

What Happens at the Lab? Current & Alternative Forms of Drug Testing

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4/21/2009



Federal Regulations

- Sept. 1986: Executive Order 12564
- Apr. 1988: “NIDA” Guidelines
- Dec. 1989: DOT Rules
- June 1994: Marijuana Cutoff Change
- Nov. 1998: Opiate Cutoff Change
- Aug. 2001: Proposed SVT Revisions/DOT Rule Changes
- Apr. 2004: Revised Mandatory Guidelines
- Apr. 2004: Proposed Mandatory Guidelines
 - ◆ Alternative Matricies
 - ◆ Alternative Technologies
- Nov. 2004: DOT Interim Final Rule
- Aug. 2008: Revised DOT Rules (SVT)
- Mar. 2010: Revised Mandatory Guidelines (Cutoff Changes, IITF)

URINE

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Urine Collection Procedure (1/2)

- Donor selects kit
- Donor provides specimen in privacy - Not Observed
- Collector measures temperature
- Collector pours specimen into bottle

Urine Collection Procedure (2/2)

- Specimen bottle sealed & CCF completed
- Bottle & CCF placed in COC bag for transport to lab
- Specimen sent via Courier
- Collection Time: 10-15 minutes
- Considered Biohazardous

Urine Specimen Validity Testing

- All Specimens:
 - ◆ pH
 - ◆ Creatinine
 - ◆ Specific Gravity when indicated
- Regulated and Optional for Non-Regulated
 - ◆ Same as above
 - ◆ Oxidizing Adulterants (Chromates, Halogens, Nitrites)
 - ◆ Glutaraldehyde when indicated

Urine Cutoffs

- Industry Standard Cutoffs
- HHS-5 (aka “NIDA”-5)

Drugs Tested

<u>CLASS</u>	<u>CUTOFF</u>
<p>“Amphetamines”</p> <ul style="list-style-type: none"> ◆ Amp, Methamphetamine 	1000/500
<p>Cocaine</p> <ul style="list-style-type: none"> ◆ BE 	300/150
<p>Marijuana Metabolite</p>	50/15
<p>“Opiates”</p> <ul style="list-style-type: none"> ◆ Codeine, Morphine 	2000/2000
<p>PCP</p>	25/25

Other Analytes

- MDMA best screened using a separate/specific test
- 6-MAM –
 - ◆ Heroin specific marker
 - ◆ Test if Morphine positive
- Prescription Drugs
 - ◆ “Expanded Opiates” (as part Opiate screen)
 - ◆ Hydrocodone, Hydromorphone
 - ◆ Requires lower cutoff (300/300)
 - ◆ Oxycodone (best detection with specific test)
 - ◆ Barbiturates, Benzodiazepines, Methadone, Methaqualone, Propoxyphene
- Alcohol

New HHS Guidelines (eff: 2010)

- Cutoffs
 - ◆ Cocaine 150/100
 - ◆ Amphetamines 500/250
 - ◆ MDMA 500/250
- Instrumented Initial Test Facility (IITF)

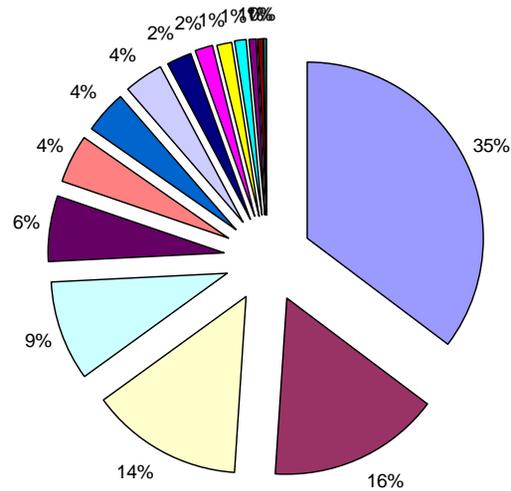
Lab Receiving Process

- Pre-Sort
 - ◆ Specimen type
 - ◆ Regulated vs. non-regulated
- Accession
 - ◆ Verify specimen identification
 - ◆ Verify specimen integrity
 - ◆ Check for “flaws”
 - ◆ Label
- Aliquot for screen

