



OraSure Technologies, Inc.

diagnostic solutions for the new millennium

Proudly presents

*Intercept<sup>TM</sup> Drugs of Abuse*

*“Laboratory Confidence,  
Oral Fluid Convenience”*

## *OraSure Technologies is . . .*

- ◆ A publicly traded, diagnostic company in business for over 12 years (OSUR, NASDAQ)
- ◆ Formed by a merger of STC Technologies and Epitope, Inc. 9/2000
- ◆ A fully integrated R&D, manufacturing and sales organization with ~200 employees
- ◆ Mission to become the world's leading oral fluid diagnostic company

## *OraSure Technologies is . . .*

- ◆ Provider of services & products both in the U.S. and abroad.
- ◆ Committed to providing substance abuse and infectious disease testing products.
- ◆ Diversified company committed to providing “Complete Systems and Solutions”.

## *Criminal Justice DOA Testing Today...*

- ◆ Based on urine collection
  - low donor/collector dignity
  - observed collection requires like-gender
  - highly subject to adulteration
  - biohazard
  - total costs can be high
- ◆ Lab based testing
  - costs increasing due to adulteration panels
  - no focus being placed on new assays

*The Solution . . .*

# OraSure's Intercept DOA Products

The ease of oral fluid collection combined with  
OTI's Microplate EIA screening kits.

**. . .with AUTOMATION to fit any size laboratory**

## *Features & Benefits of Oral Fluid Collection and Testing*

- ◆ **Easy to administer**
- ◆ **2 - minute, observed collection/difficult to adulterate**
- ◆ **Provides evidence of recent drug exposure**
- ◆ **Preserves donor/collector dignity**
- ◆ **Laboratory testing for NIDA-5 and more...**
- ◆ **Next day reporting (varies by lab)**
- ◆ **Cost effective automation**
- ◆ **Convenience of storing OF samples**

# *Oral Fluid Features & Benefits*

**Time of collection reduced by 50%**

⇒ **Lowers collection costs**

**Eliminates gender issues**

⇒ **Reduce/reallocate staffing**

**Eliminate embarrassment with urine**

⇒ **Greater dignity (staff & client)**

**Reduces bathroom/maintenance needs**

⇒ **Reduces costs**

**Lab-based screening/confirmation**

⇒ **Same lab quality you expect**

## *Oral Fluid versus Urine Testing*

- ◆ Oral fluid testing identifies recent drug usage that can be missed by urine testing.
- ◆ Window of detection is 1-3 days, while urine may detect some drugs for a longer period.

## *Intercept Micro-Plate DOA Menu*

- ◆ Amphetamine Specific
- ◆ Barbiturates
- ◆ Benzodiazepines
- ◆ Cannabinoids (THC)
- ◆ Cocaine
- ◆ Methadone
- ◆ Methamphetamine
- ◆ Opiates
- ◆ Phencyclidine(PCP)
- ◆ Human IgG

# *Intercept Assay Screening Cutoff's*

	<u>OTI</u>	<u>DTAB</u>
◆ Amphetamine Specific	100ng/mL	n/a
◆ Barbiturates	20ng/mL	n/a
◆ Benzodiazepines	1ng/mL	n/a
◆ Cannabinoids (THC)	1ng/mL	4ng/mL
◆ Cocaine Metabolite	5ng/mL	20ng/mL
◆ Methadone	5ng/mL	n/a
◆ Methamphetamine	40ng/mL	50ng/mL
◆ Opiates	10ng/mL	40ng/mL
◆ Phencyclidine(PCP)	1ng/mL	10ng/mL

## *Intercept Assay LOD's*

	<u>LOD ng/mL</u>
• Amphetamine Specific (d-amphetamine)	25.5
• Barbiturates (secobarbital)	8.2
• Benzodiazepines (nordiazepam)	0.181
• Cannabinoids ( $\Delta^9$ THC)	0.37
• Cocaine Metabolite (BE)	1.5
• IgG (human IgG)	1.5
• Methadone (methadone)	0.52
• Methamphetamine (d-methamphetamine)	8.0
• Opiates (morphine)	1.4
• Phencyclidine (PCP)	0.49

# *Cross-Reactivity Profiles\**

<u>Assay</u>	<u>Significant Cross-Reactivity</u>	
Amphetamine Specific	D-amphetamine	100%
	MDA	49%
	Mephentermine	15%
Barbiturates	Allobarbital	24%
	Amobarbital	43%
	Aprobarbital	29%
	Butabarbital	185%
	Butalbital	109%
	Pentobarbital	68%
	Phenobarbital	50%
	Secobarbital	100%
	Talbutal	170%

\*  $\geq 10\%$

# *Cross-Reactivity Profiles\**

## Assay

Benzodiazepines (nordiaz.)

