level.

Why should your company be a member of Pathology Technology Australia?

- **Advocacy** - Most of your competitors are already members; Pathology Technology Australia advocates on their behalf, influencing outcomes important to them. I am passionate about the importance of our technology to the healthcare economy - and its role in delivering quality and affordable healthcare.
- **Leadership** - Members are now represented at the DoH Health Technology Assessment workshops, where discussions around the value of their new technologies influences policy and funding decisions. We have pioneered new market access approaches to optimise MSAC outcomes. Members are taking advantage of this new approach.
- **Profile** - Membership fees support pathology awareness campaigns such as Know Pathology Know Healthcare, driving value and influence. Members can showcase technology and build awareness, including at Parliament House, Canberra. We are planning significant escalation of profile over the next 2 years. Your membership will be seen as a mark of trust and respect from your customers.
- **Information** - Social media presence to share market and member information. Regular CEO Updates that raises critical and timely topics. Training sessions and workshops covering regulatory and other topics of importance to members. Networking sessions, events and keynote speakers provide valuable opportunities for members to learn and grow.

Pathology Technology Australia has developed a standing committee structure covering topics such as Finance and Risk Management, Technical and Regulatory, Market Development and Access, Marketing Communications, and Point of Care. As a member company, you can nominate your staff to participate in these committees. This offers career extension, industry exposure and builds skills outside the company environment.

Please find the following Information Pack and Application Form for membership of Pathology Technology Australia Limited. Following acceptance of your Application by the Board, and receipt of your turnover declaration, a Tax Invoice for the current year fees will be generated. Prompt payment of this invoice is appreciated as membership of Pathology Technology Australia does not become effective until the invoice is paid.

Please call or email me if you have any questions.

