

HHS-Certified Labs and the DOT (Federal) Testing Program.

What's Happened Recently and How
Requirements May Change...

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Agenda

- 2010 Federal CCF (10/2010)
- Impact of New Drugs/Cutoffs (10/2010)
- DTAB Recommendations
 - Oral Fluid Testing
 - Schedule II Drugs

2010 Federal Custody and Control Form (CCF)

- 2010 Federal CCF

- Testing Authority

C. Donor SSN or Employee I.D. No. _____

D. Specify Testing Authority: HHS NRC DOT – Specify DOT Agency: FMCSA FAA FRA FTA PHMSA USCG

E. Reason for Test: Pre-employment Random Reasonable Suspicion/Cause Post Accident Return to Duty Follow-up Other (specify) _____

F. Drug Tests to be Performed: THC, COC, PCP, OPI, AMP THC & COC Only Other (specify) _____

- Additional Drugs

N REPORT - COMPLETED BY TEST FACILITY

POSITIVE for: Marijuana Metabolite (Δ 9-THCA) 6-Acetylmorphine Methamphetamine MDMA
 Cocaine Metabolite (BZE) Morphinine Amphetamine MDA
 PCP Codeine MDEA

2010 Federal CCF

- Eff. 12/1/2011
 - Use of 2000 version of CCF requires MFR
 - Laboratory attempts to obtain MFR from collection site
 - If unable to obtain MFR within 5 days, laboratory directed to reject test

2010 Federal CCF Conversion (one lab's experience....)

- Employers/Collectors slow to convert
 - As of 10/15/10, shipped only “2010 Federal CCF”
- In 2011....
 - Shipped 8.1MM “2010 Federal CCFs”
 - Tested 1.6MM specimens
 - \$\$\$
- “2000 Federal CCFs” rec'd in 2012....
 - Jan: 3K
 - Feb: 2.5K
 - Mar: 2.3K
- Testing Authority often not indicated...
 - §40.14 **What collection information must employers provide to collectors?**
 - (g) “..the DOT Agency which regulates the employee's safety-sensitive duties...”

Date	%2010 CCF
January-11	29%
February-11	40%
March-11	47%
April-11	53%
May-11	57%
June-11	61%
July-11	66%
August-11	70%
September-11	78%
October-11	86%
November-11	89%
December-11	92%

Federal “eCCF” Status

- OMB extended “paper” (5-part) CCF until 9/2013
- HHS Working Group w/ Industry Stakeholders
 - Meetings started 2012
- Key Questions
 - Will paper (5-part) still be permitted/required?
 - How will COC be documented?
 - “Wet” signature?
 - “Digitized” signature?
 - Is an “eOrder” required?
 - Data security

“eCCF”

- Advantages:
 - Always most current employer/MRO info
 - Fewer “flaws”
 - Required fields (e.g. RFT, Testing Authority, Collector Info)
 - “Wizard” driven process (e.g. Shy Bladder, Temp, etc.)
 - Only one “form” for a collection site
 - Easier/Faster to make regulatory form changes
 - Saves paper (“Greener”, less \$ waste)
 - All stakeholders get their “copy”
- Potential Disadvantages
 - Is there an “eSite” nearby?
 - Will employers have connectivity?

New Drugs/Cutoffs

- Still a “5-Panel”
 - MDMA (& analogues) added → “Amphetamines”
 - 6-AM specific screening added → “Opiates”
- Cutoffs
 - Amphetamines 1000/500 → 500/250
 - Cocaine (Metabolite) 300/150 → 150/100
 - Predicted ~30% increase in lab positives...

Impact of New Drugs/Cutoffs...

Drug Category	2007	2008	2009	2010	2011
Overall	1.8%	1.6%	1.5%	1.5%	1.7%
6-Acetylmorphine				0.011% ¹	0.012%
Amphetamines	0.25%	0.26%	0.29%	0.35%	0.44%
Cocaine	0.44%	0.32%	0.24%	0.24%	0.32%
MDMA				0.005% ¹	0.003%

- Cocaine up ~33% vs. 2010
 - Largely driven by cutoff changes
 - In 2011, 37% non-regulated tests mirrored new Federal cutoffs
- Amphetamines up ~26% vs. 2010
 - Impacted by cutoff changes and previous upwards trend
 - Larger change (+27%) in amphetamine positives / lesser change (+17%) in methamphetamine positives
 - In 2011, 35% non-regulated tests mirrored new Federal cutoffs
- 6-AM
 - Low positivity
 - Of interest are morphine negative (or below cutoff) specimens with 6-AM
- MDMA
 - **Very** low positivity

DTAB Recommendations

- 9/2011, DTAB Unanimously recommends.....
 - Adding oral fluid as a permitted specimen type in Federal drug testing programs
 - HHS consider adding prescription Schedule II Drugs (e.g. oxycodone) to Federal drug testing programs
- 1/2012
 - SAMHSA administrator accepts DTAB's recommendations
 - DOT endorses the opportunity improve transportation safety by addressing illicit use and abuse of the prescription drugs
 - **Start of Process – Neither HHS nor DOT have changed their requirements!**

Urine Testing for Prescription Opiates

(Quest Diagnostics Drug Testing Index™ Data)

- Specimen Source
 - Routine random specimens submitted for workplace drugs of abuse testing
 - **Non-regulated** (“General Workforce”) workplace drug tests (GW)
 - Rehab/CJ excluded
 - POCT Confirms excluded
 - Excludes high positivity
 - Specimens tested Jan 2005 – Dec 2011
 - Laboratory positive data (prior to MRO review)
- In 2005, 6.9MM GW opiates tests...5.6% test for expanded opiates
- In 2011, 4.8MM GW opiates tests...11.7% test for expanded opiates

“Expanded” Opiates Positivity (Urine Drug Tests) (General U.S. Workforce, N~500K/Yr)

	2005	2006	2007	2008	2009	2010	2011
Codeine	0.22%	0.20%	0.19%	0.20%	0.21%	0.17%	0.20%
Morphine	0.45%	0.37%	0.43%	0.43%	0.48%	0.42%	0.45%
Hydrocodone	0.88%	0.97%	1.2%	1.1%	1.3%	1.3%	1.4%
Hydromorphone	0.47%	0.54%	0.74%	0.73%	0.82%	0.71%	0.78%

“Expanded” Opiate positivity by Testing Reason (Urine Drug Tests)