## Significant Cross-Reactivity

Alprazolam	151%
Chlorazepate	70%
Desalkylflurazepam	17%
Diazepam	135%
Estazolam	130%
Flurazepam	49%
$\alpha$ -Hydroxyalprazolam	10%
Medazepam	17%
Midazolam	49%
Nitrazepam	39%
Nordiazepam	100%
Prazepam	107%
Temazepam	55%
Triazolam	26%
$\alpha$ -Hydroxytriazolam	15%

\*  $\geq 10\%$

## *Cross-Reactivity Profiles\**

<u>Assay</u>	<u>Significant Cross-Reactivity</u>	
Cannabinoids	$\Delta^9$ -THC	100%
	$\Delta^8$ -THC	105%
	11-nor 9-Carboxy $\Delta^9$ -THC	279%
	11-Hydroxy- $\Delta^9$ -THC	174%
	Cannabinol	15%
Cocaine Metab.	Benzoyllecgonine	100%
	Cocaine	64%
	Cocaethylene	200%

\*  $\geq 10\%$

## *Cross-Reactivity Profiles\**

<u>Assay</u>	<u>Significant Cross-Reactivity</u>	
Methadone	LAAM	18%
	Methadone	100%
Methamphetamine	D-Methamphetamine	100%
	Fenfluramine	26%
	MDMA	288%

\*  $\geq 10\%$

# *Cross-Reactivity Profiles\**

<u>Assay</u>	<u>Significant Cross-Reactivity</u>	
Opiates	6-Acetylmorphine	65%
	6-Acetylcodeine	>100%
	Codeine	>100%
	Diacetylmorphine	43%
	Dihydrocodeine	185%
	Hydrocodone	76%
	Hydromorphone	20%
	Morphine	100%
PCP	Phencyclidine	100%

\*  $\geq 10\%$

# *Q & A on the Collection Process*

*Q: Why does the collector have a salty taste?*

A: Intercept uses very low levels of common salts on the pad to enhance collection of oral fluids.

*Q: What type of gelatin is used on the pad and are there any religious issues?*

A: Intercept uses kosher gelatin; also, Jewish religion does allow for the intake of certain materials like this for medical purposes.

*Q: Is there anything that has been shown to interfere with the collection or tests?*

A: A variety of materials have been studied in all assays with minimal effect on results. While we have seen no common agents being used to adulterate OF testing, users should always closely monitor collections and react to any suspicious behavior.

# *Q & A on the Collection Process*

*Q: How important is the 10 minute wait period prior to collection?*

**A:** The oral cavity tends to clear itself about every 10 minutes and waiting this time is a precaution to address the occasional argument that a result was positive because of something consumed prior to collection.

*Q: What happens if the collection goes over 2 minutes?*

**A:** A 2-5 minute time period is an acceptable window for collection without any impact on test results, however, always collect at least 2 minutes to avoid an inadequate sample.

*Q: How do you know that an adequate sample was taken?*

**A:** The laboratory uses the IgG test kit which tests for human IgG. If the IgG level falls below 0.5 ng/mL, the sample is reported as being inadequate.

# *How to Perform OraSure's Intercept DOA Assays*

*(see package inserts as some methods vary)*

Add calibrator/  
control/sample  
to each well

Add 100  $\mu\text{L}$  of enzyme  
conjugate to each well  
and incubate 30 minutes  
at RT in the dark

Wash each well 6 times  
with 300  $\mu\text{L}$  of DI water

Add 100  $\mu\text{L}$  of substrate  
reagent to each well and  
incubate 30 minutes  
at RT in the dark

