NEW ZEALAND POLICE
Ngā Pirihimana o Aotearoa

IR-01-26-21350

9 July 2026

Nigel Gray
fyi-request-34578-b9f7588b@requests.fyi.org.nz

Dear Nigel

Request for information

I refer to your Official Information Act 1982 (OIA) request of 14 June 2026 in which you asked for information regarding DrugWipe 3S Procurement and independent laboratory testing. I have addressed each part of your request below.

> *On 11 June 2026, the Office of the Controller and Auditor-General (OAG) responded to my OIA request of 4 June 2026. In that response, the OAG stated:*
>
> *"The first, second and fifth categories of information you have requested will be held by New Zealand Police."*
>
> *The categories referred to were:*
>
> *All documents, reports, and data relating to the independent laboratory testing conducted on DrugWipe 3S and other tenderers' products.*
>
> *All tender evaluation documents relating to the DrugWipe 3S procurement.*
>
> *Any documents describing or summarising the testing process undertaken by Police or their contractors.*
>
> *However, in previous OIA responses, New Zealand Police have stated or implied that Police do not hold:*
>
> *independent laboratory testing reports*
>
> *validation or accuracy data*
>
> *testing methodologies*
>
> *pass/fail criteria*
>
> *scientific evaluation material for DrugWipe 3S*
>
> *Given the direct contradiction between the OAG's statement and Police's earlier responses, clarification is required.*
>
> *I therefore request the following under the OIA:*
> *1. Confirmation of whether New Zealand Police holds the information described in categories 1, 2, and 5 above.*
> *For clarity, this includes:*
>
> *laboratory reports*

NEW ZEALAND POLICE
Ngā Pirihimana o Aotearoa

validation or accuracy data

testing methodologies

pass/fail criteria

correspondence with laboratories or testing providers

technical assessments

scoring matrices

evaluation panel notes

conflict-of-interest declarations

risk assessments

internal or external summaries of the testing process

2. If Police do hold this information, please provide it.

For tender evaluation documents, I refer you to pages 17-18 of the 'Oral Fluid Testing Equipment Request for Proposal' document which outlines the evaluation criteria and scoring matrix used during procurement. This document is publicly available; the link has been previously provided to you but has been reattached to this OIA for your reference here: https://www.police.govt.nz/about-us/publication/proactive-release-papers-relating-implementation-roadside-drug-driving-testing

For testing documents regarding the DrugWipe 3S Device, please also find included with my response the 'IFC Expert Report', and the 'abf diagnostics Evaluation Report'.

These reports contain technical scientific data that is generated and assessed in accordance with AS/NZS 4760:2019, the Standard that sets the performance and verification criteria for oral-fluid testing devices. To ensure the information is understood within the framework it was designed for, the response notes this context, and only the detailed dilution/spiking tables, containing non-public laboratory methodology, have been withheld under the relevant provisions of the OIA.

As such, some of the information has been withheld pursuant to the following sections of the OIA:

- 9(2)(b)(ii), as the withholding of the information is necessary to protect the commercial position of the person who supplied or who is the subject of the information, where release would be likely to unreasonably prejudice that commercial position (the withheld material comprises detailed, non-public laboratory methods).
- 9(2)(ba)(i), as the withholding of the information is necessary to protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied.
- 9(2)(k), as the withholding of the information is necessary to prevent the disclosure or use of official information for improper gain or improper advantage (the withheld material includes precise bench-level preparation recipes that could be used to probe or game screening thresholds).

The following certification was also provided to NZ Police for the DrugWipe 3 S:

- Compliance with EN ISO 10993 *Biological evaluation of medical devices*, confirming there has no sensitizing potential.
- Compliance with ISO 14971 *Medical devices – Application of risk management* and ISO 10993 *Biological evaluation of medical devices* and confirmation of there being no detection of harmful substances.

4. Any internal Police communications discussing the OAG's statement that Police hold this material.

Purpose of this request
This request is necessary to reconcile:

the OAG's explicit statement that Police hold the independent laboratory testing and tender evaluation material, and

Police's earlier statements indicating that such material is not held.

