

## Summary

Oral fluid is increasingly being used for the rapid screening of drugs of abuse owing to its ease of collection. Rapid oral fluid testing (ROFT) devices are particularly useful in roadside testing for drugged driving. There is currently a lack of data on the performance of ROFT devices in detecting ketamine, which is one of the commonly abused drugs locally and among the 6 illicit drugs specified in the Hong Kong Road Traffic Ordinance (also included are heroin, methamphetamine, cannabis, cocaine and MDMA). The current study aims to evaluate 3 ROFT devices (DrugWipe<sup>®</sup> 6S, Ora-Check<sup>®</sup> and SalivaScreen<sup>®</sup>) on their ability to detect these 6 drugs in oral fluid.

The performance of the ROFT devices was evaluated using the European Union (DRUID) standards, including sensitivity (proportion of positive cases that are correctly identified as such); specificity (proportion of negatives correctly identified as such); and accuracy (proportion of correct results). Acceptable performance was defined as >80% in each of these 3 parameters. Additionally, it was observed that a proportion of the tests failed to pass quality control and was considered invalid. Hence, the test completion rate (proportion of tests successfully completed with quality control passed) was also documented.

In order to calculate the sensitivity, specificity and accuracy, a confirmatory liquid chromatography-tandem mass spectrometry method was firstly established in the laboratory to give the “true” result (positive or negative) in an oral fluid sample. Subsequently, the ROFT field test was conducted on participants recruited from substance abuse clinics and a rehabilitation centre - the 3 ROFT devices were tested on each subject; an extra portion of oral fluid was sent back to the laboratory for confirmation analysis. The ROFT and confirmation analysis results were then compared in order to calculate the sensitivity, specificity and accuracy of each device.

Results showed that the overall specificity and accuracy were satisfactory and met the DRUID standard of >80% for all 3 devices. However, the sensitivity was variable. A summary of the sensitivity values is tabulated below:

	Ketamine	Methamphetamine	Opiates (incl. heroin)	Cocaine	THC	MDMA
DrugWipe <sup>®</sup> 6S	41%	83%	93%	43%	22%	--
Ora-Check <sup>®</sup>	36%	63%	53%	60%	0%	--
SalivaScreen <sup>®</sup>	76%	83%	100%	71%	0%	--

MDMA had no positive cases; hence the sensitivity could not be evaluated. All devices performed poorly for THC. Ora-Check<sup>®</sup> had the poorest sensitivity among the 3 devices and did not achieve 80% in any of the tests. DrugWipe<sup>®</sup> 6S achieved >80% sensitivity in the methamphetamine and opiates tests but performed relatively poorly for ketamine and cocaine. Among the three devices, SalivaScreen<sup>®</sup> achieved >80% sensitivity in the methamphetamine and opiates tests, and was found to have the highest sensitivity for ketamine, cocaine and opiates. In terms of the test completion rate, DrugWipe<sup>®</sup> 6S had the best performance (99%), followed by SalivaScreen<sup>®</sup> (78%) and lastly Ora-Check<sup>®</sup> (52%).

In conclusion, whilst the specificity and accuracy were satisfactory, none of the devices achieved 80% sensitivity in all the tests. SalivaScreen<sup>®</sup> had on average the highest sensitivity among the candidates and its completion rate was reasonable.