Pre-Employment

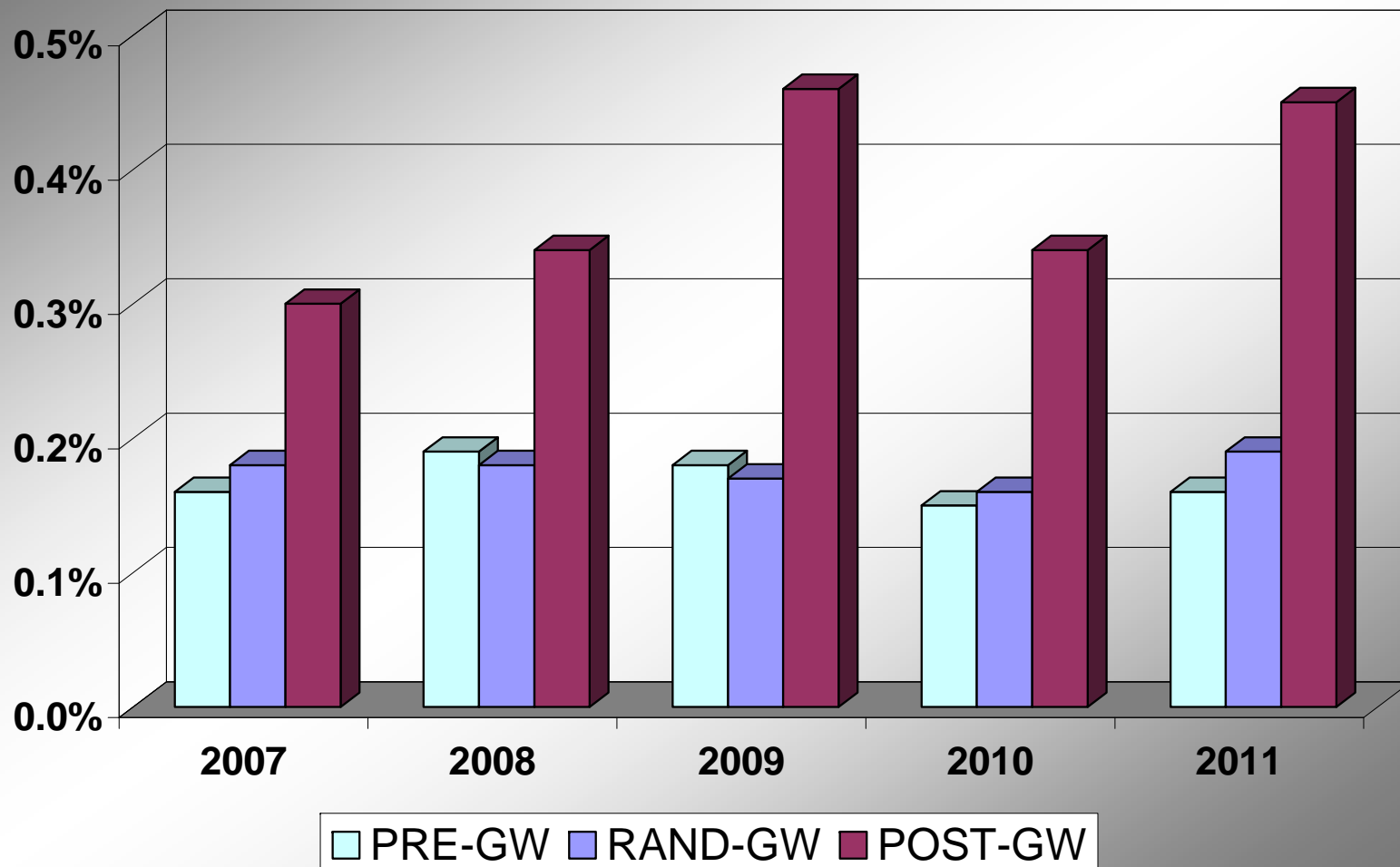
	2005	2006	2007	2008	2009	2010	2011
Codeine	0.22%	0.18%	0.16%	0.19%	0.18%	0.15%	0.16%
Morphine	0.33%	0.30%	0.29%	0.31%	0.32%	0.28%	0.28%
Hydrocodone	0.69%	0.70%	0.79%	0.78%	0.78%	0.81%	0.87%
Hydromorphone	0.37%	0.38%	0.48%	0.50%	0.47%	0.45%	0.51%

Post-Accident

	2005	2006	2007	2008	2009	2010	2011
Codeine	0.36%	0.31%	0.30%	0.34%	0.46%	0.34%	0.45%
Morphine	1.0%	0.9%	1.0%	1.2%	1.2%	1.1%	1.1%
Hydrocodone	2.3%	2.1%	2.9%	3.2%	3.7%	3.6%	3.6%
Hydromorphone	1.2%	1.2%	1.8%	2.2%	2.3%	1.9%	2.1%

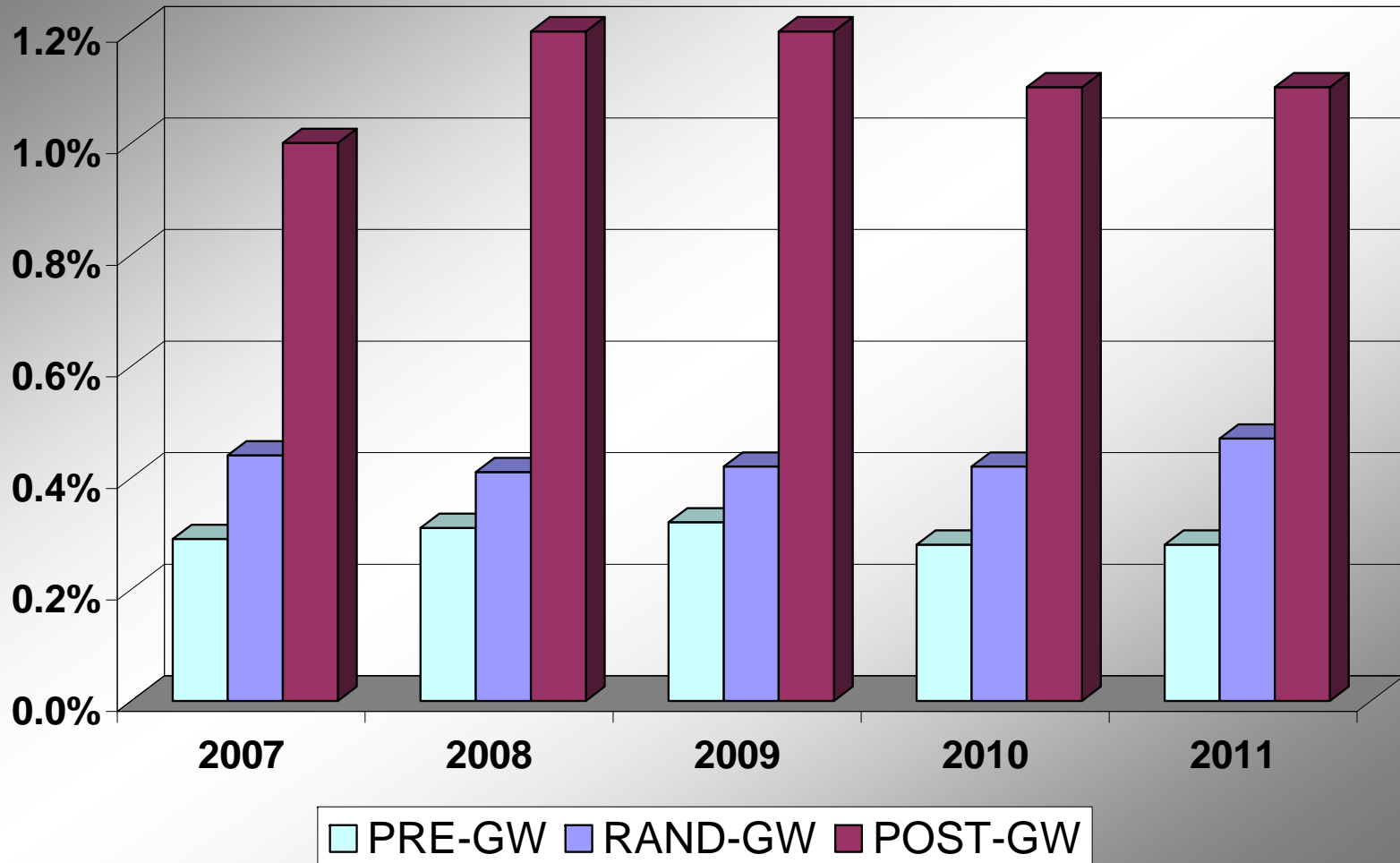
Codeine Positives by Testing Reason (Urine Drug Tests)

