

SOLUTIONS AT WORK™

ORAL FLUID DRUGS OF ABUSE TESTING

INTERCEPT® ORAL FLUID COLLECTION DEVICE



- Volume indicator turns blue when collection is complete (average 3 minutes)
- Non-invasive collection – test anytime, anywhere
- Directly observed, no gender specific personnel or special equipment required
- Eliminates dilution, substitution and adulteration tactics



- Dilute, Filter & Shoot
- Only 1 Transfer step from Collection Device to Mass Spectrometer
- Minimizes sample prep time, solvent usage/disposal and transfer steps
- Eco Friendly
- Compatible with most UPLC, HPLC and GC Systems

EXTREME/FV

INTERCEPT® i2™

Oral Fluid Collection Device

For 20 years, OraSure Technologies has led the oral fluid drug testing industry and the scientific community through extensive research, education and tools that have pioneered a highly accurate and efficient method of collection and testing drugs of abuse.

As the leader in oral fluid specimen collection and testing, we proudly present our latest advancement in oral fluid collection with the Intercept® i2™ Oral Fluid Collection Device.



Part # 1001-0362

ORAL FLUID COLLECTION ADVANTAGES ARE WELL KNOWN AND INCLUDE:

- Non-invasive collection – test anytime, anywhere
- Directly observed, no gender specific personnel or special equipment required
- Eliminates dilution, substitution and adulteration tactics
- Established legal defensibility
- Scientifically-proven technology captured in hundreds of peer-reviewed publications

Now collections made even easier

COLLECTION WITH CONFIDENCE

- Volume adequacy indicator
- Increased precision of collected sample volumes
- Robust collection pad design safeguards against collection pad failures

COLLECTION WITH EASE AND CONVENIENCE

- 3-minute collection time (average) with our patented treated pad
- No pre-collection sample pooling required
- Ergonomic collector designed for comfortable end-user experience

COLLECTION WITH SUPERIOR PERFORMANCE

- Greater stability at higher temperature ranges
- Enhanced for consistent drug recovery
- Increased sample volume allows for larger drug panels



EXTREME/FV

Multi-Layered Filtration

Thomson eXtremelFV® (patented) offer multi-layer filtration for viscous samples and samples containing up to 30% solid particulates. The filter vial consists of two parts: a filter vial shell and a plunger which includes a multi-layer filter on one end and a vial cap on the other end.

eXtremelFV® allows for compounds to be separated from the matrix, which results in both a higher signal-to-noise ratio and peaks that are more differentiated.

Prior to the introduction of the eXtremelFV®, many samples containing high levels of particulates were “filtered” by using an SPE/SLE step in the method. This method is easily amendable: simply replace the SPE/SLE step with a rapid and lower cost eXtremelFV® step.

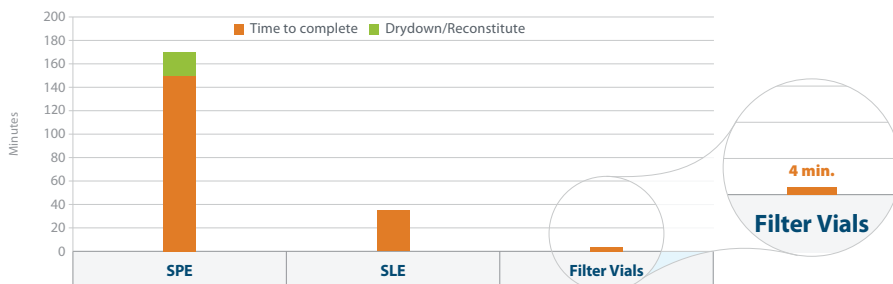


Max Fill Vol. = 450 μ L
Dead Vol. = 120 μ L

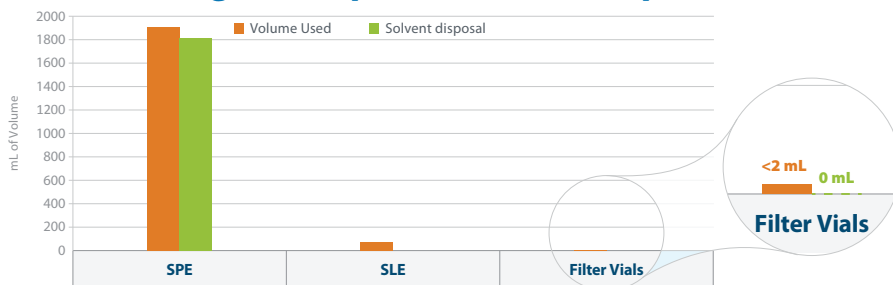
Orasure Intercept collector & Thomson Filter vials Optimized for Routine Drug Testing.

