IFC
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Specialising in Pharmacology & Forensic Toxicology

23 November 2022

Alisha Rayns
Acting Team Leader: Portfolio Delivery
Portfolio Management Office
National Road Policing Centre
Police National Headquarters
180 Molesworth St
Wellington, New Zealand

Re: Assessment of Roadside Drug Testing Devices
IFC Expert Case: 22-0227

Dear Ms Rayns,

You and your organisation have retained Independent Forensic Consulting represented by [redacted] as consultants in toxicology and analytical chemistry in the above captioned matter.

You have requested that I review the results of drug device verification and comment on whether the results of one or more devices conform to the requirements of Appendix C of the current oral fluid standard: AS/NZS 4760 - Procedure for specimen collection and the detection and quantitation of drugs in oral fluid (the Standard). You have also asked me to provide a qualified expert opinion on how the results and device would meet the meet the evidential test under the New Zealand Solicitor General's Prosecution Guidelines.

I declare that I have no affiliation with any organisation that has any real or perceived interest in the urine and/or oral fluid drug testing industry.

BACKGROUND

The NZ Government recently passed legislation that has provided for the introduction of roadside drug testing. As the enforcement authority and as part of the implementation of the legislation, NZ Police are undertaking a procurement process for the selection of an appropriate device to meet the needs of the legislation, which we have termed the Oral Fluid Testing (OFT) device.

As part of this process, NZ Police are looking to undertake an independent evaluation of short-listed devices to establish:

i) Alignment to the NZ Standards in respect to the term 'recent', how this relates to the specific oral fluid device, if it's possible to actually determine this.

ii) Are there any issues with the specific devices testing in the identification of the specified drugs.

iii) Comparison and evaluation of the stated specificity and sensitivity to real world performance. Paying specific attention to the likelihood of false negatives and worse, false positives.

With respect to the New Zealand Solicitor General's Prosecution Guidelines, it is understood that should a road side oral fluid drug test return a 'positive' result, a second test will be performed using the same device. Should the same result be returned, the driver will face the relevant penalties.

As stated in the Foreword of the Standard:

An oral fluid specimen may be used to provide an indication of relatively recent drug exposure at a workplace or at the roadside for drivers, but may also have other applications. For some drugs, there is a relationship between a blood or plasma concentration of drug and oral fluid concentration which may allow an inference of relatively recent exposure to drugs to be made (within hours) compared to the longer window of detection in urine (days to weeks). There is no relationship between oral fluid concentration and urine concentration and it is not appropriate to relate the presence of drugs in oral fluid to impairment, but rather to relatively recent exposure.

Therefore, testing of oral fluid detects relatively recent drug use, a time when a person is more likely to be impaired. This is in contrast with urine that detects any drug use in the recent days. The oral fluid and urine standard are intended to complement each other in this regard.

Whilst there are many variables such as dose of drug used, drugs such as THC are generally present in the oral fluid for only a few hours after use. Drugs such as the amphetamines (i.e.

methylamphetamine, MDMA) however may be present for many hours or a day or more after last use etc. In rare circumstances where the user is a very heavy, daily, chronic user of cannabis, residual THC may reside in the oral fluid for more than 6 hours and up to 24 hours[1].

REPORT

The following report includes a summary of the testing methods and results of verification testing of eight (8) devices according to paragraph C3 of Appendix C of AS/NZS 4760:2019. Followed by an interpretation or the results and conclusion on the performance of each of the devices.

The methods and results are based on the provided reports from HASTA dated: 29 August 2022; 6 September 2022; 20 September 2022; and 13 October 2022. Further detail, if required, can be sourced from the relevant HASTA reports.

METHODS

A total of eight (8) oral fluid testing devices were verified according to paragraph C3 of Appendix C of AS/NZS 4760:2019 by HASTA laboratories, 400 Epson Road Flemington, Victoria 3031 Australia.

The eight devices that had their performance assessed were:

s9(2)(b)(ii) [redacted]

s9(2)(b)(ii) [redacted]

[1] Odell et al. Residual cannabis levels in blood, urine and oral fluid following heavy cannabis use. *Forens Sci Int.* 2015;249:173-80

HASTA laboratories are a fully accredited laboratory that routinely perform verification of oral fluid devices and one of the most experienced laboratories currently performing verification of devices within New Zealand and Australia.