Police does not hold any communications discussing the Office of the Controller and Auditor General's statements, including their statement to you that Police hold the independent laboratory testing and tender evaluation material. Their statement to you is referring you to Police as the appropriate agency to address your request. Therefore, your request is refused under section 18(e) of the OIA as the document alleged to contain the information requested does not exist.

For clarity, Police has provided you publicly available information before regarding the DrugWipe 3 S device. In our letter to you dated 1 May 2026 (IR-01-26-11763), we confirmed that Police holds operational and procurement-related scientific validation and accuracy assessments of the DrugWipe 3 S. However, your request at the time was specifically for assessments in relation to legislative vetting or Bill of Rights Act (BORA) analysis which we had confirmed as not held by Police.

I trust this information is satisfactory in answering your request. If you are not satisfied with the way your request has been responded to, you have the right under section 28(3) of the OIA to ask the Ombudsman to review our decisions. Information on how to do this is available online at www.ombudsman.parliament.nz.

Yours sincerely

Inspector Peter McKennie
Acting Director: Road Policing
New Zealand Police

IFC
INDEPENDENT
FORENSIC
CONSULTING

Specialising in Pharmacology & Forensic Toxicology

***** FINAL REPORT *****

6 August 2025

Phil Wheeler
Procurement Lead
Impaired Driving Programme
National Road Policing Centre
Police National Headquarters
180 Molesworth St
Wellington, New Zealand

Re:	Assessment of the Pathtech Roadside Drug Testing Device
NZ Police:	RFP TN/25/18
IFC Expert Report No.:	25-0105

Dear Mr Wheeler,

You and your organisation have retained Independent Forensic Consulting represented by Dr Michael Robertson as consultants in toxicology and analytical chemistry in the above captioned matter.

You have requested that I review the results of the Pathtech Securetec Drugwipe® 3 S drug device verification and comment on whether the results of the on-site testing device 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).

EXECUTIVE SUMMARY

In response to a request for tender, an analogue device was received from Pathtech.

The device was verified according to section C3 of Appendix C of AS/NZS 4760:2019.

The verification of the device was performed by HASTA laboratories in Flemington Victoria. 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.

Verification was restricted to the compounds listed in the tender i.e. methamphetamine, MDMA, cannabinoids (THC) and cocaine (and metabolites).

The methods and results referred to below, are based on the provided report from HASTA dated 13 March 2025. Further detail, if required, can be sourced from the relevant HASTA report.

The following table outlines the results of the verification of the Pathtech device.

Supplier	Device	MA	Cocaine	Δ9-THC	MDMA	Overall
Pathtech	Securetec Drugwipe 3 S					

Green – successful verification; Red – unsuccessful verification.

In summary, the Securetec Drugwipe® 3 S complied with and meets the requirements of AS/NZS 4760:2019.

METHODS / PROCEDURE

Device verified - Pathtech: Securetec Drugwipe 3 S. Batch Y1647.25092, Expiry 2026-02.

The device was assessed against the screening cut-offs for on-site immunoassay screening test listed in Table A1; Appendix A of AS/NZS 4760:2019 and are as follows:

Class of Drug	Cut-off Concentration ng/mL	-50% Cut off ng/mL	+50% Cut off ng/mL
Amphetamine type substances - Methamphetamine	50	25	75
Amphetamine type substances - MDMA	50	25	75
Cannabinoids	15	7.5	22.5
Cocaine and metabolites	50	25	75

Stock solutions of the required calibrators (methamphetamine, cocaine or benzoylecgonine and THC) were prepared immediately prior to performing the verification.

Blank human oral fluid specimens were spiked with the appropriate volume of the stock solutions, one spiked at +50% of the screening cut-off concentrations and the other at -50% of the screening cut-off concentrations.

A separate set of stock solutions of MDMA were also prepared immediately prior to performing the verification.

The concentrations of the MDMA stock solutions prepared were dependent on the cross reactivity of MDMA on the methamphetamine strip of the respective device.