- Prevent mistakes, 1 transfer step from collection device to data analysis.
- Minimize time from receipt of sample to Mass Spectrometer.
- Significantly reduce the amount of solvents needed for sample preparation.

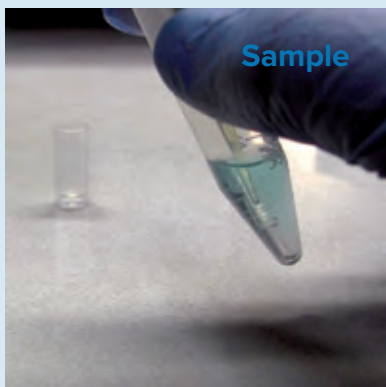
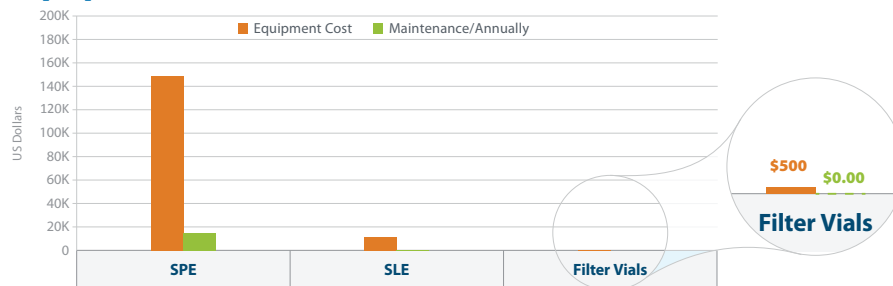
Time (Labor) Cost for 96 Samples



Solvent Usage & Disposal for 96 Samples



Equipment Cost



Improved Method for the Analysis of 31 Drugs of Abuse in Oral Fluid samples using the eXtremeFV® by LC-MS/MS

Introduction:

This validated method streamlines the sample preparation performed for the analysis of drugs of abuse/pain management panels in oral fluids collected with Intercept® i2he™ Oral Fluid Collection Devices. The diluted oral fluid samples were filtered using Thomson Filter Vials, followed by LC/MS/MS analysis. thereby reducing the amount of equipment required, solvent usage and sample preparation time. Samples are filtered by pipetting the sample into the filter vial shell, inserting the plunger into the shell, and then pushing the plunger into the shell. The filtration process from sample pipetting to autosampler ready only requires 15 seconds. Benefits to the use of Thomson eXtremeFV® include less samples transfer steps, lower cost, faster sample preparation time, less use and disposal of organic solvents. The most critical aspects of reliable Oral Fluid analysis are the reduction of interferences from the sample matrix and analyte recovery.

Equipment:

- Thomson 48 position Vial Filter Press (Part # 35010)
- AB Sciex 4500 Mass Spectrometer
- Shimadzu Prominence HPLC equipped
 - Column: Restek Ultra Biphenyl Columns (5µm, 50 x 2.1 mm)
 - Flow Rate: 0.5 mL/min
 - Injection Volume: 15µL
 - Mobile Phases:
 - A: 0.1% Formic Acid in HPLC Water
 - B: 0.1% Formic Acid in Methanol

Sample Preparation:

1. Add 100 µL of 10% Methanol / Water to 100 µL of Standard/Control/oral fluid sample + 10uL Internal Standard
2. Place Thomson Filter Plunger on top of the Thomson eXtreme/FV®, 0.2µm PVDF (p/n #85531).
3. Press filter plunger down approximately ¼ of the way into each of the Thomson Vial outer shells and vortex for 10 seconds.
4. Press Filter plunger the rest of the way down using the Thomson 48 position Vial Filter Press (p/n 35015) making extracts are ready for LC/MS/MS analysis

The following 31 drugs in oral fluid were be analyzed and validated by this method:

6-Monoacetylmorphine (6-MAM)	7-Aminoclonazepam (7AMINO)	Alprazolam (ALPR)
Amphetamine (AMPH)	Benzoyllecgonine (BE)	Buprenorphine (BUP)
Carisoprodol (CARIS)	Clonazepam (CLONZ)	Cocaine
Codeine (CODE)	Diazepam (DIAZ)	Fentanyl (FENT)
Hydrocodone (HCOD)	Hydromorphone (HMOR)	Lorazepam (LOR)
Meprobamate (MEPRO)	Methadone (MTHD)	Methamphetamine (MAMP)
Methylenedioxyamphetamine (MDA)	Methylenedioxymethamphetamine (MDMA)	Morphine (MORP)
Norbuprenorphine (NBUP)	Nordiazepam (NDIAZ)	Norfentanyl (NFENT)
Oxazepam (OXAZ)	Oxycodone (OCOD)	Oxymorphone (OMOR)
Phencyclidine (PCP)	Temazepam (TEM)	Zolpidem (ZOLP)
α-hydroxy-Alprazolam (OH-AL)		

Solvent Usage & Disposal, Time (Labor) & Equipment Cost for 96 Samples

	# Samples	Vol. Solvent used	Vol. Solvent used	Time to complete	Equipment Cost	Maintenance/Annually
SPE	96	1632 mL	1632 mL	150 min. + 20 min. dry down/reconstitute	~\$150,000.00	\$15,000.00
SLE	96	76.8 mL	76.8 mL	35 min.	~\$11,400.00	~\$100.00
Filter Vial	96	<1 mL	<1 mL	4 min.	\$500.00	\$0.00

For more information please see the full application note at:

http://htslabs.com/downloads/Improved_Method_for_the_Analysis_of_31_Drugs_of_Abuse_in_Oral_Fluid_samples_using_the_Thomson_eXtremeFV_by_LC-MS-MS.pdf

The Intercept® i2™ Collection Device



OraSure Technologies, Inc.

Performance Characteristics

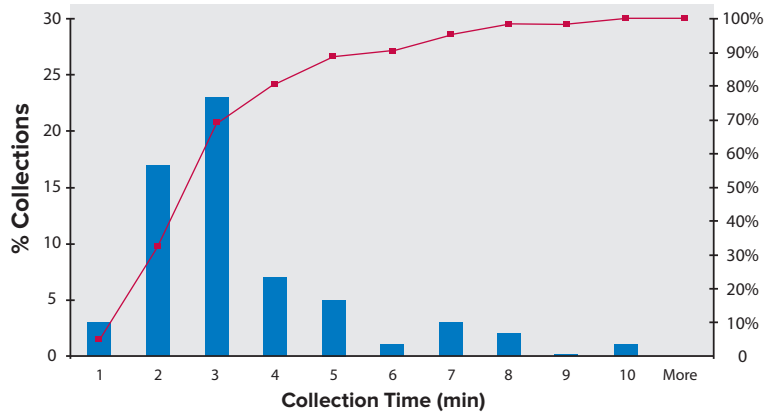
The Intercept® i2™ collection device has a volume indicator to control the amount of oral fluid collected. The device is designed to collect 1 mL of oral fluid on a treated cellulose collection pad. On average, the collection weight of oral fluid is 1.07 grams with a coefficient of variation of 8.2%. (See figure below for OraSure’s studied Collection Time Distribution needed to collect 1 mL of oral fluid.)

The collection pad is treated with a small amount of salt and citrate buffer. The salt is present to promote saliva collection in individuals with “dry” mouths and the citrate buffer is added to maintain the pH of the collected oral fluid at a pH of 6 to promote the stability of drugs of abuse. Studies have been performed that demonstrate that the amount of salt/citrate used on the collection pad improves collection times in high drug use populations such as drug rehabilitation sites without effecting the drug concentration.¹ After oral fluid collection, the collection stick is placed into 2 mLs of preservative solution diluting the original oral fluid by a factor of 3.