Yours sincerely,

Dean Whiting
CEO, Pathology Technology Australia Limited

Ph: +61 (0)2 8007 6632

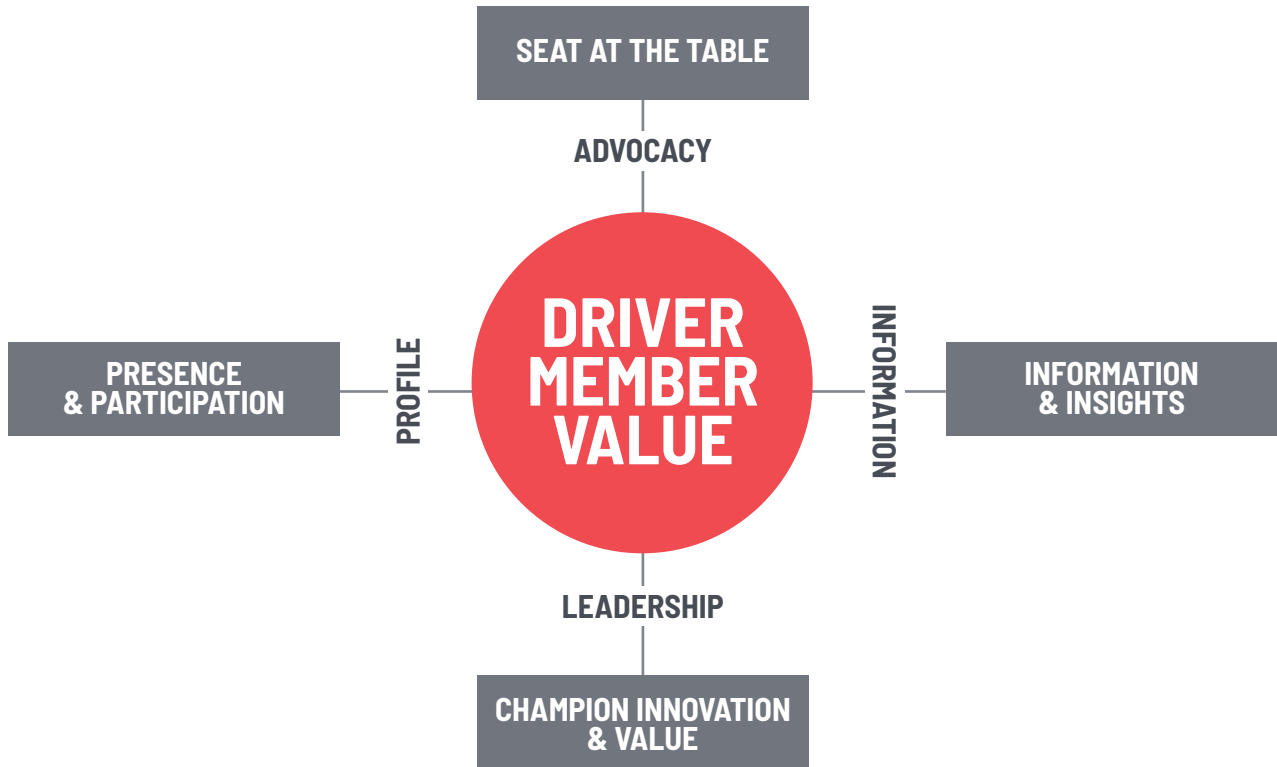
Mb: +61 (0)497777688

Email: ceo@pathologytechnology.org.au

Web: www.pathologytechnology.org.au

Twitter: @PathologyTechnologyAu

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

ENERGISE 2019-2020

- Reconnect with members past, present and future to demonstrate our value prop
- Leverage new brand identity
- Gain recognition and trust with policy makers, regulators & payers
- Re-energise committee structure & membership
- Support PAA and participate in KPKH activities

ACTION 2021

- Voice on government advisory committees, working groups
- Use compelling health economic and other data to inform policy and funding for pathology technology
- Drive the issues that matter to our members
- Actively promote and showcase our technology and Value Proposition
- Initiate policy discussion on new technology, solutions and software

ACHIEVE 2022

- Represent industry players, who are actively engaged
- We are financially viable with good reserves
- We are invited to provide data and trends to inform better policy and funding decisions
- TGA and DoA regulations and policies specifically recognise IVD products and their low risk profiles
- Valued for the new technologies and solutions we bring the health economy
- We actively showcase our technology and continue to support PAA

WHY JOIN PATHOLOGY TECHNOLOGY AUSTRALIA

Because we need government to understand and value the critical role our IVD technology companies have played and will increasingly play in the healthcare economy of the future...

We can't do this without you.

- Would your business benefit from regular information on the best way to manage the new TGA requirements? Even better, would you like to have input into the submissions we make on these substantial registration changes?
- Would you like to take advantage of a better way to submit MSAC applications or a smoother way to navigate biologicals import permits?
- Would you want to participate in Australia's first Pathology Technology Expo?
- Do you want to be involved in Canberra Innovation Days? – Showcasing innovation directly to government.
- Most importantly, do you want to have your say on how new and disruptive technologies are regulated, funded and used in Australia?

Representing the industry as a broad voice

The broader the voice we have, the more influential we can be. We already have a majority of the pathology supply companies as signed up members. As a member, you will be providing the input and direction we use to advocate to policymakers, regulators and funders. You need to be part of Pathology Technology Australia if you want to have your say on the changes that will make a difference to your business.

Respected by customers and professional bodies

We are trusted and respected by our customers and our peers.

- The confidence we provide by member's compliance to our Code of Conduct.
- The respect we garner from customers as their vital R&D division
- The trust we develop because, as members we bring products to market through the exceptional Market Access activities we adopt,

Feedback and insights from government bodies and key industry stakeholders

Members enjoy the benefits of the feedback and insights Pathology Technology Australia obtains through interaction with government departments and other industry stakeholders. This helps member companies stay close to critical information, to formulate strategy and to plan. We are invited to contribute to regulatory changes and do so on a regular basis. As a member, you gain insights to proposed changes and you can contribute to our response.

MSAC

We have pioneered a methodology for more effective MSAC submissions. You will be able to participate in these.