Log-In (Accession)



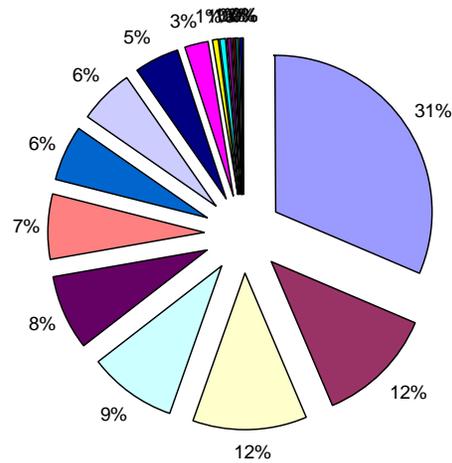
Fatal Flaws 2006-2008 (FMSS) (n~8.4K)



- | | |
|--|--|
| Insufficient quantity | Collector's Name and Signature Missing |
| Specimen leaked in transit | Donor ID on COC form does not match specimen container |
| Tamper-Evident Seal Broken | No COC form received with specimen |
| No specimen received with COC form | No tamper-evident seal on specimen container |
| Tamper-evident seal misapplied/missing | No Donor ID on specimen container |
| Generic Reject message | Lab accident |
| Unauthorized changes on specimen container or COC form | Wrong CCF Used |
| Collector signature missing | |

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Fatal Flaws 2006-2008 (GW) (n~43K)

