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# A REPORT ON THE EVALUATION OF ON-SITE TESTING DEVICES FOR COMPLIANCE WITH APPENDIX C3 OF AS/NZS 4760:2019

Prepared for Oranoxis, Inc.

Test Kit evaluated:
Oranoxis ToxWipe™ Oral 7+
Ref: TW-100701 Lot #OR-3725 Expiry July 1 2027

## Introduction

AS/NZS 4760:2019 Appendix C3 stipulates that for on-site devices to be used, their performance must be verified against the screening cut-offs indicated in the standard. The screening cut-offs for on-site devices are listed in Table A1; Appendix A of AS/NZS 4760:2019 and are as follows:

| Class of Drug | Cut-off Concentration ng/mL |
|---|---|
| Amphetamine type substances (amphetamine, methamphetamine) | 50 |
| Cannabinoids | 15 |
| Cocaine and metabolites | 50 |
| Opiates | 50 |
| Oxycodone | 40 |

Although benzodiazepines are not listed in the above table, they can similarly be verified at the cut-off levels on the device.

Device verification is achieved by testing a minimum of ten kits with oral fluid (**OF**) samples spiked at -50% of the screening cut-offs, and ten kits with OF samples spiked at +50% of the screening cut-offs.

The standard states that if a total of twenty kits are tested, there shall be no more than two failures in total, whether that be false positives in the case of the -50% spiked OF samples, or false negatives with respect to the +50% spiked OF samples for each drug class tested.

Blank OF was supplied by Oranoxis Inc. (OR-3725, Lot # S-QLS-POF-NEG-37252025, Pooled Human Donor Saliva Toxicology Negative) and was centrifuged prior to use. OF samples used for the verification were spiked with the following calibrators (Cerilliant certified reference standards) at -50% and +50% of the cut-off concentrations.

| Calibrator | Lot Number |
|---|---|
| A-008 S(+)-Amphetamine | FE03162220 |
| M-020 S(+)-Methamphetamine | FE04282302 |
| B-004 Benzoylecgonine | FE04132309 |
| M-005 Morphine | FE11172301 |
| O-002 Oxycodone | FE08312139 |
| T-005 Δ9-THC | FE06212201 |
| O-902 Oxazepam | FE03012312 |

## Protocol

Stock solutions of all required calibrators were made immediately prior to performing the verification. OF specimens were spiked with the appropriate volume of each stock solution, one spiked at +50% of the screening cut-off concentrations and the other at -50% of the screening cut-off concentrations.

Aliquots of the blank OF, -50% spiked OF and +50% spiked OF were removed for LCMS confirmation to verify the concentrations for all analytes. The LCMS method used is the current NATA assessed method for the six drug groups. All assays include four calibrators, 2 ALT spike controls (high and low), one blank and the prepared spiked OF samples at +50% and -50% of the cut-off concentrations.

The devices were evaluated by two staff members according to the supplied Product Insert (IFU Doc #: ID-IN-701-L2, Issue date: 12/12/2024, Revision 2.2). The Oranoxis ToxWipe ™ Oral 7+ device has the following drug test strips and cut-off concentrations:

| Class of Drug | Target Drug | Cut-off Concentration ng/mL | AS\NZS 4760:2019 cut-off concentration |
|---|---|---|---|
| Amphetamines | (+) amphetamine | 50 | Yes |
| | (+) methamphetamine | 50 | Yes |
| Cannabinoids | Δ9-THC | 15 | Yes |
| Cocaine and metabolites | benzoylecgonine | 50 | Yes |
| Opiates | morphine | 50 | Yes |
| Benzodiazepines | oxazepam | 10 | Not Applicable |
| Oxycodone | oxycodone | 40 | Yes |

Blank or spiked OF (300µL) was added to the collection pad of each device and absorbed by the collector. The blank or spiked OF soaked onto the collection pad until the blue indicator line was wicking. The collector was then inserted into the device by puncturing the buffer cap seal and inserting the collection pad into the buffer cap cavity. The samples were read at 5 minutes as described in the Product Insert. A colour score card was provided (no identifiers) in order to give a scale reading of the results. Using the colour score card provided and instructions as described in the Product Insert, lines with a colour intensity of 3 and above are negative, lines with a colour intensity of 2 and below are positive and a control line needs to be present to show that the test is working correctly.

## Results

The results for the evaluation of the Oranoxis ToxWipe™ Oral 7+ device using the colour score card are shown in the table below:

| Oranoxis ToxWipe™ Oral 7+ Ref: TW-100701 Lot #OR-3725 Expiry July 1 2027 | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **amphetamine** | **methamphetamine** | **benzoylecgonine** | **morphine** | **Δ9-THC** | **oxycodone** | **oxazepam** |
| **Blank device 1** | neg: 4 | neg: 4 | neg: 4 | neg: 4 | neg: 3 | neg: 4 | neg: 3 |
| **+50% device 1** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 2** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 3** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 4** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 5** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 6** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 7** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 8** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 9** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **+50% device 10** | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 | pos: 2 |
| **Blank device 2** | neg: 4 | neg: 4 | neg: 4 | neg: 4 | neg: 3 | neg: 4 | neg: 3 |
| **-50% device 1** | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 2** | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 3** | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 4** | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 5** | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 6** | neg: 3 | neg: 3 | neg: 3 | neg: 4 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 7** | neg: 3 | neg: 3 | neg: 3 | neg: 4 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 8** | neg: 3 | neg: 3 | neg: 3 | neg: 4 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 9** | neg: 3 | neg: 3 | neg: 3 | neg: 4 | neg: 3 | neg: 3 | neg: 3 |
| **-50% device 10** | neg: 3 | neg: 3 | neg: 3 | neg: 4 | neg: 3 | neg: 3 | neg: 3 |

These results of the Oranoxis ToxWipe™ Oral 7+ device can be summarised as per the table below:

| Summary of evaluation of Oranoxis ToxWipe™ Oral 7+ Ref: TW-100701 Lot #OR-3725 Expiry July 1 2027 | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **amphetamine** | **methamphetamine** | **benzoylecgonine** | **morphine** | **Δ9-THC** | **oxycodone** | **oxazepam** |
| **+50%** | 10/10 positive | 10/10 positive | 10/10 positive | 10/10 positive | 10/10 positive | 10/10 positive | 10/10 positive |
| **-50%** | 10/10 negative | 10/10 negative | 10/10 negative | 10/10 negative | 10/10 negative | 10/10 negative | 10/10 negative |
| **Blank OF** | 2/2 negative | 2/2 negative | 2/2 negative | 2/2 negative | 2/2 negative | 2/2 negative | 2/2 negative |

Control lines were present for all tests.
The blank OF was negative for all the drug groups tested.
The device worked as expected for all the drug groups tested.

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

## Conclusion

The amphetamine, methamphetamine, morphine, benzoylecgonine, oxycodone and THC results are verified and comply with the criteria laid down by Appendix C3 of AS/NZS 4760:2019.

The benzodiazepine results are verified to the cut off level on the device.

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