According to paragraph C3 of Appendix C of AS/NZS 4760:2019, device verification was assessed by testing a minimum of twenty (20) spiked samples, ten kits with oral fluid samples spiked at -50% of the screening cut-offs, and ten kits with oral fluid samples spiked at +50% of the screening cut-offs.

Paragraph C3 of Appendix C states that if a total of twenty kits are tested, there shall be no more than two failures in total (10%), whether that be false positives in the case of the -50% spiked oral fluid samples, or false negatives with respect to the +50% spiked oral fluid samples for each drug class tested.

In the absence of matrix provided by the manufacturer, fresh frozen oral fluid was supplied by Innovative Research Inc. – Pooled Normal Human Saliva, Catalogue Number IR100044P was used and oral fluid samples used for the verification were spiked with the analytes which the manufacturer of each of the devices uses as its calibrators.

Fresh oral fluid was collected from laboratory staff prior to testing.

All oral fluid (fresh or commercial) was frozen prior to use and when required was centrifuged to remove any unwanted material i.e. residual food, bubbles etc. Whilst it is acknowledged that this is not what happens roadside, it allows for a more accurate measurement of oral fluid volume, an important aspect of verification.

To ensure the correct concentration of drugs were spiked into the samples, aliquots of the blank oral fluid, -50% spiked oral fluid and +50% spiked oral fluid were also assessed by LCMS to verify the concentrations for all analytes.

Techniques specific to each device are summarised below:

s9(2)(b)(ii)

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

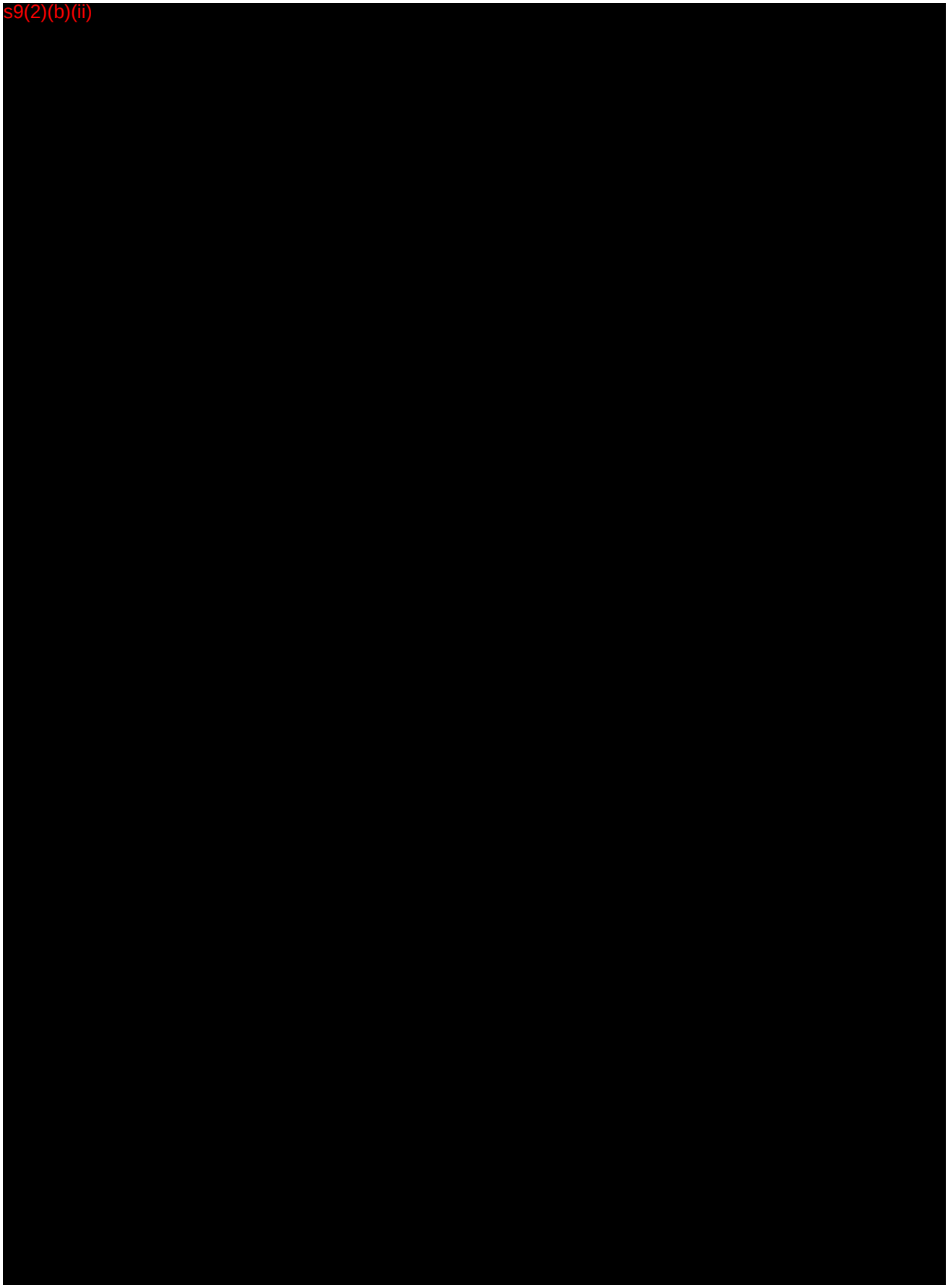
[redacted]