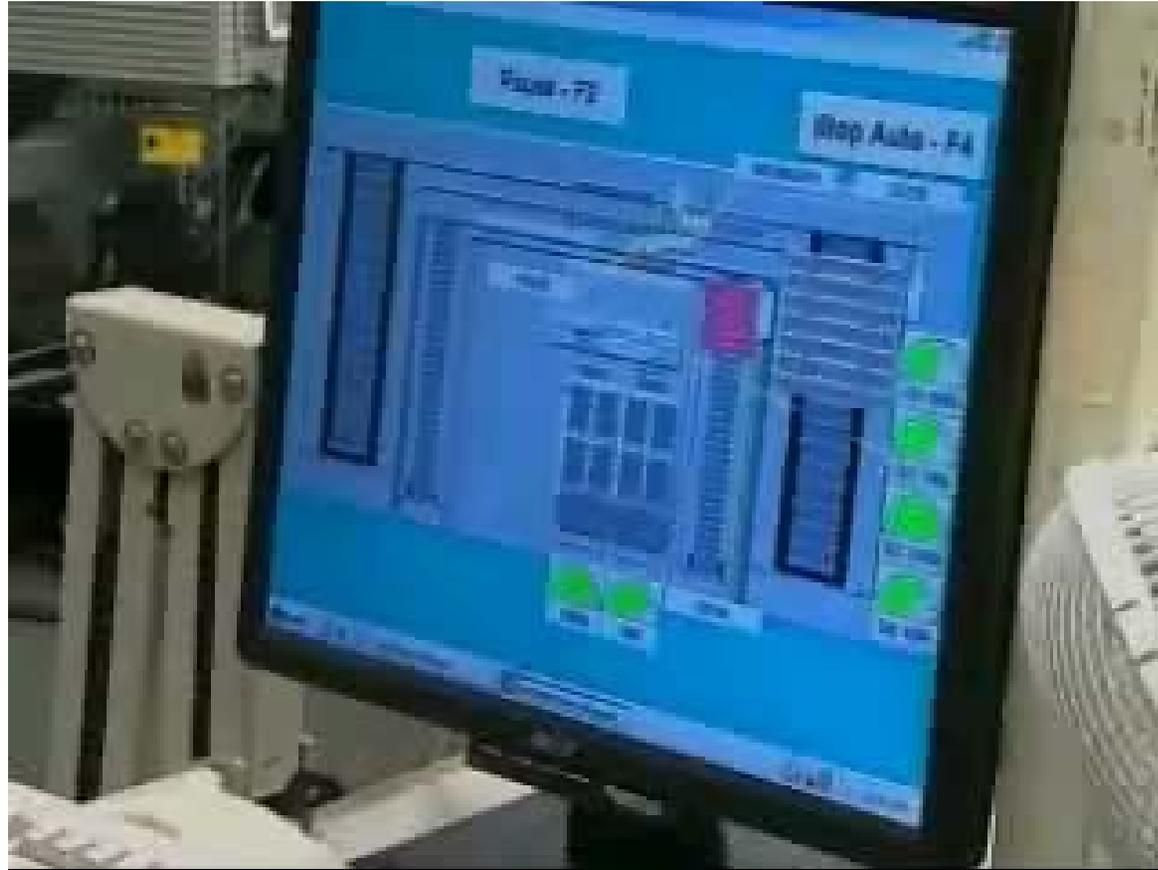


- | | |
|--|--|
| Collector's Name and Signature Missing | Tamper-Evident Seal Broken |
| Specimen leaked in transit | No tamper-evident seal on specimen container |
| Donor ID on COC form does not match specimen container | No specimen received with COC form |
| Tamper-evident seal misapplied/missing | No Donor ID on specimen container |
| Insufficient quantity | No COC form received with specimen |
| Generic Reject message | Lab accident |
| Temperature Outside Range at Collection Site | Donor Name/SSN Present on COPY-1 |
| Unauthorized changes on specimen container or COC form | No Donor Intials on Tamper-Evident tape |
| Wrong CCF Used | COC section incomplete or incorrect |
| Collector signature missing | |

Aliquot



Urine Aliquotting



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Lab Testing Processes

- Screen: enzyme immunoassay (EIA)