In order to test to section C3 of Appendix C of AS/NZS 4760:2019, device verification was assessed by testing a minimum of twenty (20) spiked samples. Ten (10) kits with oral fluid samples spiked at -50% of the screening cut-offs, and ten (10) kits with oral fluid samples spiked at +50% of the screening cut-offs.

All testing was performed in accordance with the provided manufacturer's instructions.

Section C3 of Appendix C states that if a total of twenty kits are tested, no more than two failures in total (either false 'not-negative' or false 'negatives') are permitted for each drug class tested.

A separate verification was performed for MDMA due to its cross reactivity on the methamphetamine strip.

Prior to testing, all components were brought to room temperature prior to verification.

Fresh oral fluid was collected from drug free human donors. Specimens were pooled, centrifuged and frozen until required for evaluation. Centrifugation was required to remove bubbles etc. to allow 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.

The Pathtech: Securetec Drugwipe® 3 S device has the following drug test strips and cut-off concentrations, all of which conform to the Standard:

Class of Drug	Target Drug	Cut-off Concentration ng/mL	AS\NZS 4760:2019 cut-off concentration
Amphetamines	(+) methamphetamine	50	Yes
Cannabinoids	Δ9-THC	15	Yes
Cocaine and metabolites	cocaine	50	Yes

Aliquots (3 x 10µL) of the appropriate spiked oral fluid specimen were added to the sample collector pads before being placed back onto the test device. The test device was held upright, a thumb placed over the word PRESS before pressing down hard once, breaking the internal ampoule. The device was held upright for a further 10 seconds before being placed on the bench surface (Instructions for Use, S 304 G.91).

A control line must be observed for the test to be valid. Any visible line or part thereof on the test strip indicates a positive or non-negative result. No visible line indicates a negative result. All results were read at 5 minutes after the test was started.

The temperature during verification was recorded by a calibrated data logger and was 23.2°C.

RESULTS

1. All compounds and cutoff concentrations comply with AS/NZS 4760:2019.

2. The results for the evaluation of the Pathtech: Securetec Drugwipe® 3 S device are shown in the tables below.

Securetec Drugwipe® 3 S Batch: Y1647.25092; Expiry: 2026-02			
	methamphetamine	cocaine	Δ9-THC
+50%	10/10 positive	10/10 positive	10/10 positive
-50%	8/10 negative	10/10 negative	9/10 negative
Blank OF control	2/2 negative	2/2 negative	2/2 negative

Securetec Drugwipe® 3 S Batch: Y1647.25092; Expiry: 2026-02	
	MDMA
+50%	10/10 positive
-50%	9/10 negative
Blank OF control	2/2 negative

3. Control lines were present for all observed tests.

4. There were two false positives for methamphetamine and one false positive each for THC and MDMA, however this is within the required criteria of the Standard.

5. Concentrations of the spiked oral fluid samples were confirmed by LCMS and were within acceptable ranges for all drug groups.

CONCLUSION

The Pathtech: Securetec Drugwipe® 3 S device was verified and complied with the criteria outlined in Appendix C3 of AS/NZS 4760:2019 for methamphetamine, cocaine, THC and MDMA.

The Pathtech: Securetec Drugwipe® 3 S device has been tested and does comply with the Standard and therefore does meet the required cut-off thresholds defined in Table A1 of the joint AS/NZS4760:2019 Standard and it's cut off thresholds and false positive/negative results as required by pre-condition 5 of NZ Polices OFTE RFP.

Sincerely,

Dr Michael Robertson
Pharmacologist, Forensic Toxicologist, Analytical Chemist

Qualifications, 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 the Victorian Institute of Forensic Medicine (Monash University), specialising in toxicology. I subsequently completed my post-doctoral fellowship in forensic toxicology at National Medical Services (NMS) in Pennsylvania (USA).