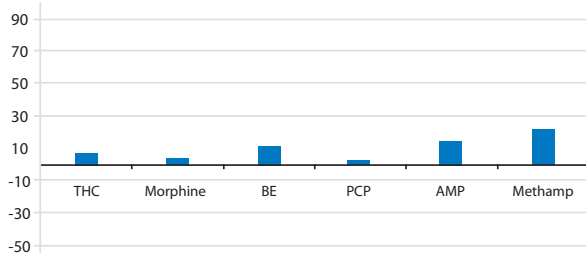
The Intercept® i2™ Specimen Vial with collection stick is then sent to the laboratory where the tip is broken off the bottom of the collector vial and the sample is centrifuged into a polypropylene tube for analysis and storage.

OraSure has conducted stability studies of drugs of abuse in both the collection vial before centrifugation and in the polypropylene tube after centrifugation at varying temperatures (see charts on following page).

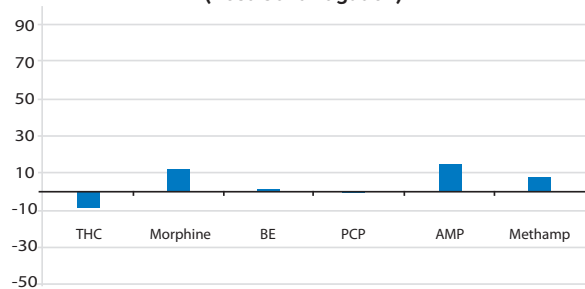
Collection Time Distribution



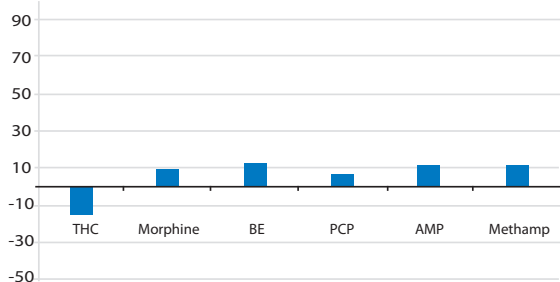
% Change After 6 Months at -20°C (Post-Centrifugation)



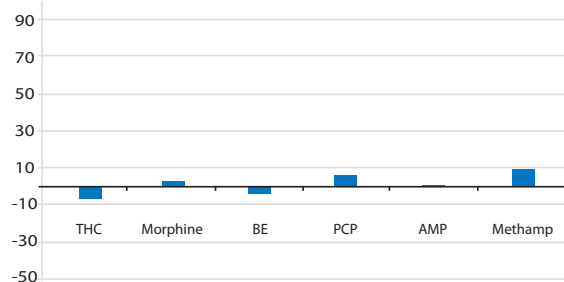
% Change After 2 Weeks at 30°C (Post-Centrifugation)



% Change After 3 Weeks at 25°C (on Device)



% Change After 30 Days at 4°C (Post-Centrifugation)



There was no loss of drug greater than 20% for any of the conditions tested.

1. Effect of Salt on Collection Time and Drug Concentration on Intercept® i2™ Oral Fluid Collector, 2013 Society of Forensic Toxicology Poster Session. http://soft-tox.org/sites/default/files/101713_scientific%20program%20draft%20%28portrait%20style%29.pdf



OraSure Technologies, Inc.

THOMSON Solutions™
INSTRUMENT COMPANY At Work

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Intercept® i2™ Oral Fluid Collection Device & the eXtreme Filter Vial streamline the oral fluid drug testing process from collection to results. The Intercept® i2™ provides a non-invasive collector with volume indicator making it an accurate and efficient way to collect oral fluid samples. Once collected, the oral fluid samples can be quickly and safely transferred to the outer shell of the eXtremeFV®. Simply add diluent, vortex and inject onto an LC-MS for analysis. This streamlined approach using the Intercept® i2™ and the eXtremeFV® requires only 1 sample transfer step from collection to results.

Part Numbers



Intercept® i2™ Oral Fluid Collection Device

Collect with Confidence & Convenience

Case Qty: 50 | Part # 1001-0362

Case Qty: 100 | Part # 1001-0498



PVDF eXtremeFV® 0.2µm

With tiered filtration | patented

Case Qty: 200 | Part # 85531-200

Case Qty: 500 | Part # 85531-500



Multi-Use Press

48 Position for Autosampler Ready

Filter Vials

Case Qty: 1 | Part # 35015-476

TIC-PL-082-246 Rev. A

THOMSON
MADE IN USA