Access to government advisory committees and groups

We are gaining access to further government advisory committees and groups. For example; we are now on the DoH Health Technology Assessment group for genome-based cancer testing (the only technology group invited). This will have a substantial impact on future policy, regulation and funding.

Recently we have been able to advocate specifically for members at both Department of Agriculture on Biologicals import permits and to TGA for product registrations. All with very good success.

Access to global diagnostic market statistics

Pathology Technology Australia subscribes to the Global Diagnostic Market Statistics (GDMS) Program. The data we get from this helps inform our approach to government. Member companies also have access to this market data.

Participation in the Know Pathology Know Healthcare initiative

We are actively involved on the Board of Pathology Awareness Australia. We ensure your voice is heard and provide the opportunity for active participation in the Know Pathology Know Healthcare initiative, to promote the Value of Pathology to the general public, government and other relevant stakeholders. This globally unique program is having remarkable success with;

- Social media conversion rates 5 times higher than industry standard
- More than \$4 million in gratis mainstream media coverage
- Completing 97 politician laboratory visits
- Engaging major Consumer Health Organisations

This project is instrumental in focussing unprecedented attention on healthcare at the federal political level, as evidenced by the substantial funding commitments made.

Your staff development - participating on specialised committees and panels

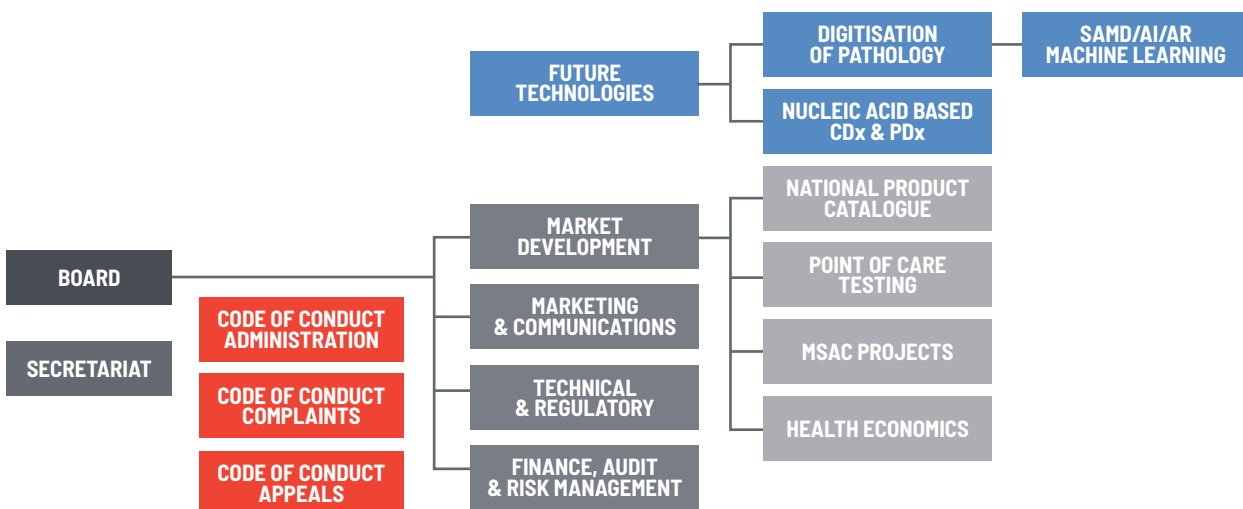
You, your staff and management team can participate on our board of directors, committees and expert panels; keeping you up to date with industry changes (that will impact you and your company's success and future growth potential) and providing staff development opportunities.

All this to create a sustainable pathology industry for the long term. Valued because of the clear understanding - by policymaker, regulators and funders - of the critical importance our technology brings to a sustainable healthcare sector of the future.

Committees

The detailed work of Pathology Technology Australia is undertaken through an expertise based committee structure, focused on the strategic priorities of the organisation.

Pathology Technology Australia Committees and Working Groups



WHY JOIN PATHOLOGY TECHNOLOGY AUSTRALIA

MDC – Market Development Committee

The role of this Committee is to assist in the ongoing development of the market for in vitro diagnostic products in Australia. To this end, the Committee participates in the development of policies and activities that assist in the growth of the overall market for human pathology testing.