Positivity Rates for Codeine by Testing Reason– Urine Drug Tests
(For General U.S. Workforce, as a percentage of all test for “Expanded Opiates”)



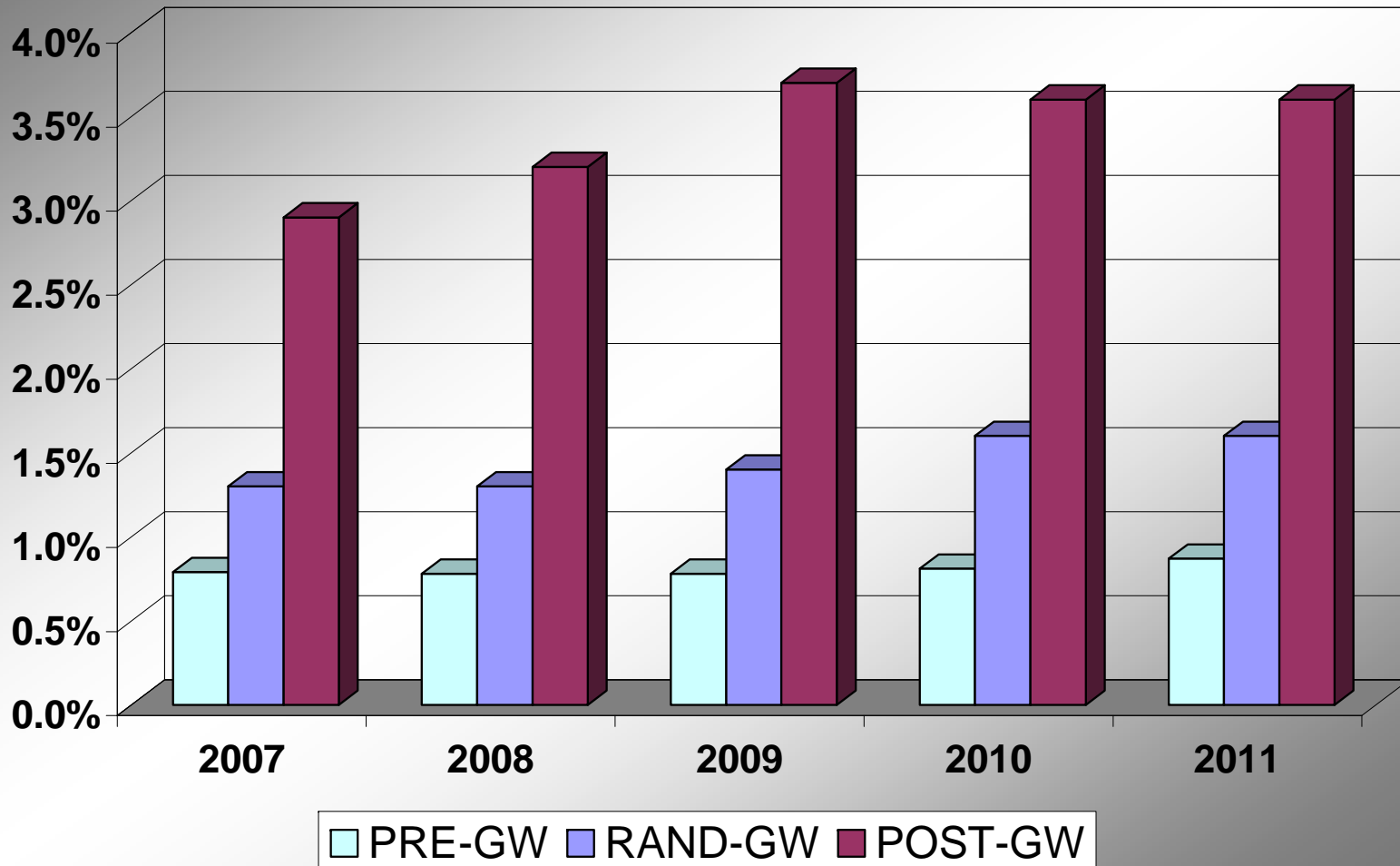
Morphine Positives by Testing Reason (Urine Drug Tests)

Positivity Rates for Morphine by Testing Reason– Urine Drug Tests
(For General U.S. Workforce, as a percentage of all test for “Expanded Opiates”)



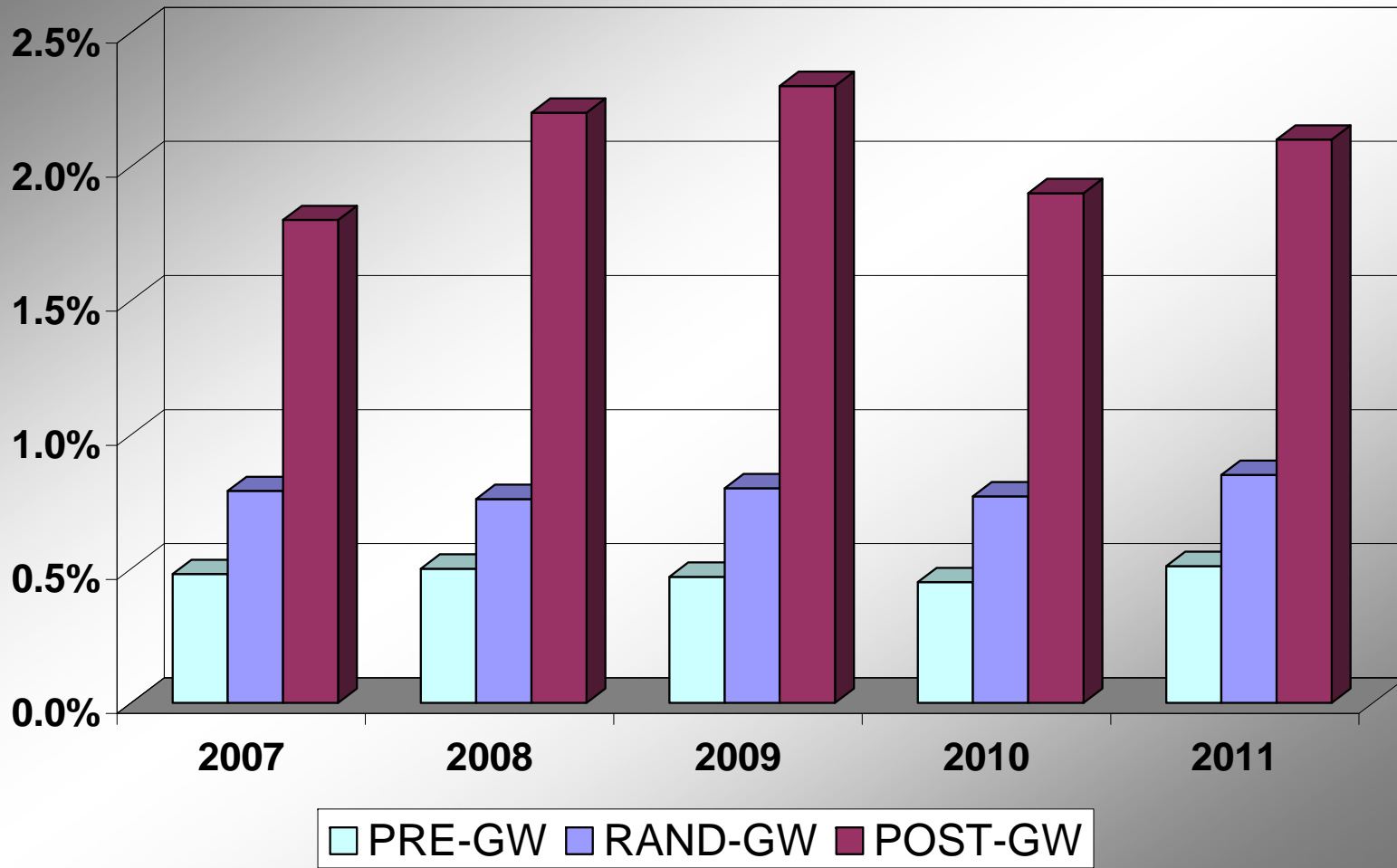
Hydrocodone Positives by Testing Reason (Urine Drug Tests)