s9(2)(b)(ii)

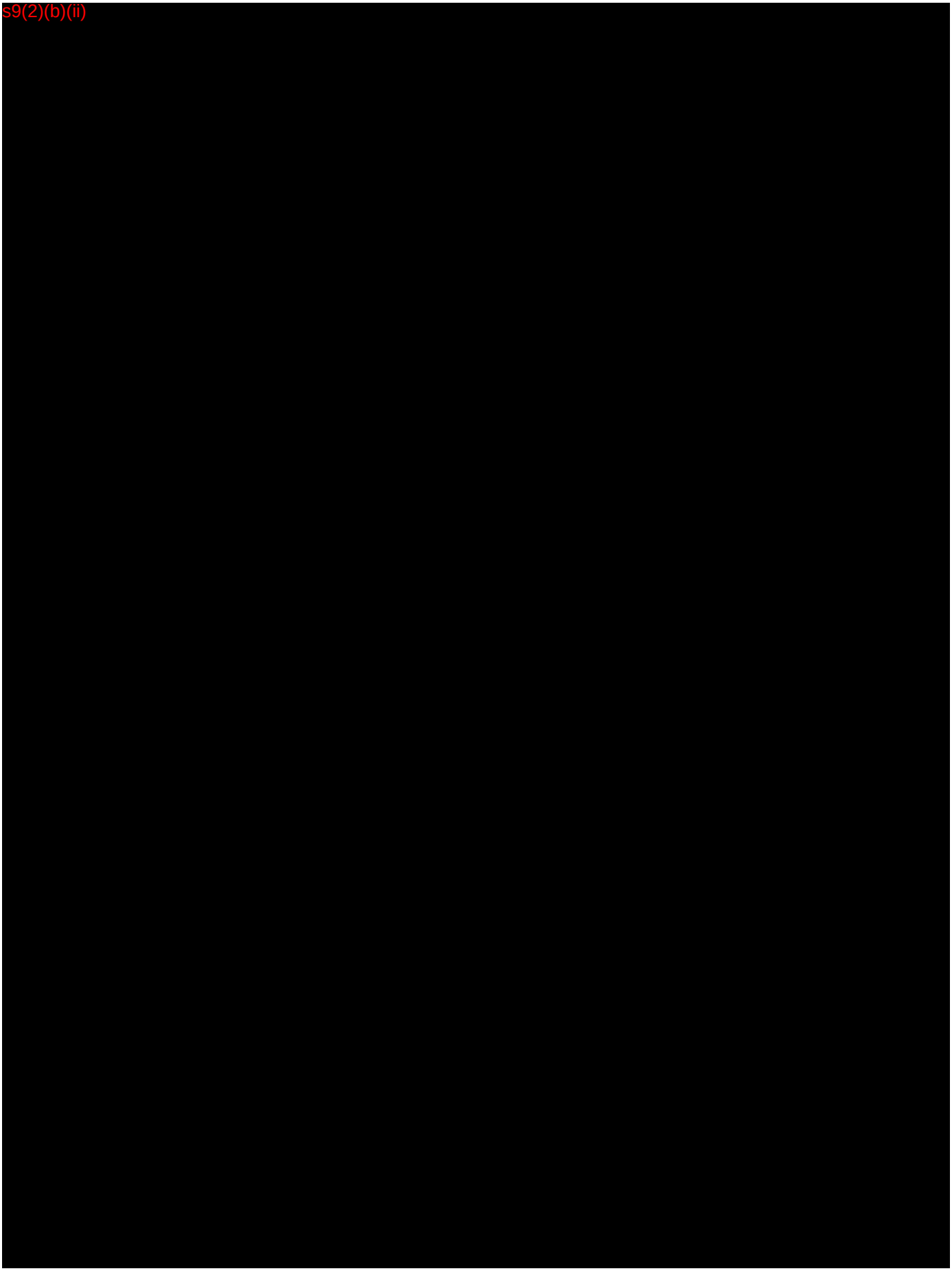
[redacted]