M&C – Marketing & Communications Committee

The role of this Committee is to oversee the development and implementation of strategic communications relevant to identified IVD Industry Stakeholders. It provides strategic advice on the delivery of promotional campaigns and events designed to increase awareness of Pathology Technology Australia and our brand and positioning, including the retention and attraction of Pathology Technology Australia members. It also supports the management of media issues.

TARSC – Regulatory Policy & Technical Committee

The role of this Committee is to minimise the regulatory burden for IVD sponsors and manufacturers and ensure timely entry to market of leading-edge diagnostic testing while ensuring appropriate levels of safety and efficacy of IVD products supplied to the Australian market. TARSC is focused on all regulatory issues that affect the IVD industry. For example: this Committee is an active participant in the Biological Consultative Group (BCG) - an industry group composed of organisations involved in the importation of biological products. The BCG acts as a consulting mechanism between the Department of Agriculture and industry groups that import biological materials. Issues addressed include anything topical for either the Biologicals Unit or the relevant industry groups. Examples include permit application fees, import conditions placed on various products and BiCon clearance procedures.

Code of Conduct Administration Committee

The Code of Conduct Administration Committee is charged with the administration and on-going development of Industry Code of Practice. The Code of Conduct Administration Committee is comprised of 7 representatives from stakeholder groups, consumers and member companies and is supported by the Executive Assistant as Secretary.

Future Technologies Committee

Formed to focus on the technologies and software that will transform the pathology industry. The aim

of this committee will be to provide leadership and advice on the role of new technology. In collaboration with other stakeholders, we will use this advice to inform and change policy, regulation and funding directions to make sure Australians have access to the latest technology – driving quality, affordable and accessible healthcare solutions in Australia. This committee will be subject expert based and in the first place be focussed on nucleic acid and IT based technologies. The committee's focus and expertise will change as necessary to meet changing needs.

Member Classes & Definitions

There are three classes of Members, namely:

- (i) Honorary Life Members;**
- (ii) Voting Members; and**
- (iii) Associate Members;**

The Board shall have absolute discretion for the allocation of Members into categories of membership.

Honorary Life Members

A person may be an Honorary Life Member if that person has, by determination of the Board, made outstanding contributions to the Company or to the field of in-vitro diagnostics or a related field of endeavour.

An Honorary Life Member is entitled to attend and participate in Company proceedings.

An Honorary Life Member is not entitled to vote in Company general meetings.

Voting Members

A person may be a Voting Member if that person is a Corporation, Incorporated Association or Unincorporated Association formed under any laws of the Commonwealth or States or Territories of the Commonwealth and is actively involved in any field of in-vitro diagnostics. In special circumstances, the Board may admit persons not so qualified to Voting Membership of the Company. A Voting Member is entitled to attend and participate in Company proceedings.

A Voting Member is entitled to vote at any General Meeting of the Company.

Associate Members

A person may be an Associate Member if that person is ineligible to be a Voting Member but is involved in any allied industry, studies or research.

An Associate Member is entitled to attend and participate in Company proceedings.

An Associate Member is not entitled to vote in Company general meetings.

MEMBERSHIP BENEFITS AND SERVICES

BENEFITS	VOTING MEMBERS	LIFE MEMBERS	ASSOCIATE MEMBERS
Eligible to hold office and Eligible to vote 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 Assist in shaping the regulatory framework	✓	✓	✓
Use of Pathology Technology Australia Logo Differentiating Pathology Technology Australia Members and other affiliated organisations	✓	✓	✓
Participate in Strategic Planning Influence the direction and work of Pathology Technology Australia	✓	✓	✓
Access to Industry Members	✓	✓	✓
SERVICES	VOTING MEMBERS	LIFE MEMBERS	ASSOCIATE MEMBERS
Pathology Technology Australia Website Login and password to access member-only services	✓	✓	✓
Pathology Technology Australia Updates 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 Ensuring you remain at the forefront of your industry	✓	✓	✓
Pathology Technology Australia Member Directory Electronic	✓		✓