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 4308:2023 and AS/NZS 4760-2019 respectively). I am the immediate past Chair of the Standards Australia oral fluid committee reviewing and updating AS/NZS 4760 – Procedure for specimen collection and the detection and quantitation of drugs in oral fluid. I am the immediate past Chair of the Standards Australia urine committee reviewing and updating AS/NZS 4308 – Procedure for specimen collection and the detection and quantitation of drugs in urine. I am the current Chair of Standard Australia's technical committee (CH-039) that is responsible for the 'Detection and Analysis of Drugs in Specimens of Human Origin'. I am a contributing member of the FACTA technical committee on Hair Drug Testing Guidelines.

I have been involved in and testified 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/NZS 4308:2023; 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 ensuring compliant collection, on-site testing, storage, and transportation to the laboratory. 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.

abf diagnostics GmbH
Gewerbepark 14
D-85402 Kranzberg
Germany
T.: +49/8166-9986-130
F.: +49/8166-9986-140
E.: info@abfdiagnostics.com

Kranzberg, 14th of March 2025

Evaluation Report - Securetec DrugWipe 3 S (S303G.91)

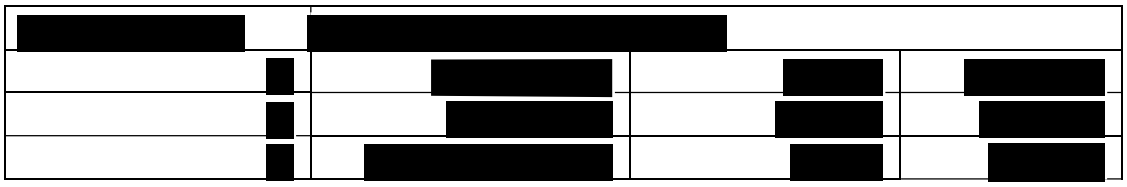
Introduction

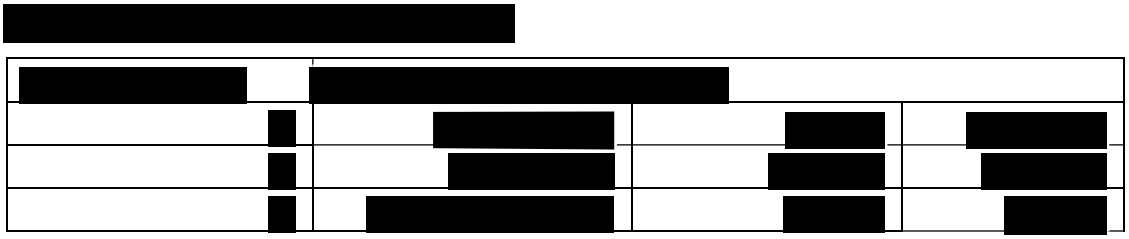
DrugWipe 3 S test kits were evaluated for specificity and sensitivity in compliance around nominated cut-offs for each of the three analyte groups in accordance to Appendix C3 auf AS/NZS 4760:2019 with the following protocol.

Methods:

Drug solutions were prepared by spiking pooled saliva of 10 volunteers with the analytes. The final dilutions provide a test sample with a concentration 50 % above (high drug “spiked” solution) or 50 % below (lower drug “spiked” solution) the specified cut-off.

s 9(2)(b)(ii) OIA, s 9(2)(k) OIA, s 9(2)(ba)(i) OIA





s 9(2)(b)(ii) OIA, s 9(2)(ba)(i) OIA, s 9(2)(k) OIA

Specificity testing:

10 µL of each lower drug “spiked” solution was pipetted onto the respective wiping fleece of the DrugWipe® sample collectors and tests were performed according to the enclosed instructions for use. The tests were evaluated visually as described in the instructions for use.

An appearing red control line and no red test line shows a negative result.

Sensitivity testing:

10 µL of each high drug “spiked” solution was pipetted onto the respective wiping fleece of the DrugWipe® sample collectors and tests were performed according to the enclosed instructions for use. The tests were evaluated visually as described in the instructions for use.

An appearing red control line and a red test line shows a positive result.

