

To: Impaired Driving Governance Board (ID GB)

From: Oral Fluid Testing Project

Date: 9 November 2022

Subject: Impaired Driving OFT Device Procurement Outcomes Update

Executive Summary

The Land Transport (Drug Driving) Amendment Act 2022 (the Act) introduces the use of a random roadside Oral Fluid Test (OFT) regime to detect and deter drug driving as part of a significantly enhanced impaired driving programme. The regime sets out that two consecutive positive roadside tests for the same qualifying drug establishes an infringement offence.

Commercially available OFT devices are designed as screening tests that lack accuracy resulting in false positive and false negative results. The basis of the device technology is such that the individual channels are cross-reactive which lacks the specificity to know for which qualifying drug a positive result has been returned.

If random roadside OFT testing is unable to be rolled out as envisaged by the Act and the underlying policy outcomes it seeks to achieve, there is a risk that the policy intent is undermined, and public trust and confidence in Police to deliver road safety outcomes is impacted.

It is recommended that Police raise these concerns with the Ministry of Transport and Waka Kotahi to review the options identified. Working collaboratively with our agency partners to further explore and develop joint advice on potential responses that support the road safety outcomes the introduction of OFTs is intended to deliver.

Recommendations

It is recommended that the Impaired Driving Governance Board:

a)	Note the content of this report	
b)	Endorse the Tender Evaluation Report;	Endorse
c)	Endorse the Outcomes of the Procurement Process report;	Endorse
d)	Note the Independent Expert Report.	Noted

Purpose

This memorandum provides the board with an update on the outcomes of the procurement process for an oral fluid testing device.

Background

The Land Transport (Drug Driving) Amendment Act 2022 (The Act) will come into effect in March 2023.

The amended legislation provides NZ Police (NZP) with the lawful authority to conduct random roadside drug testing of drivers using an oral fluid testing (OFT) device.

Following Royal Assent in March 2022 NZP commenced the procurement process for a suitable OFT device which can meet the requirements set out in The Act.

Procurement Process

In late 2020, NZ Police issued a Request for Information (RFI) to the market outlining an opportunity to provide information about oral fluid testing devices.

On 23 March 2022 an RFP was released to market through the Government Electronic Tender Service (GETS).

Ten responses were received. All respondents were asked to provide as part of their submission independent results for their products, as tested against the Standard. On initial review, two were disregarded as the device didn't physically exist.

For the eight remaining devices, the procurement evaluation process was broken down into the eight stages which are

STAGE 1-2: EVALUATION OF NON-PRICE CRITERIA & SHORTLISTING

- Responses were evaluated against a Qualitative Criteria to reach a moderated result for each response. This is a non-weighted criterion, using a narrative approach to assess and distinguish the relative merits of each response.

STAGE 3: TRIALS & ASSESSMENT

- As part of the Request for Proposal response, responders were asked to submit device samples that could be trialled if shortlisted.
- The trial and assessment took place over a two-day period in a controlled environment through a range of scenarios involving volunteers being tested.
- Evaluating officers evaluated the devices and assessed them individually against the operability requirements.
- Following the testing, as a team, participants met to discuss and reach a moderated score.

STAGE 4-6: CONFORMING TENDERS, PRICE EVALUATION, RANKING

- Following the trial, follow-up questions were asked to all remaining responders to address points raised from the evaluation team where information was missing, or clarification was needed.
- Responses were then reviewed and evaluating on pricing.
- A single preferred device could not be chosen due to consensus that referee check and scientific evidence should be collected before reaching a decision.

STAGE 7: REFEREE CHECKS

- References were requested from all referees provided by the remaining responders, with responses received on each device.

STAGE 8: FINAL RANKING & DUE DILIGENCE

- The shortlisted devices were laboratory tested by an external provider, with the process overseen and results reviewed by an independent scientific expert. The testing was to identify compliance with the AS/NZ standards and validate the manufacturer claims.
- Once the outcome of the independent expert review was completed, a preferred device recommendation was submitted for approval.