MEMBERSHIP FEES

Fees and other Payments

When an applicant has been accepted for membership the Secretariat will forthwith send to the applicant written notice of the applicant's acceptance and a request for payment of the entrance fee (if any) and first annual subscription. Upon payment of any entrance fee and first annual subscription the applicant will become a member of the Company provided nevertheless that if such payment be not made within two (2) calendar months after the date of the notice, the Board may in its discretion cancel its acceptance of the applicant for membership of the Company.

Annual subscriptions for each of the members will become due and payable in advance at the beginning of each financial year.

If the subscription of a member will remain unpaid for a period of three (3) calendar months after it becomes due then the member may after notice of the default will have been sent to him by the Secretary, or person appointed by the Board for such purpose, be debarred by resolution of the Board from all privileges of membership and such member's name may be removed by the Board from the Register of Members provided that the Board may reinstate the member and restore the member's name to the Register on payment of all arrears if the Board thinks fit to do so.

Calculation of Annual Membership Fees

Turnover is based on Australian (non-export) sales only of IVD related products for the period the preceding financial year.

Definition of IVD Products

Turnover is based on Australian (non-export) sales only of IVD related products for the period the preceding financial year, including:

- Reagents, instruments, and systems intended for use in:
 - diagnosis of disease or other conditions;
 - determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae);
- Related services, including IT and consulting;
- Such products as are intended for use in the collection, preparation, and examination of specimens taken from the human body;
- IVD products used for development of in-house IVD assays;
- IVD products used for companion and personalised diagnostics and treatments;
- Includes revenue booked by or to a related entity outside Australia, attributed to sales made within Australia;
- Research Use Only sales are not included in turnover.

Application Process

1. Complete the Application form
2. Email it to ceo@pathologytechnology.org.au
3. Complete the Pathology Technology Australia Annual Turnover Declaration Form
4. Email it to APeade@nexiasydney.com.au
5. Receive and pay invoice from Nexia Australia
6. Receive Pathology Technology Australia Certificate of Membership & copy of your Membership Record.

PATHOLOGY TECHNOLOGY AUSTRALIA MEMBERSHIP RENEWAL FEES FY20

Turnover Declaration for Membership Renewal

Annual Turnover Declarations are made directly to Nexia Australia, using the Pathology Technology Australia Membership Renewal Form – Annual Turnover Declaration Form. **No information about company turnover will be disclosed by Nexia Australia to Pathology Technology Australia and/or other parties.**

Calculation of Annual Membership Fees FY20

BAND	TURNOVER (TO)	ANNUAL FEE (EX-GST)	MAXIMUM FEE FOR EACH BAND FY20
1	\$1 – \$1,000,000	1,200	
2	\$1,000,001 – \$5,000,000	1,200 + 0.15% (turnover – 1,000,000)	
3	\$5,000,001 – \$10,000,000	7,200 + 0.14% (turnover – 5,000,000)	
4	\$10,000,001 – \$15,000,000	14,200 + 0.08% (turnover – 10,000,000)	
5	\$15,000,001 – \$20,000,000	20,200 + 0.08% (turnover – 15,000,000)	
6	\$20,000,001 – \$50,000,000	28,200 + 0.06% (turnover – 20,000,000)	\$37,230
7	\$50,000,001 – \$100,000,000	46,200 + 0.03% (turnover – 50,000,000)	\$43,697
8	\$100,000,001 – \$200,000,000	51,200 + 0.014% (turnover – 100,000,000)	\$45,778

BAND CAPS	BAND 6	BAND 7	BAND 8
FY20 Band Cap	37,230	43,697	45,778



**PATHOLOGY
TECHNOLOGY**
AUSTRALIA

PO Box 298
Parramatta CBD BC
NSW 2124, Australia

Phone +61 (02) 8007 6632
Email: info@pathologytechnology.org.au

www.pathologytechnology.org.au