Positivity Rates for Hydrocodone by Testing Reason– Urine Drug Tests
(For General U.S. Workforce, as a percentage of all test for “Expanded Opiates”)

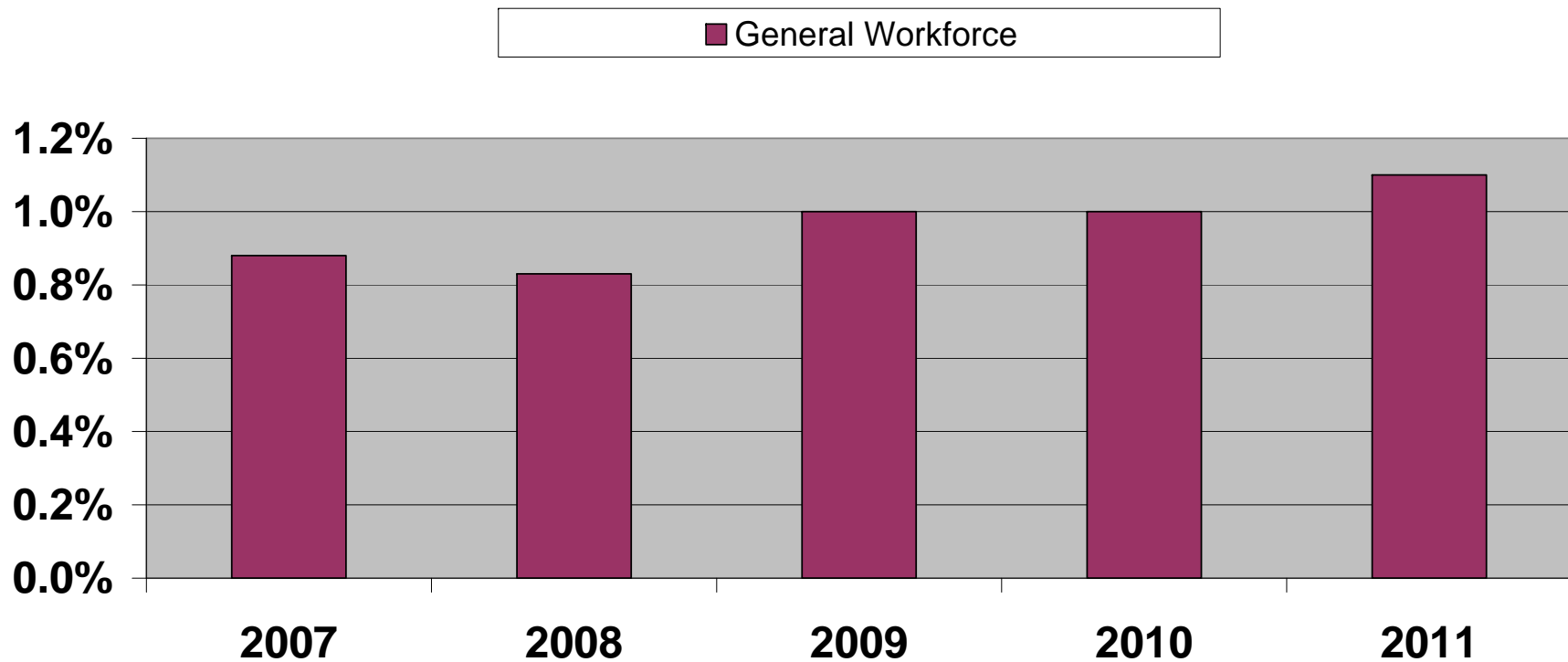


Hydromorphone Positives by Testing Reason (Urine Drug Tests)

Positivity Rates for Hydromorphone by Testing Reason– Urine Drug Tests
(For General U.S. Workforce, as a percentage of all test for “Expanded Opiates”)