RESULTS

s9(2)(b)(ii)



s9(2)(b)(ii)



s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii)

[redacted]

s9(2)(b)(ii) [redacted]

s9(2)(b)(ii) [redacted]

s9(2)(b)(ii) [redacted]

13) With respect to the New Zealand Solicitor General's Prosecution Guidelines I have the following comments.

a. It is currently intended that when a roadside test is performed and is 'positive', a second or repeat test will be performed using a second device of the same type as 'confirmation test'.

b. Immunoassay devices are not designed to 'identify' a specific drug and are also susceptible to 'false positive' and 'false negative' results from time to time. These are well known and accepted limitations of this technology that is typically used as an inexpensive and rapid test that can be performed on the roadside.

c. The use of two immunoassay tests, one to confirm the results of the other is not a generally accepted practice within the medico-legal or forensic community. This practice would not conform to the Standard nor any forensic guidelines largely due to the inability of the devices to 'detect' or 'identify' drugs and the possibility of 'false positive' or 'false negative' results either due to device faults and / or cross reactivity to other non-targeted drugs that may result in a 'positive' result to a drug that is not the intended drug.

d. Cross-reactivity occurs when the antibodies detect a part of a chemical structure on a drug or compound that is not the drug it is designed to detect. This may result in a 'false positive' result i.e. a positive result when it should have been negative. This may also occur when other waste products are found in urine that is detected by the antibody

and is somewhat unpredictable. Examples include pre-gym supplements; biogenic amines etc. that may be present in an individual's urine.

e. The device manufacturers test their devices for cross-reactivity to drugs within the same class (e.g. amphetamines) however typically do not publish the cross-reactivity of their devices to other drugs etc. of other categories that may also be present in the oral fluid of the donor. As such there remains some uncertainty with respect to whether devices may incorrectly detect other commonly prescribed, legal drugs e.g. antidepressants.

f. According to the cross-reactivity tables published by the device manufacturers, with respect to the drug-groups listed in AS/NZS 4760:2019, methylamphetamine and opiates are the most likely to result in cross-react.

g. With respect to the opiates morphine and codeine generally produce the same results. Some opiate medications not prescribed in Australia e.g. hydrocodone and oxymorphone, also produce 'false-positive' results.

h. With respect to methylamphetamine, MDMA and amphetamine (i.e. dexamphetamine) are also likely to produce a positive result for 'methylamphetamine' when present.

i. The drug or drug groups less likely to produce false positives are cocaine and cannabis, although false positives can never be completely excluded given the absence of testing performed.

14) This general level of uncertainty, due in part to cross-reactivity, is the reason confirmatory testing is required following a 'not-negative' immunoassay result. It is also why AS/NZS 4760:2019 stipulates that following an initial or presumption screen, an 'unconfirmed' result must be confirmed by a technique utilising chromatography and mass-spectrometry. The use of chromatography and mass-spectrometry unequivocally determines the presence of a specific drug or metabolite.