 - ◆ TAT: < 24 hrs



Urine Screening

Urine Testing

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Lab Testing Processes

- **Screen: enzyme immunoassay (ELISA)**
 - ◆ TAT: < 24 hrs

- Re-aliquot if non-negative

- Extract

- **Confirmation:**
GC(LC)/MS(/MS)
The “Gold Standard”
 - ◆ TAT: 48 - 72 hrs.



GC/MS Extractions



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GC/MS

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Lab Certification Process

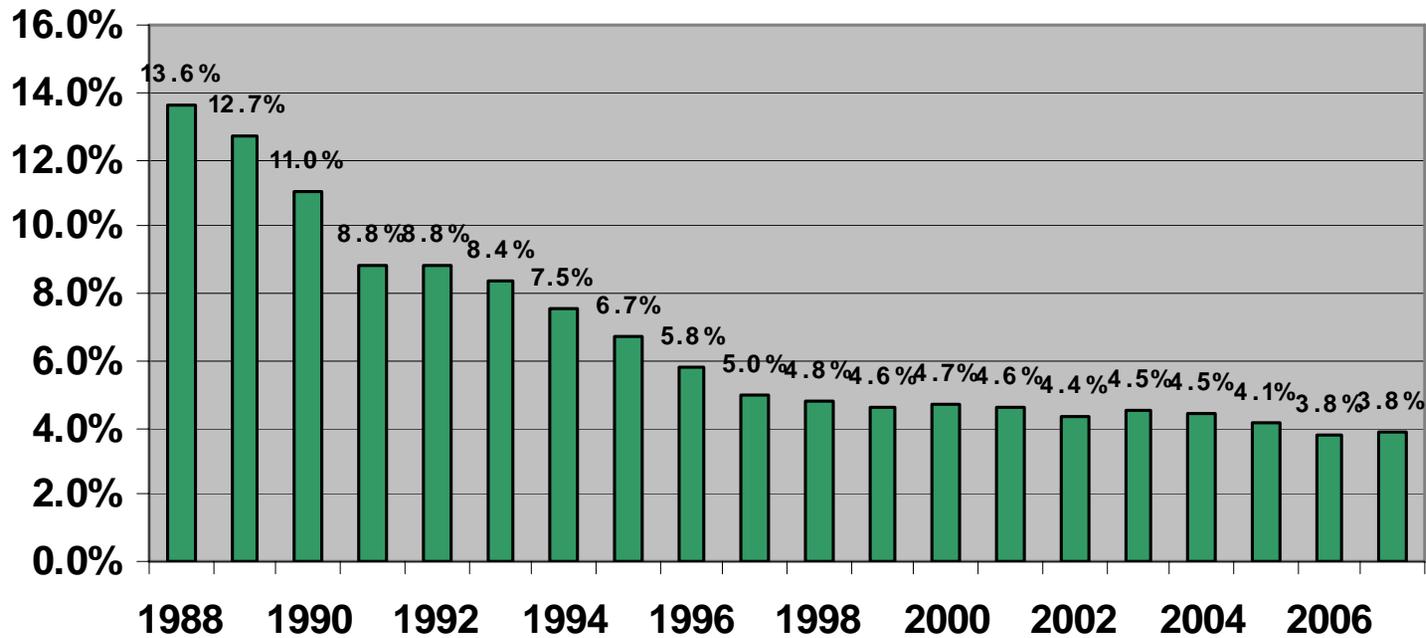
- Review chain of custody
 - ◆ External – CCF
 - ◆ Internal – Specimen & Aliquot
- Review analytical data
- If negative:
 - ◆ Complete CCF
 - ◆ Initial CCF
- If non-negative:
 - ◆ Same CS reviews screen and confirmation data
 - ◆ Complete CCF and compare CCF w/ Electronic report
 - ◆ Sign CCF
- Report results
 - ◆ Negative? → Electronic
 - ◆ Non-Negative? → CCF & Electronic