Add 100  $\mu\text{L}$  of  
stopping reagent  
to each well

Read absorbance at  
450/630 nm within  
15 minutes

## *OraSure's Capabilities...*

**Reagents: Full Menu**

**Hardware: Many options**

**Software: Automates...**

**Analyzes...**

**Reports!**

## *Platform Options*

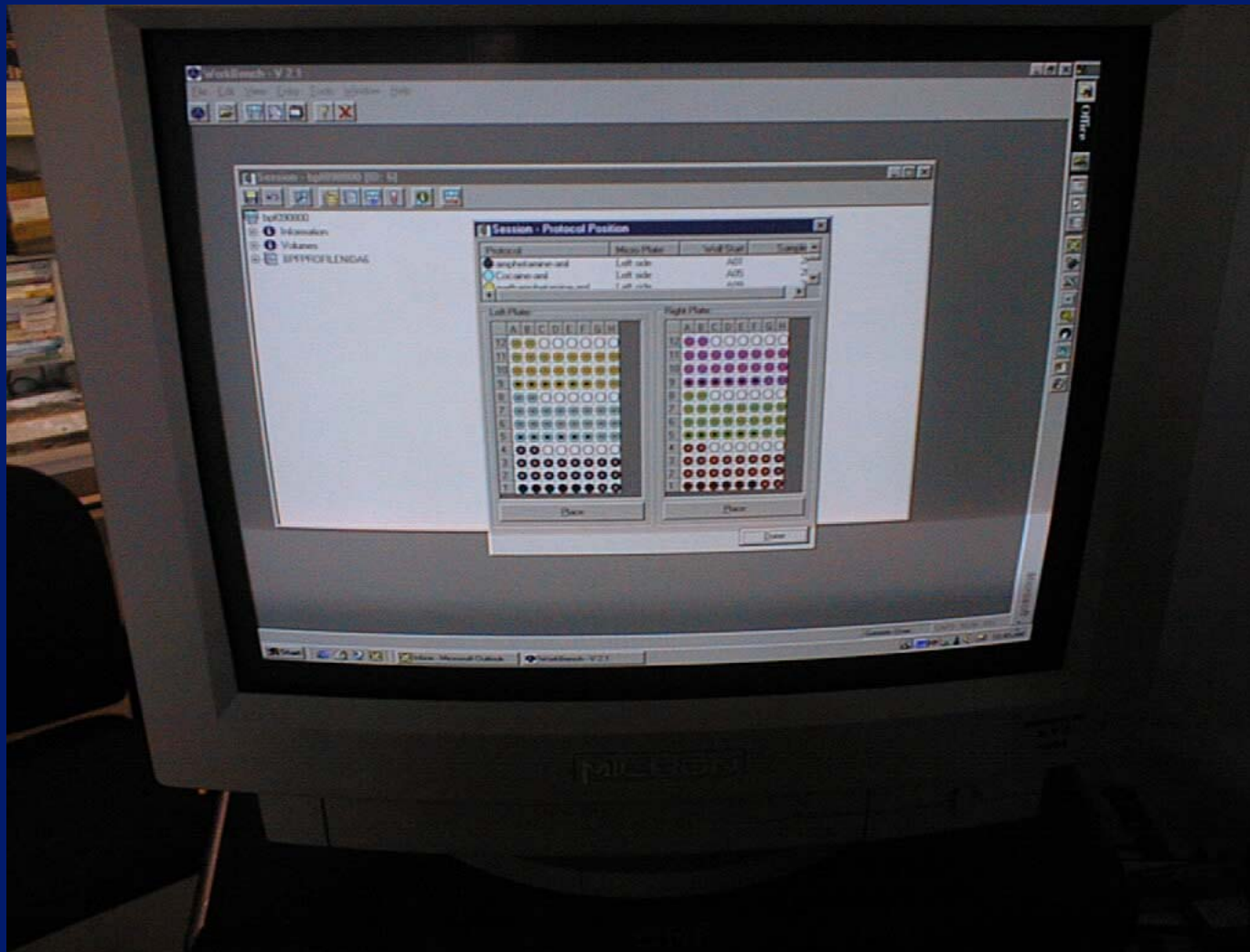
Small Automated MP system (PersonalLAB):

- Pipets sample, reagents, washing and reading
  - Two plates/run
  - Six assays/run
  - ~88 specimens/shift (NIDA5+IgG)
- + Fully automated, small, low cost
- Low throughput

# PersonalLAB™ Microplate System



# PersonalLAB Session Field



## *Platform Options*

Automated Tecan Approach:

Tecan Clinical Workstation w/ touch screen monitor

Up to ten plates/run

200-400 specimens/shift (NIDA5+IgG)

Can increase throughput significantly with Genesis  
Front-end pipeter and additional TCW's (2000-  
3000/day)

+ Fully automated system, software advanced,  
expandable

- More moving parts, new system quirks, high cost

# Tecan Clinical Workstation



## *Platform Options*

Semi-automated, production approach:

Hamilton Microlab AT+2

Titertek Multidrops, washer, reader all with  
Stacker/Magazine capability

Up to ~600 specimens/shift (NIDA5+IgG)

600 - 2000 by adding a second Hamilton

+ **Throughput, flexibility**

- Semi-automated, higher labor

## *Selected Data on Intercept*

### Oral Fluid vs Urine Test Statistics (Positive Rates)

	OF	Urine Non-DOT	Urine DOT
Amp	0.3%	0.4%	0.3%
Coc	1.2%	0.8%	0.6%
THC	2.8%	2.9%	1.4%
Opi	0.3%	0.2%	0.2%
PCP	0.0%	0.0%	0.0%

\* Data represents oral fluid specimens tested at LabOne, Inc., Lenexa, KS (Jan 1 – Sept 30, 2001)

# *Q & A on Assays & Lab Services*

*Q: Does the Methadone assay cross-react with methadone metabolites?*

**A:** This assay does not cross-react greatly with metabolites, however, testing of these classes is more common in urine testing where methadone spiking/adulteration is more common.

*Q: How similar are the windows of detection for urine versus oral fluids?*

**A:** The WOD for most drugs are very similar for urine and OF, with the exception of THC, which tends to be somewhat shorter in OF.

*Q: What is the turn-around time on negatives/positives from the lab?*

**A:** 24 hours for negatives and 48-72 hours for confirms (labs may vary; check with each lab for their specific turnaround time).

# *Q & A on Assays & Lab Services*

*Q: How quickly are orders processed for new collection kits?*

A: An ordering system may be set up so that inventory is always on-hand; if needed, kits can be sent overnight.

*Q: How do we get our data?*

A: Data can be provided by fax, electronic or mail.

*Q: How will we be trained?*

A: The laboratory and OraSure Technologies will provide the training for your staff. It is best to train a group of staff members in one location or several selected locations who then become the trainers for each site.

*Q: Can confirmations be performed on the original sample?*

A: Yes. This is not the case with all other OF tests on the market.

*Q: Can the lab provide expert testimony? If so, at what cost?*

A: Yes. Both the lab and OraSure can provide experts if needed. Costs will vary with travel location and duration.

# *Q & A on Assays & Lab Services*

*Q: Do the assays pick up Ecstasy?*

A: Yes. The Intercept Methamphetamine assay has a very high cross-reactivity with MDMA.

*Q: Will the Opiates assay pick up oxycodone?*

A: Use of the standard 10ng cutoff will not lead to high cross-reactivity with oxycodone but the lab can run a 1ng application which will pick up oxycodone positives.

*Q: Does the Benzodiazepine assay react with many of the low dose drugs in this class?*

A: Yes. The assay does cross-react with the standard classes as well as many of the low dose drugs in this class (see insert for specific data).

## *Observations from ARTC, NYC*

- ⇒ More sensitive to patient needs by being less embarrassing and easier for patients to provide an oral fluid specimen compared to urine specimen.
- ⇒ Security officers and other team members report that it is “safer” and “cleaner” to handle an oral fluid specimen as opposed to urine specimens.
- ⇒ Difficult to adulterate as team members can directly observe the entire collection process.
- ⇒ More than one patient can be tested at a time.
- ⇒ Facility seemed cleaner as the usual clutter of paper towels and/or cups were not present in the bathrooms.
- ⇒ Eliminates many of the reasons previously offered by patients not providing a urine sample for drug testing, such as, can't urinate, I just went, menstruation, etc.

# *Observations from Washington DOC*

- ⇒ Officers were always able to collect OF samples from their clients (no male/female gender issues), providing more direct and candid interactions and outcomes.
- ⇒ OF collection took about 1/2 the time to collect compared to that of urine resulting in labor savings and more quality time available for Officers and clients to interact.
- ⇒ Both Officers and clients reported a greater degree of dignity in the collection process.
- ⇒ OF collection eliminates the occurrence of “shy bladder”.
- ⇒ Some Officers did not feel they need to wear latex gloves with OF samples providing additional cost savings.
- ⇒ OF testing picks up more recent drug use than urine, eliminating the argument that screen positives are due to past positive events.

*For Results . . .*

Rely on  
OraSure's Oral Fluid Drugs  
of Abuse Testing Products

COMPLETE SYSTEMS &  
SOLUTIONS!

*OraSure thanks you for your  
time and interest . . .*

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