Sincerely,

s9(2)(a) [redacted]

s9(2)(a) [redacted]

Pharmacologist, Forensic Toxicologist, Analytical Chemist

Experience and expertise in the field of drug and alcohol policies, procedures and testing

I am a pharmacologist and forensic toxicologist at Independent Forensic Consulting (IFC). After completing my undergraduate degree majoring in pharmacology and toxicology, I earned my Ph.D. in medicine studying at s9(2)(a) specialising in toxicology. I subsequently completed my post-doctoral fellowship in forensic toxicology s9(2)(a)

As a pharmacologist and forensic toxicologist with more than 30 years professional experience, I have studied the affects and effects of drugs and poisons on humans and animals including mechanism of action; desirable effects and non-desirable or adverse effects. I have also performed research in the field of pharmacology and toxicology including methods of drug analysis; affects of drugs on humans; evaluation of the safety and efficacy of drugs on humans. I have assigned, supervised, performed, certified and interpreted hundreds of toxicological analyses for a range of clients including pathology and forensic laboratories, pharmaceutical companies, regulatory agencies and legal professionals.

I have prepared expert reports and testified throughout Australia and overseas in local, state, federal and military courts for prosecution, defence and plaintiff lawyers relating to forensic toxicology including matters involving:

- Criminal Law (including drug facilitated sexual assault; DUI and DUID; cause or contribution to death; human performance and behaviour; poisonings; drug possession and matters of legal status of drugs including the evaluation of Synthetic *Cannabis* and Synthetic Stimulants e.g. 'Bath Salts' and issues associated with analogue provisions);
- Family Law (including the interpretation of urine, drug and hair follicle testing; Liver Function Tests (LFT), Carbohydrate Deficient Transferrin (CDT) and Ethyl Glucuronide (EtG) testing and result interpretation);
- Personal Injury, Medical Negligence, CTP, Insurance claims;
- Workplace Disputes (including the interpretation of urine, oral fluid and/or hair test results and compliance with acceptable drug testing procedures);
- Workplace Accidents (involving the cause and contribution of drugs and alcohol to an incident); together with matters including exposure to chemicals and other poisons;
- Doping disputes and investigations including professional athletes (ASADA; WADA) and Steward enquiries involving the racing industry (jockeys, riders, racehorses, harness racing, greyhounds etc.);
- Miscellaneous civil matters and disputes involving drugs and chemicals.

I have lectured at numerous Universities on topics such as pharmacology and forensic toxicology. I have authored a number of peer-review papers and I routinely attend national and international scientific conferences. I currently hold membership of The International Association of Forensic Toxicologists (TIAFT), the Society of Hair Testing (SoHT), the Society of Forensic Toxicologists

(SOFT), The Australian and New Zealand Forensic Science Society (ANZFSS) and the Forensic and Clinical Toxicology Association (FACTA) and am bound by the Code of Ethics of these Societies. I have been a member of the SOFT Drugs and Driving Committee and SOFT Drug Facilitated Sexual Assault Committee and served as an invited reviewer on the SOFT Scientific Advisory panel. I currently serve as an invited reviewer for the international journals, Forensic Science International and Forensic Science, Medicine, and Pathology.

With respect to workplace drug testing, I am a consulting toxicologist to a number of national drug testing organisations and an expert in Australian Standard compliant drug testing for both urine and oral fluid (AS/NZS 4308:2008 and AS/NZS 4760-2019 respectively). s9(2)(a) [redacted] AS/NZS 4308 – Procedure for specimen collection and the detection and quantitation of drugs in urine. I have been involved in a number of workplace disputes before Fair Work Australia and other tribunals including: Endeavour Energy and CEPU, ASU and APESMA; The Maritime Union of Australia v DP World Brisbane Pty Ltd and Ors; and CFMEU v PKCT; among others.

As a qualified trainer in the workplace collection and testing of breath, urine and oral fluids in compliance with AS 3547:2019, AS/NZS 4308:2008; AS 4760-2006 and AS/NZS 4760-2019 respectively, I perform drug and alcohol training throughout Australia for a number of clients to ensure compliance with the Australian Standards. This training includes policy review and recommendations to ensure the respective drug-testing program in place is both compliant to the respective Australian Standard and is able to achieve the desired outcome or intent of the client. In the last 10 years I have performed more than 200 training sessions across more that 150 organisations.