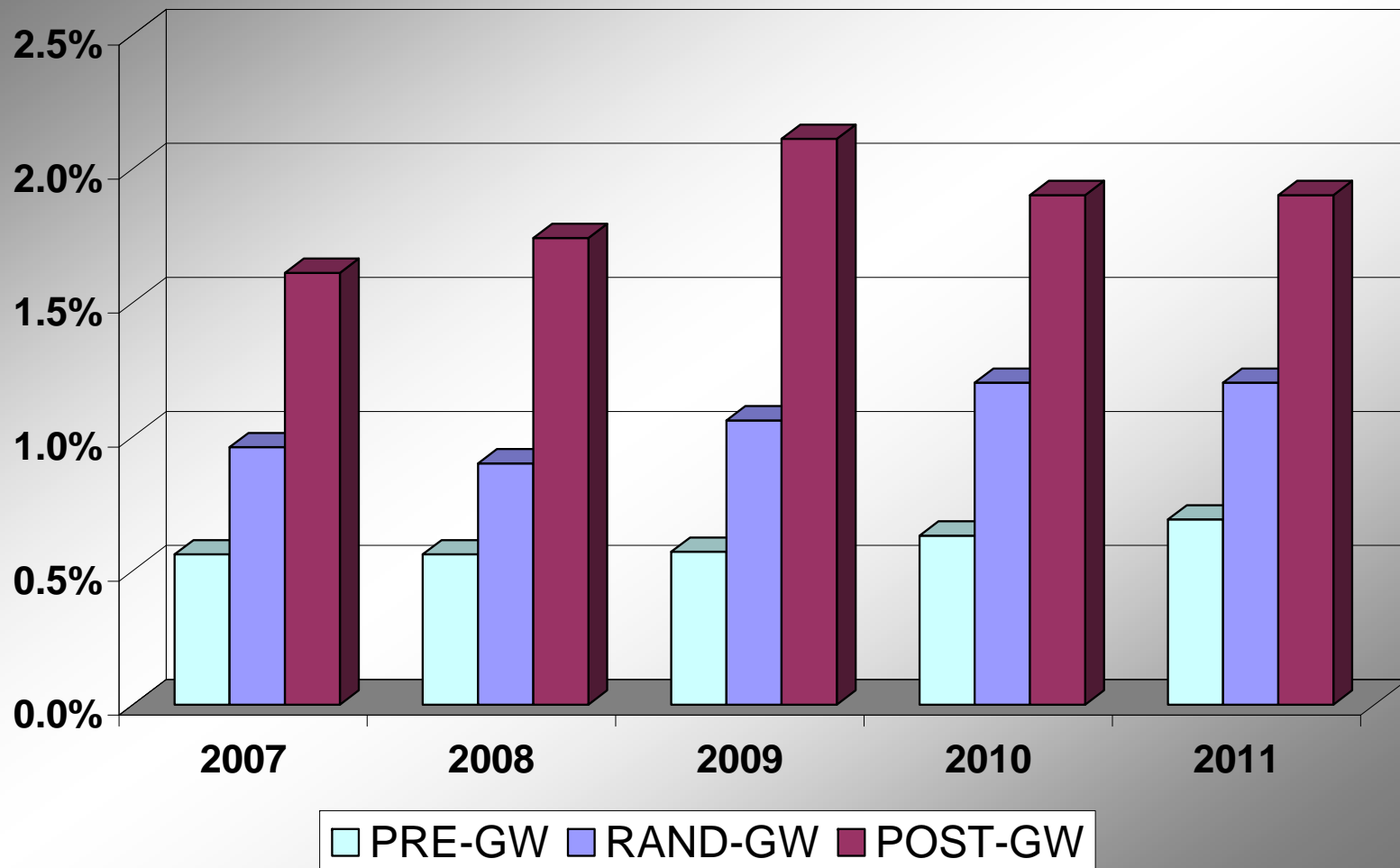


Oxycodone / Metabolite (Urine Drug Tests)



Oxycodone Positives by Testing Reason (Urine Drug Tests)

Positivity Rates for Oxycodones by Testing Reason– Urine Drug Tests
(For General U.S. Workforce, as a percentage of all such tests)



Summary – “Expanded” Opiates in Urine Drug Tests

- “Expanded” opiate drug positivity (urine) in the general U.S. workforce up 20% from 2005 to 2011
 - Morphine positives unchanged from 2005 to 2011
 - Hydrocodone positives increased 59 percent in the same period
 - Hydromorphone positives increased 66 percent in the same period
- In urine, Hydrocodone and hydromorphone positivity in 2011 higher than codeine and morphine, with rates of 1.4 percent and 0.78 percent, respectively.
- In urine, Oxycodone positivity in 2011 was 1.1%, between that of hydrocodone and hydromorphone
- Today, 2nd only to marijuana in workplace positivity
- Random positivity, ~2x higher than pre-employment
- Post-accident positivity, ~3-4x higher than pre-employment
 - Data doesn’t show cause and effect, but suggests drugs may have played role in incident

Oral Fluid Drug Testing



Oral Fluid Testing

- How is it collected?
 - Usually, a cotton swab placed in mouth (between cheek and gum or under tongue)
- How is it sent to lab?
 - Specimen is typically diluted with a buffer preservative solution in collection/transport tube
 - Sealed
 - Sent via overnight courier (like urine)
- What drugs are tested?
 - Typically a “5-panel” (“illicit” drug) test for workplace testing
 - May include prescription opiates, methadone, benzodiazepines, or barbiturates

Some Key Oral Fluid Questions for Federal Program (Collection)

- Specimen/Collection
 - Diluted or “neat”
 - Minimum volume
 - +/- ?% (10, 20, 30...?)
 - Recovery from collection system
 - +/- ?% (70, 80, 90...?)
 - Stability
 - How long
 - What temperature
 - “Shy Mouth”?
 - “Split” specimen process

Some Key Oral Fluid Questions for Federal Program (Testing)

- Drugs/Cutoffs
 - Illicit only (i.e. “5-panel”)?
 - Schedule II (e.g. Oxycodone, Hydrocodone) drugs?
 - With different devices, how are cutoffs represented?
 - New cutoffs as technology now permits or existing “industry standard” cutoffs?
- Testing Technologies
 - Newer technologies provide options not reflected in current guidelines
- Harmonization with Current Urine Guidelines
 - Drugs / Technologies

What is the Current Oral Fluid Experience?

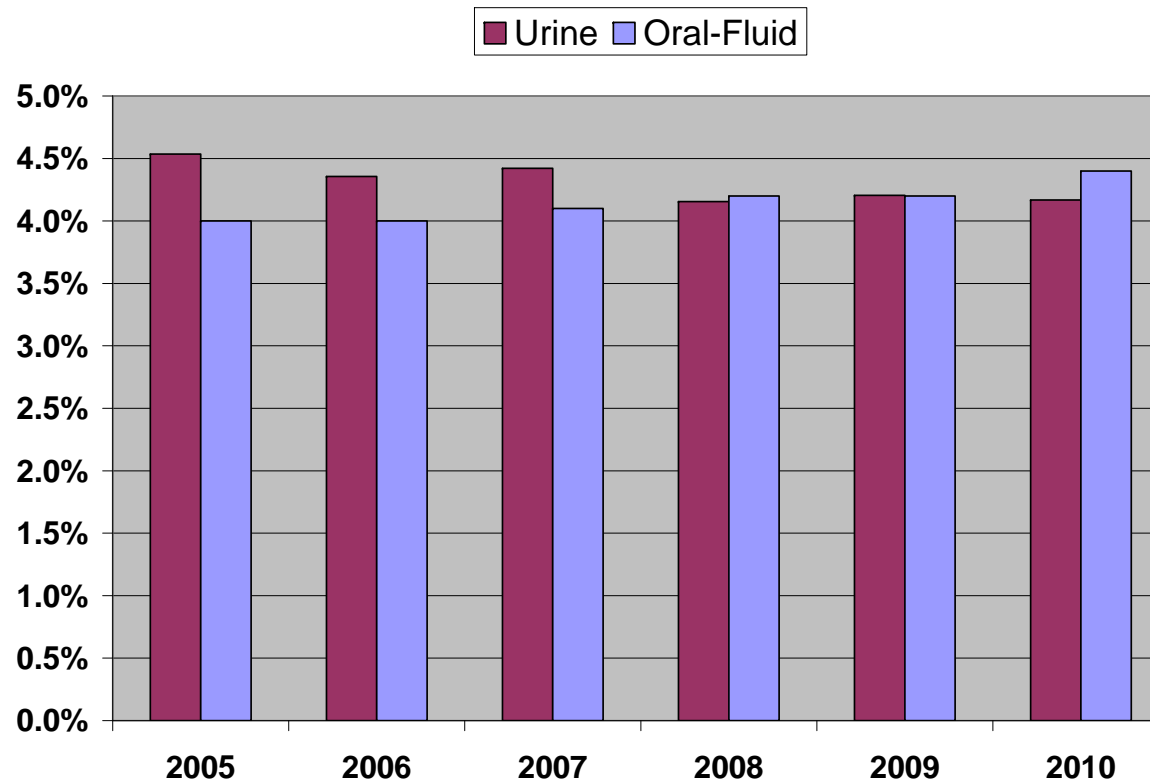
- Specimen Types
- Specimen Demographics
- Positive Prevalence Rates
 - Overall
 - By Drug