Independent Expert Report

An independent expert, s9(2)(a) of Independent Forensic Consulting, was engaged to undertake an independent evaluation of shortlisted devices to establish:

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

The full Independent Expert conclusions are contained within the report with an abridged summary being:

Accuracy

Then 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. With the outcome of the testing being:

“Overall the s9(2)(ba)(i) only device that conformed with the Standard and had suitable performance. The s9(2)(ba)(i) performed well at the manufacturer’s cut-off concentrations however the cut-off concentrations varied to those required by the Standard for all drugs and oxycodone was not included.”

[illegible]

Recent Use

On relation to recent use, the report highlights that

"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.”

Specificity

On specificity, the report highlights that

“...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”

In general

In addition, the experts comments;

“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.

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.”



IFC Expert
Report_220227_DRA

To provide assurance on the Expert report, NZ Police commissioned an Peer review of the report from s9(2)(a) of ESR. At the time of writing Memo, the report from Dr Poulson is outstanding, but will be incorporated when available.

Tender Evaluation Report

The outcome of the procurement process is captured in full report on the Tender Evaluation Process which has been submitted and approved by the business owner and Procurement. To provide assurance of the process an independent Probity auditor was engaged. Both reports are:

Tender Evaluation Report



Tender Evaluation
Report (TER) - OFT E

Probity Auditor Report and Probity Audit Attestation



NZ Police OFT
Probity Audit Attest:



OFT Probity Auditor
Report November 20

The conclusions of the Tender Evaluation Report are:

- Based on final outcomes of the independent review and field testing, it is recommended that both the [REDACTED] s9(2)(ba)(i)
- s9(2)(ba)(i) [REDACTED] is black and white, it doesn't require the officer to have to make a judgement call and the outcome is easy to establish if required to be defended.
- To be noted though, while both devices passed the verification criteria as defined in the standard, the following device results found during the testing were recorded;

- s9(2)(ba)(i) [REDACTED]

- [REDACTED]

- [REDACTED]

The recommendations of the Tender Evaluation Report were;

- Once outcomes on considerations of accuracy and qualifying drug have been completed, s9(2)(ba)(i) [REDACTED] notified they are joint preferred vendor status for the provision of the supplies;
- All unsuccessful tenderers be offered formal debriefings prior to commencing contract negotiations, with the format for the debriefings to be in accordance with National Procurement Group procedures;
- NZ Police's next step is to proceed to negotiations with both organisations subject to commitment to proceed based on current legislation.

Outcomes of Procurement

Having reviewed the results of the procurement process, it is identified that there are a number of the key constraints for NZ Police when operationalising the Legislation, being;

- The form of the Bill constrains the options for NZP to recommend an appropriate drug testing device on the basis of:
 - The lack of the ability of a device to test for the most prevalent qualifying drugs, and
 - Devices are not sufficiently accurate and, even if approved and gazetted, are likely to be subject to legal challenge, and
 - The ability to meet the relevant considerations of the Standard.
- There are likely resourcing implications for multiple workgroups as a result of this Bill. For some, such as PPS and NRPC, there is no funding arrangement in place for the resourcing implications.
- The potential impacts of the indicated increase in testing from 33,000 to 66,000 tests would likely mean staff time would be redirected from alcohol testing (or other RIDS activity), given there is no indicated addition in staff resourcing. This currently represents an opportunity cost.

Operationalising a device that is subject to scrutiny in respect of accuracy and it not being used as designed could lead to significant impact on public trust and confidence in NZP's road safety initiative.

Testing for only THC and cocaine fails to meet the policy intent of testing for the most prevalent drugs used by New Zealand drivers as:

Not testing for methamphetamine, seen in 16% of crash statistics data, or prescription drugs, seen in 21% of crash statistics data, greatly reduces policy intent of targeting the most prevalent impairing drugs.

- To be seen as not being an effective deterrence to reducing drug driving.
- Once drivers are aware that only THC and cocaine are tested for, they may transfer to drugs not tested for which will further reduce general deterrence capability.
- The availability of a medical defence for lawfully prescribed medicinal cannabis negatively impacts the roadside testing.

Not being able to test specifically for methamphetamine could be seen by the public as a significant failure of the policy intent of the legislation.

New Zealand Police do not believe that there is a device currently available that meets the policy intent and requirements adequately, that will not impact on trust and confidence and legal challenge.

The full report on the Outcomes of Procurement:



Memorandum -
OFT Outcome of Proc