Results:

Specificity at – 50% cut-off

Analyte	Concentration	Negative results	% Correct results
Δ9-THC	7 ng/ml	27/30	90%
D-Methamphetamine/ D.L-MDMA	25 ng/ml	27/30	90%
Cocaine	25 ng/ml	29/30	96%

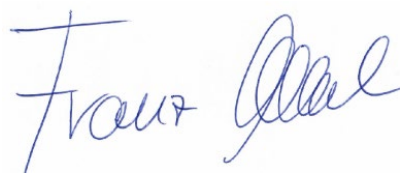
Sensitivity at + 50% cut-off

Analyte	Concentration	Positive results	% Correct results
Δ9-THC	22 ng/ml	28/30	93%
D-Methamphetamine/ D.L-MDMA	75 ng/ml	30/30	100%
Cocaine	75 ng/ml	29/30	96%

Summary:

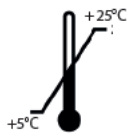
DrugWipe 3 S (S304G.91) test kits fulfilled the criteria of Appendix C3 of AS/NZS 4760:2019 with not more than a total of 10% false positive results in specificity testing at – 50% of the respective cut-offs and not more than a total of 10% false negative results in sensitivity testing at + 50% of the respective cut-offs for THC, Methamphetamine/MDMA and Cocaine.

Kranzberg, 14th of March 2025



……
Dr. Franz Aberl
abf diagnostics GmbH

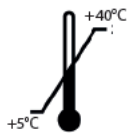
Storage



+5 to +25°C Only store DrugWipe® within this temperature range.

Incorrect storage conditions, such as high temperatures or frost, will damage the test.

Use



+5 to +40°C Use DrugWipe® within this temperature range.

If using the test in the rain or snow, ensure that DrugWipe® 3 S is protected from moisture.

Dispose of used and expired tests with other non-recyclable waste. Please comply with your local regulations for waste disposal.

Quality Control

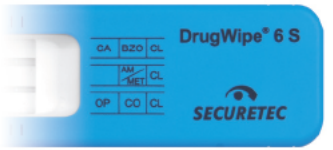
DrugWipe® 3 S has an integrated control line (CL). The control line indicates that the test is fully functional and that the screening test has been performed correctly.

Please observe any additional quality control regulations that apply in your institution or establishment.

Cut-off Concentrations and Calibrators

Test Chemistry	Calibrator (Test Drug)	Cut-off Concentration (ng/ml)
THC	(-)-Δ9-tetrahydro-cannabinol	15
Cocaine	Cocaine	50
Meth-amphetamines	D-meth-amphetamine	50
MDMA/ecstasy	D-meth-amphetamine	50

Other DrugWipe® Products



Saliva

Surfaces

Surfaces, sweat, saliva

For the detection of cannabis, opiates, cocaine, amphetamines/methamphetamines/ecstasy, ketamine and benzodiazepines.

Exclusive Australia and NZ Distributor:

Pathtech™
First Choice In Science

PO Box 109, Heidelberg West, Vic 3081 Australia
Phone: 03 8480 3500 Toll Free: 1800 069 161
Fax 03 8480 3555 Email drugwipe@pathtech.com.au
website: www.pathtech.com.au

SECURETEC
DETEKTIONS-SYSTEME AG

Securetec Detektions-Systeme AG · Lilienthalstraße 7 · 85579 Neubiberg · Germany
T +49 89 203080-1651 · F +49 89 203080-1652
info@securetec.net · www.securetec.net

SECURETEC
DETEKTIONS-SYSTEME AG

ANALOGUE

DRUGWIPE® 3 S
for saliva testing

Detects

- THC
- Cocaine and metabolites
- Methamphetamines/MDMA/ecstasy

S 304 G.91

we detect to protect

Intended Purpose

DrugWipe® 3 S is intended to be used for the qualitative detection of drugs in human saliva by trained professionals.

The test detects THC, cocaine and its metabolites, meth-amphetamines/MDMA/ecstasy. The measurement procedure delivers a preliminary result (screening procedure). Verification of the results is required, in particular if these are positive. Liquid or gas chromatography combined with mass spectrometry (LC/MS, GC/MS) are the preferred broad-spectrum methods.