Specimen Demographics

- Source
 - Routine random, oral-fluid (N~5.2MM) and urine (non-regulated) specimens (N~35MM) submitted for drugs of abuse testing
 - Workplace
 - Rehab/CJ excluded
 - POCT Confirms excluded
 - Excludes high positivity
 - Specimens tested Jan 2005 – Dec 2010
 - Laboratory positive data (prior to MRO review)
- Testing Reason (Urine / Oral-Fluid)
 - Pre-Employment – 73% / 80%
 - Random – 13% / 9%
 - Post-Accident – 6% / 6%

Overall Positive Rates

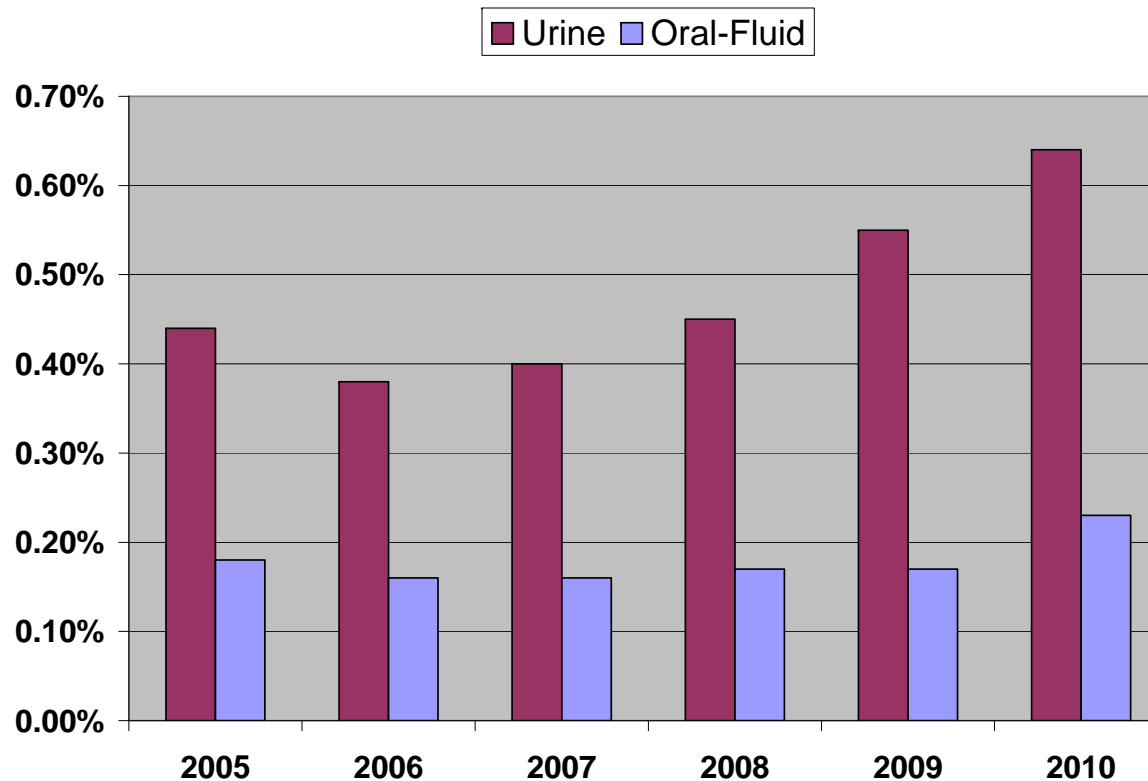
Overall Prevalence (2005 – 2010)		
Urine ¹	Oral-Fluid	% Difference
4.3%	4.1%	-4.7%



¹Includes testing for “non-SAMHSA” drugs
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Amphetamine Positive Rates

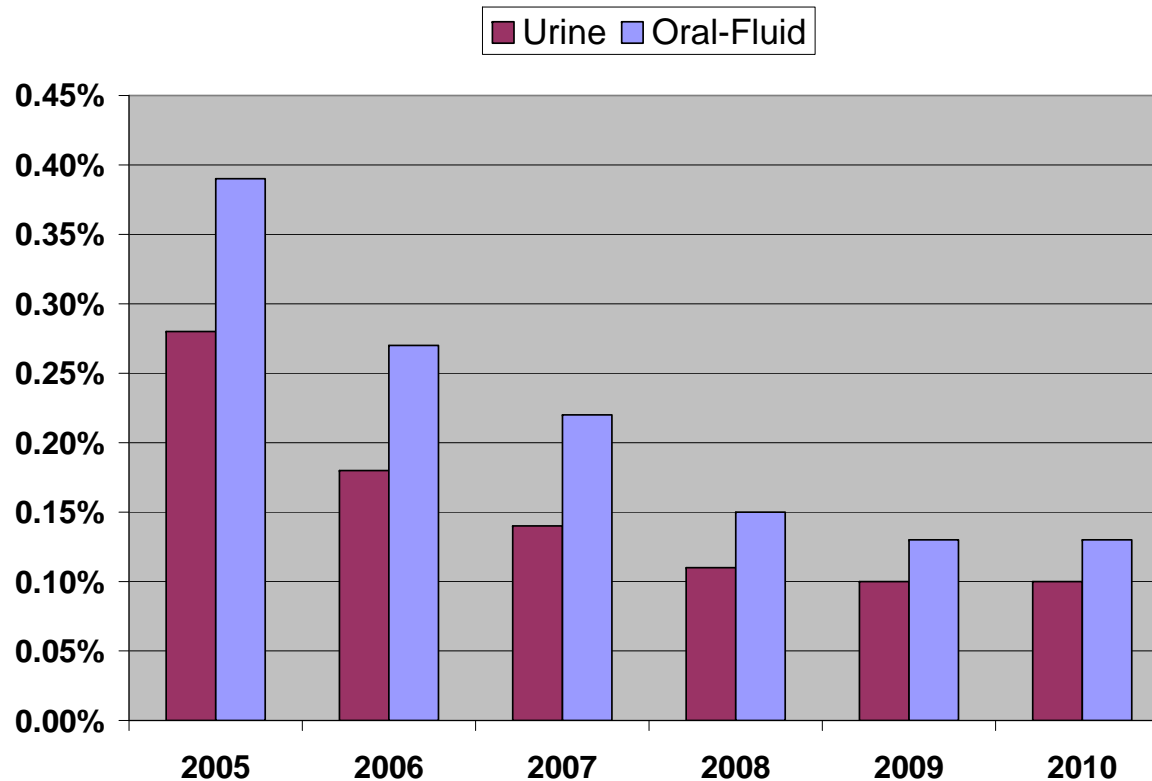
Amphetamine Prevalence (2005 – 2010)		
Urine ¹	Oral-Fluid	% Difference
0.46%	0.18%	-61%



