Performance of the NeoSal® Oral Fluid Collection System

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BACKGROUND

- Oral fluid testing is an increasingly important and non-invasive tool for the routine monitoring of drugs of abuse. Several commercialized oral fluid collectors are available. Most collectors utilize an absorbent pad, sample volume adequacy indicator (SVAI), sample storage tube and sample stabilization/recovery buffer. The NeoSal Oral Fluid Collection System was designed with similar collector element features and was optimized for ease of use and recovery of key opiates, amphetamines, benzoylecgonine, PCP, Delta-9-THC and diazepam drugs from oral fluid.
- Studies have shown that drug recoveries for commercial devices are variable and dependent on the device and drug analyte.[1,2,3,4,5]
- The goal of this study is to describe the features of the NeoSal and to compare the drug recovery performance with three commercially available collectors.

METHOD

- Donor oral fluid or EIA buffer was absorbed using the NeoSal. Testing was performed with a minimum of five samples (n=5). The time to activate the SVAI was recorded. Sample volume absorbed was measured gravimetrically using a NIST traceable analytical balance.
- At a third party oral fluid testing laboratory, oral fluid from drug-free volunteers was spiked (n=5) at the SAMHSA suggested confirmatory cutoff levels.[6] Hydrocodone (HC), oxycodone (OXY), hydromorphone (HM), oxymorphone (OM), and diazepam were spiked at concentrations of 40, 40, 40, 40, and 4 ng/mL, respectively.
  - ➤ One mL of the spiked oral fluid was applied to each device (NeoSal and 3 commercially available collectors) and incubated overnight in the dark at room temperature. The samples were then processed using solid-phase extraction and analyzed using a LC-MS-MS. Recovery was calculated based on paired samples with no collection pad.

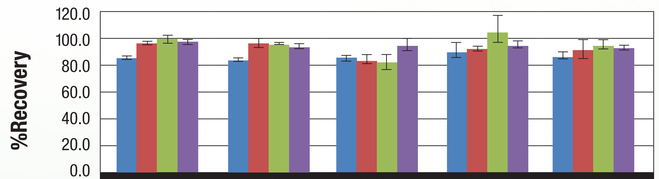
SAMHSA Suggested Oral Fluid Cut-offs

Drug		Concentration (ng/mL)
THC Parent	THC	2
Benzoylecgonine	BZE	8
Morphine	MOR	40
Codeine	COD	40
6-Acetylmorphine	6MAM	4
Phencyclidine	PCP	10
Amphetamine	Amp	50
Methamphetamine	Meth	50
MDA	MDA	50
MDMA	MDMA	50
MDEA	MDEA	50

NeoSal Performance

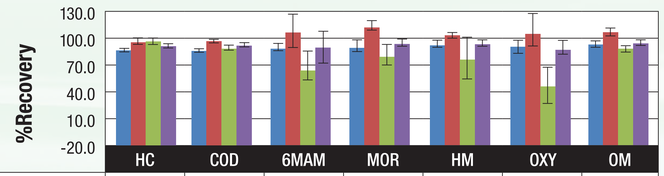
Sample Type	Sample Absorbed on Pad (mg)	Collection Time (Seconds)
Oral Fluid	730 ± 70	75.0 ± 36.7
EIA Buffer	789 ± 2	20 ± 1

Amphetamines Drug Recovery



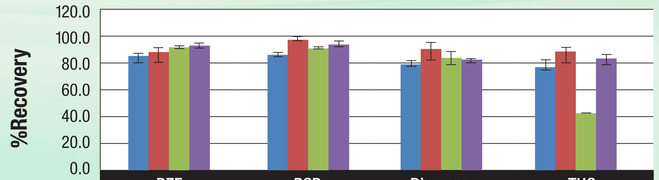
	Amp	Meth	MDA	MDMA	MDEA
Commercial Device 1	87.3	84.7	86.7	87.0	84.2
Commercial Device 2	94.7	95.0	83.9	90.7	90.3
Commercial Device 3	99.5	94.2	82.0	103.9	93.1
NeoSal	95.3	91.8	92.3	91.5	90.8

Opiates Drug Recovery



	HC	COD	6MAM	MOR	HM	OXY	OM
Commercial Device 1	85.8	85.0	86.7	90.3	90.3	88.4	89.1
Commercial Device 2	95.6	96.8	106.7	117.3	103.9	106.3	109.8
Commercial Device 3	95.9	88.0	65.4	81.3	78.7	47.6	86.5
NeoSal	91.8	91.7	90.7	94.2	92.5	88.1	93.9

Benzoylecgonine, PCP, Diazepam and THC Drug Recovery



	BZE	PCP	Diazepam	THC
Commercial Device 1	83.1	84.0	79.3	77.6
Commercial Device 2	85.3	97.0	88.0	83.9
Commercial Device 3	90.0	87.3	81.8	40.3
NeoSal	90.2	93.1	81.5	82.8

RESULTS

- The oral fluid and buffer volume recoveries demonstrated that the NeoSal has the potential to absorb oral fluid consistently.
- The general drug recovery using the NeoSal was comparable to the other commercial collectors evaluated.
- The recovery of THC for all devices ranged from 40.3 to 83.9%. The NeoSal had a mean THC recovery of 82.8%.
- The recovery of Opiates for all devices ranged from 47.6–117.3%. The NeoSal had an overall recovery range of 88.1–94.2%.

CONCLUSION

- The NeoSal is sufficiently consistent in its ability to absorb oral fluid.
  - ➤ As expected, real oral fluid sample collection timing had noticeably more variability when compared to EIA buffer.
- Overall drug recoveries for the NeoSal were comparable or in certain cases higher than the three other commercial collectors tested.
  - ➤ Most noticeable device drug recovery differences were observed in the opiates group (6-Acetylmorphine and oxycodone) and Delta-9-THC.
- The NeoSal should produce results comparable to the three commercial oral fluid collectors tested.

REFERENCES

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