Test Principle

DrugWipe® 3 S is an immunological quick screening test. The sample collector transfers the sample to the test strips, which contain drug-specific antibodies. If the sample contains drugs, they will bind to the antibodies.

The test starts as soon as you break the integrated glass and release the liquid. With the help of the liquid, the drugs bound to the antibodies can migrate to the test line. The red test line is evaluated visually.

Package Content

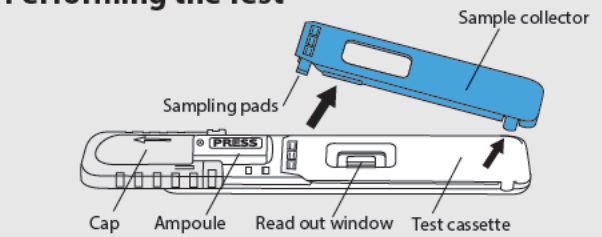
1 DrugWipe® 3 S saliva test

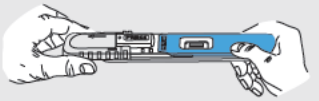
1 package with desiccant

Read Before Performing the Test

1. DrugWipe® 3 S is for single use only.
2. Discard the test if the expiry date has been exceeded.
3. Avoid temperatures in excess of +40°C. Damage to the test may occur.
4. Discard the test if the packaging is damaged, if any moisture has penetrated the packaging, or if a control line has already changed colour to red.
5. Do not open the packaging until shortly before the test is to be used.
6. Saliva is potentially infectious. We recommend that you wear disposable gloves to avoid contact with saliva.

Performing the Test



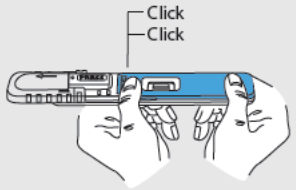


1. Slide the cap in the direction of the arrow until you can read all of the word PRESS.

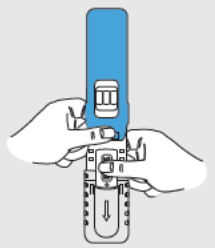
2. Remove the blue sample collector from the white test cassette. **Do not touch the sampling pads.**

3. Ask the person taking the test to run their tongue around the inside of their mouth in a circular motion three times. Then use the sample collector to collect saliva from the tongue or the inside of the cheek.

   If the colour of the sampling pads changes from red to yellow, this indicates that a sample has been successfully collected.



4. Place the sample collector back on the test cassette. **The sample collector must slot into place with an audible double click.**



5. Hold the test cassette vertically with the ampoule at the bottom. **Place your thumb over the centre of the word PRESS and press down hard once** until the ampoule breaks. Hold the test cassette **as shown for a further 10 seconds**.

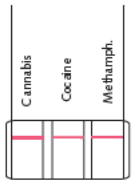
6. Leave the test undisturbed on a horizontal surface. After 5 minutes, read the test result.

Results Interpretation

- In the case of strongly positive samples, a result may be visible after just 3 minutes.
- The test result can be read after 5 minutes.
- The test result is to be interpreted as positive even if the test lines only undergo a slight or incomplete colour change.
- Ensure that you have sufficient lighting when evaluating test results, e.g. by using a torch if necessary.

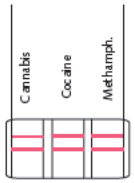
The read out window shows a drug group and a control group for each test strip. The following abbreviations are used:

CA	THC
MET	Methamphetamines (MDMA/ecstasy)
CO	Cocaine and metabolites
CL	control line



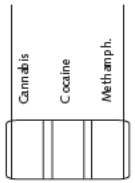
Negative result = no drugs consumed

All control lines must turn red in order for the test to be valid. The test is negative for those drugs where none of the test lines turn red.



Positive result = drugs consumed

All control lines must turn red in order for the test to be valid. The test is positive for the drugs for which the test line turns red.



Invalid result

The test is invalid if one or more control lines do not turn red. Repeat the analysis with a new DrugWipe® 3 S test.