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Detection Window

- Detects use within past several days
- Detection times are dependent on Cutoff
- Cannot be used to determine if donor was “under the influence”

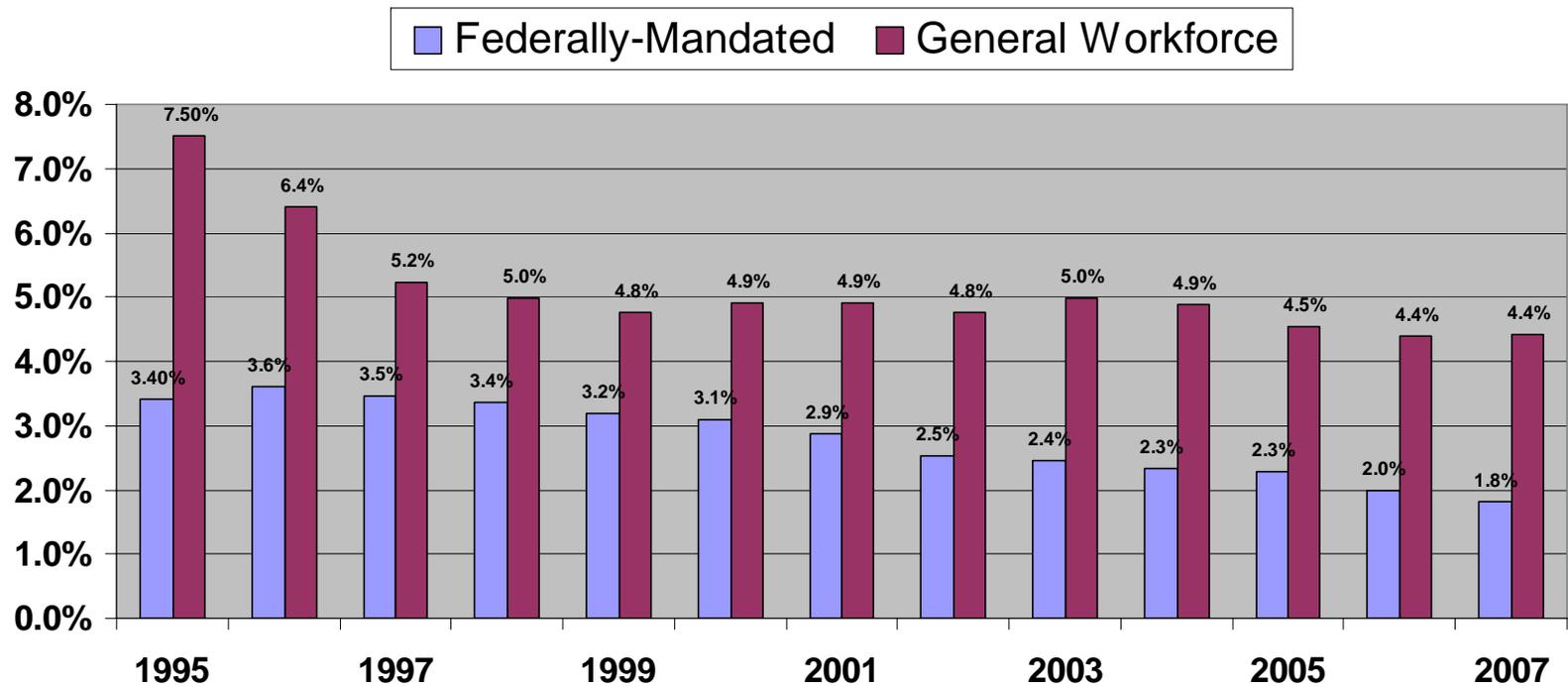
Overall Positivity Combined Workforce



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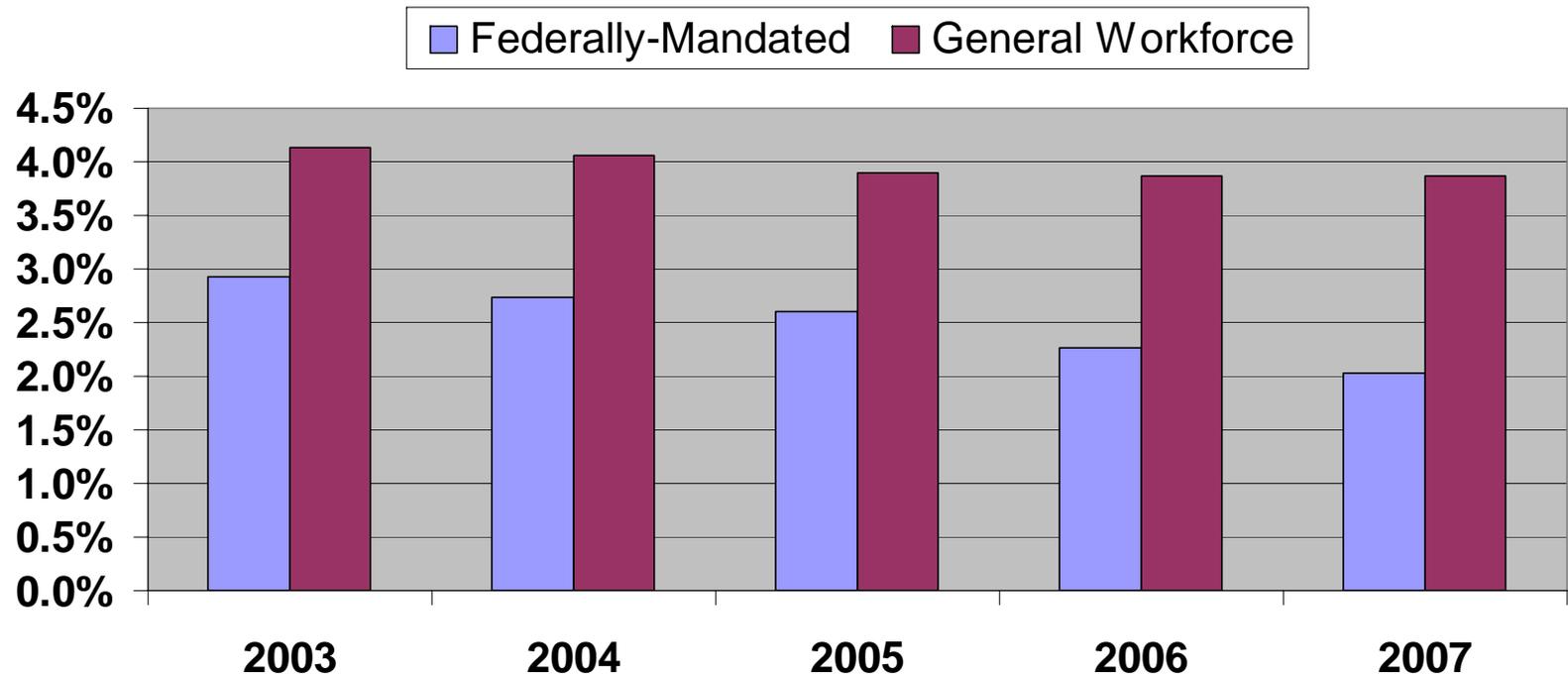
Overall Positivity