¹As a percentage of all tests for “Amphetamines”
Quest Diagnostics

Methamphetamine Positive Rates

Methamphetamine Prevalence (2005 – 2010)		
Urine ¹	Oral-Fluid ²	% Difference
0.16%	0.23%	44%

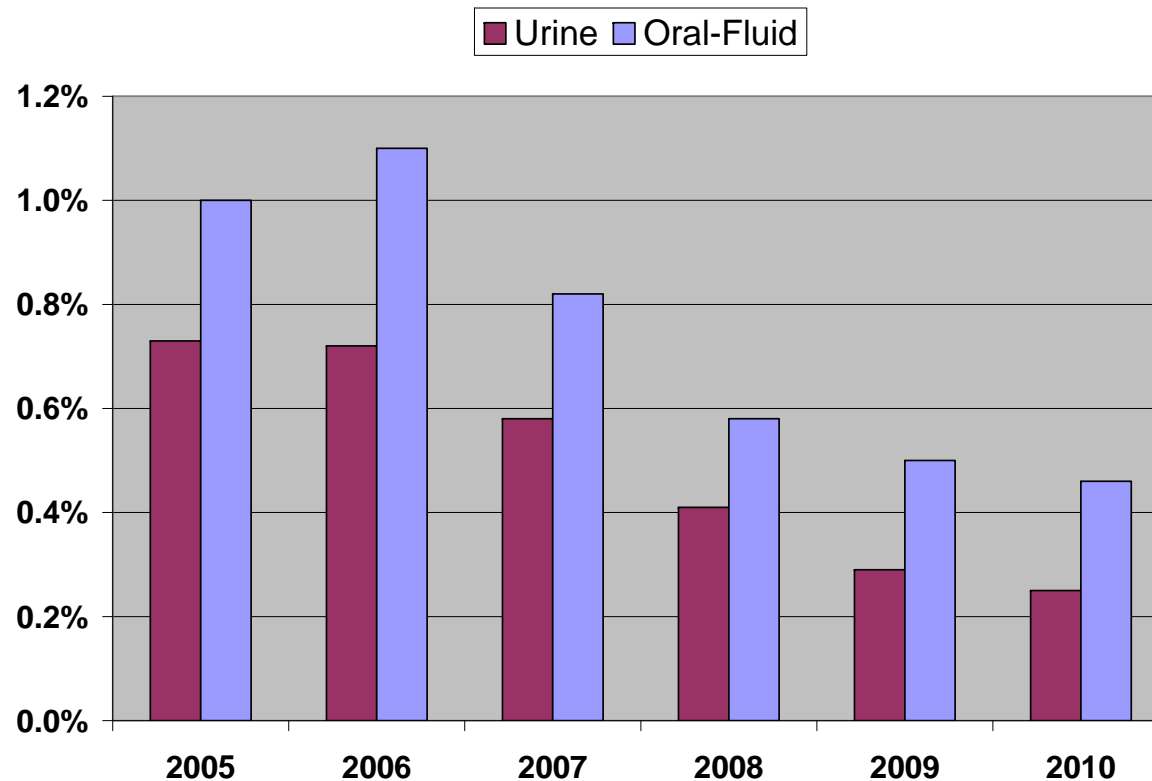


¹As a percentage of all tests for “Amphetamines”

²Includes MDMA and analogues

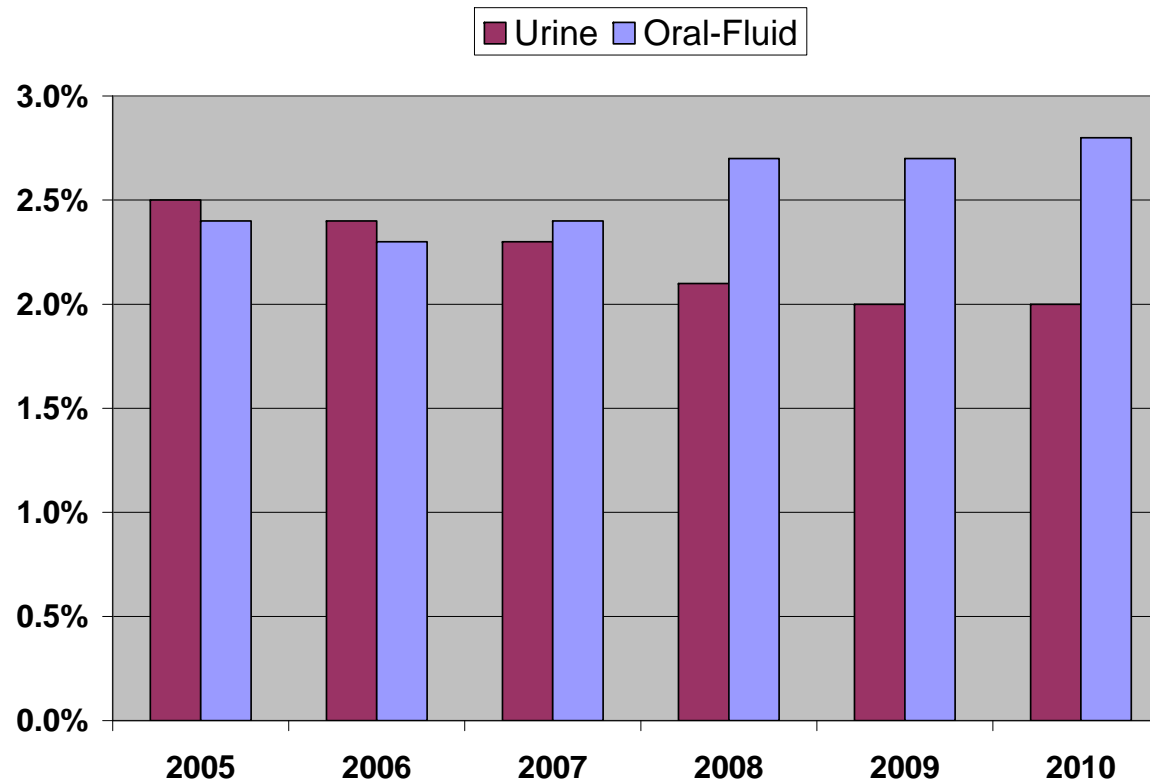
Cocaine Metabolite Positive Rates

Cocaine Metabolite Prevalence (2005 – 2010)		
Urine	Oral-Fluid	% Difference
0.53%	0.78%	47%