Securetec Detektions-Systeme AG Lilienthalstrasse 7 · 85579 Neubiberg ·Germany

To whom it may concern

For the sample collector DrugWipe, we requested an independent laboratory for testing according EN ISO 10993 Biological evaluation of medical devices (biocompatibility).

The results are written in the report:
Overall Biological Safety Assessement DrugWipe® Sample Collector Declaration of Compliance with EN ISO 10993-1 (2017 Dr. Dannhorn Consulting & More)

The report points out that the DrugWipe® Sample Collector has no sensitizing potential in terms of EN ISO 10993-10.

Neubiberg, February 20th, 2018

Denise Bockholt
Head of Quality Management

SECURETEC
DETEKTIONS-SYSTEME AG

Certified: EN ISO 13485:2016

Neubiberg, January 28th, 2019

To whom it may concern

It is our highest priority that our customers/patients/user/other are never endangered when using our products. We have implemented a risk management according ISO 14971 from beginning of every R&D project to the post market surveillance.
The sample collectors of all DrugWipe® types (also our non-medical devices) were tested in 2017 according to the requirements of ISO 10993 (Biological evaluation of medical devices, biocompatibility) from an independent laboratory in Germany. The compliance with this standard is necessary e.g. for invasive medical devices. The laboratory confirmed the harmlessness of the identified organic substances from a toxicological point of view and for the intended purpose of the investigational DrugWipe® Sample Collector[1].The contact between the DrugWipe® Sample Collector and the mucous membranes only lasts a few seconds, because DrugWipe® needs a maximum of only 10 µl saliva for the chromatography. Furthermore, the Fraunhofer-Institute of Toxicology and Experimental Medicine (ITEM) also evaluated the toxicity of the DrugWipe® Sample Collector in 2011. This analysis contained also the worst-case assumption of the daily dose of exposure. The conclusion is, that the DrugWipe® Sample Collector is not expected to pose a risk at all[2]. An additional investigation of the DrugWipe® sample collector test-fleeces for potentially harmful substances in 2016 confirms that no toxicological relevant xenobiotics were detected in the test fleeces of the DrugWipe® sample collector[3].
The probability of an allergic reaction when using DrugWipe® products is very low and can almost be excluded. DrugWipe® does not contain food allergens in respect to the foods and reference doses stated by Taylor et al. (2014)[4].
I hope, I could clarify your question. In case of further questions, please don't hesitate to contact us.

Denise Bockholt
Head of Quality Management

[1] Dannhorn (2017): Overall Biological Safety Assessment DrugWipe® Sample Collector, Declaration of Compliance with EN ISO 10993-1
[2] Pinheiro et al. (2011): Report on data evaluation on toxicity of sampling pads used in DrugWipe® test systems (Fraunhofer-Institute of Toxicology and Experimental Medicine)
[3]Dr. rer.nat. Hans Sachs (2016): Investigation of DrugWipe® test-fleeces for potentially harmful substances, Analytical Report FTC Nb.: 160129-025 (Forensisch Toxikologisches Centrum GmbH)
[4]Taylor et al. (2014): Establishment of Reference Doses for residues of allergenic foods: Report of the VITAL Expert Panel; Food and Chemical Toxicology 63 (9-17)

Securetec Detektions-Systeme AG
Lilienthalstr. 7
85579 NeubibergGermany

Tel: +49 89 203080-1651
Fax: +49 89 203080-1652
Internet: www.securetec.net
E-Mail: info@securetec.net

Legal form:
Aktiengesellschaft
(stock corporation)

Trade register: HRB 136885
VAT-ID: DE173817641
Local tax office:
Finanzamt München für Körperschaften

Director:
Verena Zimmermann

President of the Supervisory board:
Dr. Oliver Wulff

Bank details: HypoVereinsbank AG
IBAN: DE 767 002 027 000 403 305 00
BIC: HYVEDEMMXXX

Sparkasse Rosenheim – Bad Aibling
IBAN: DE 917 115 000 000 001 973 19
BIC: BYLADEM1ROS