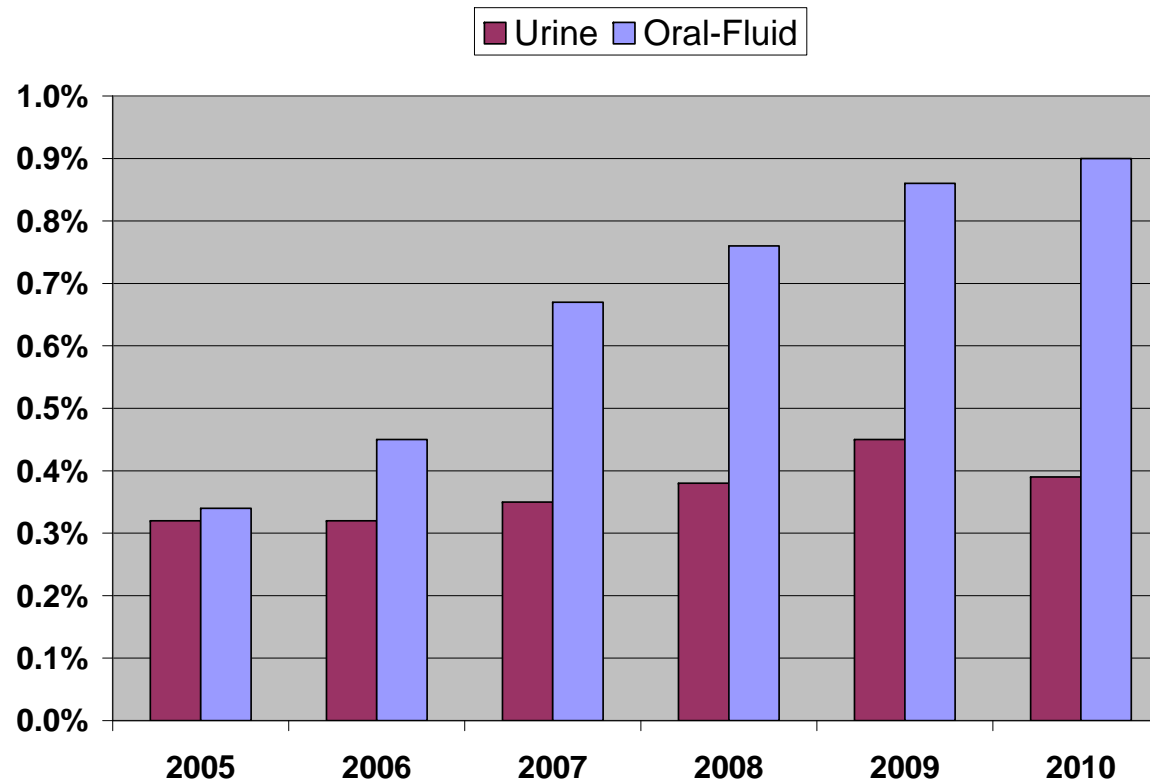
Marijuana / Metabolite Positive Rates

Marijuana / Metabolite Prevalence (2005 – 2010)		
Urine	Oral-Fluid	% Difference
2.3%	2.5%	8.7%



Opiates Positive Rates

Opiates Prevalence (2005 – 2010)		
Urine ¹	Oral-Fluid ²	% Difference
0.36%	0.64%	78%



¹Approximately 9% of tests include hydrocodone and hydromorphone

²Approximately 50% of tests include hydrocodone and hydromorphone

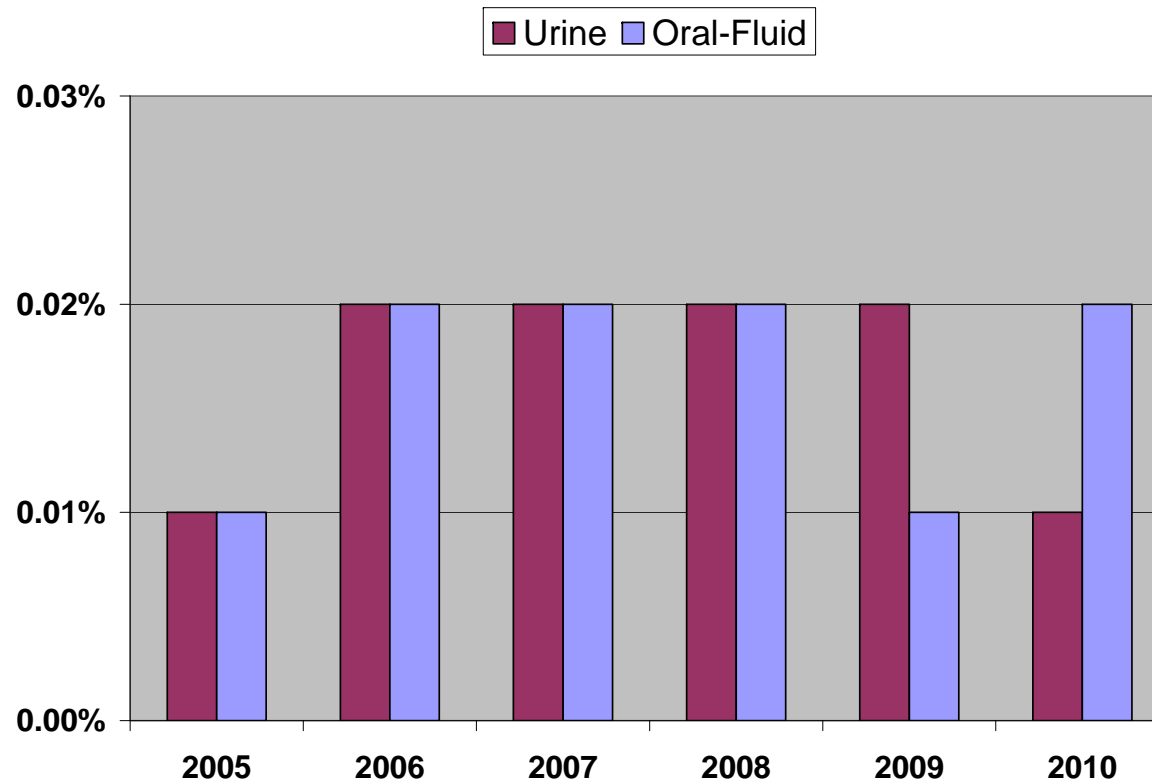
Oral-Fluid Opiates Detail (as a percentage of all tests for "Opiates"¹)

	2005	2006	2007	2008	2009	2010
Overall	0.71%	0.72%	0.67%	0.76%	0.86%	0.90%
Codeine	0.09%	0.08%	0.09%	0.09%	0.10%	0.08%
Morphine	0.03%	0.04%	0.05%	0.06%	0.07%	0.06%
Hydrocodone	0.60%	0.60%	0.54%	0.61%	0.69%	0.75%
6-MAM	0.01%	0.02%	0.03%	0.04%	0.05%	0.04%
Codeine & Morphine	0.00%	0.01%	0.01%	0.01%	0.01%	0.01%
Morphine & 6-MAM	0.01%	0.01%	0.02%	0.02%	0.03%	0.03%

¹Approximately 50% of tests include hydrocodone and hydromorphone
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Phencyclidine Positive Rates

Phencyclidine Metabolite Prevalence (2005 – 2010)		
Urine	Oral-Fluid	% Difference
0.02%	0.02%	0.0%



Summary – Oral Fluid

- Oral-fluid and urine provide insights into an individual's recent drug use
- Oral-fluid and urine exhibit similar trends
- Positive prevalence rates for most analytes are similar in oral-fluid and urine
- Oral-fluid data shows a significantly higher level of positives for cocaine metabolite
 - Gap expected to narrow with recent cutoff changes as non-regulated testing incorporates new Federal requirements
 - In 2011, cocaine metabolite positives up 33% vs. 2010
- Significantly more 6-AM positives in oral-fluid than urine
- Widening gap for marijuana (Oral Fluid > Urine) positives
- In oral fluid, hydrocodone accounts for ~80% of “opiates” positives

Questions



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