Federally-Mandated Safety-Sensitive / General Workforce

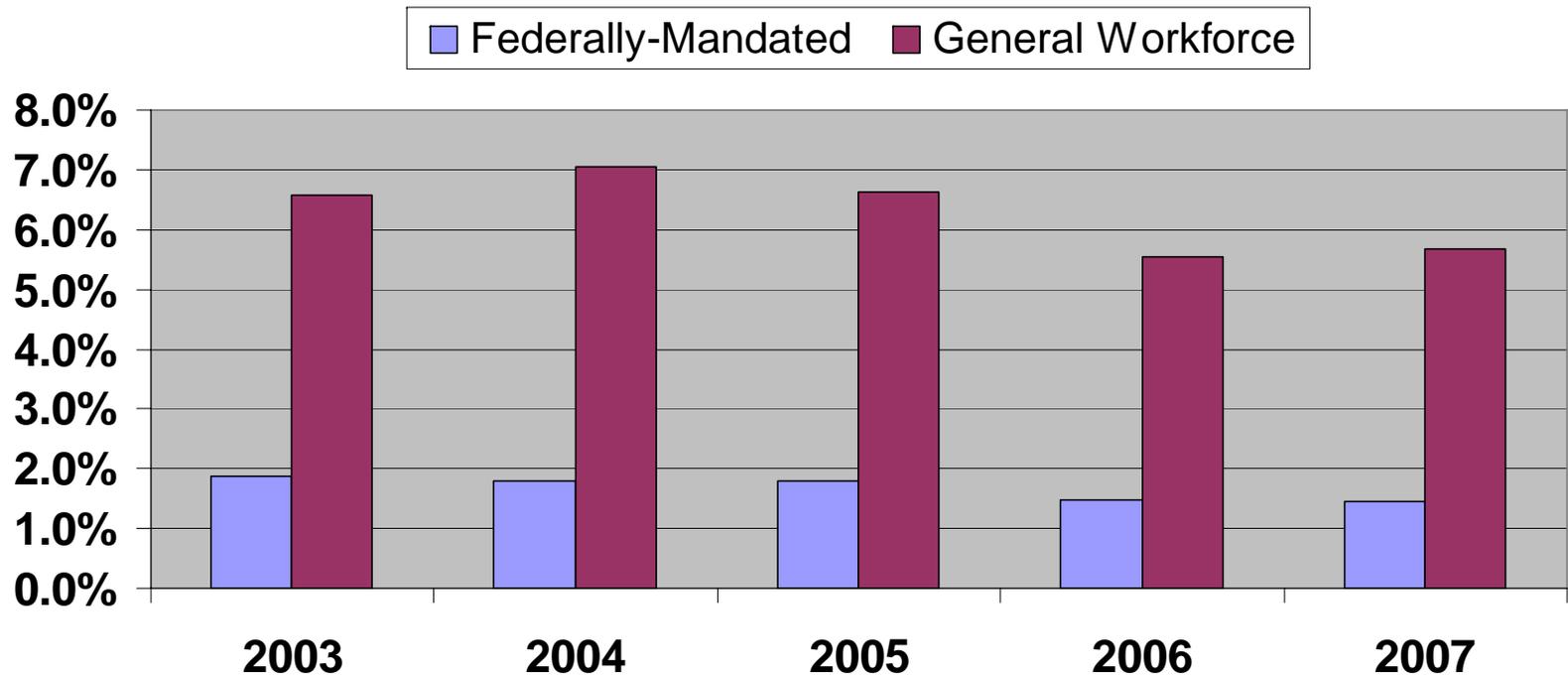


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Pre-Employment



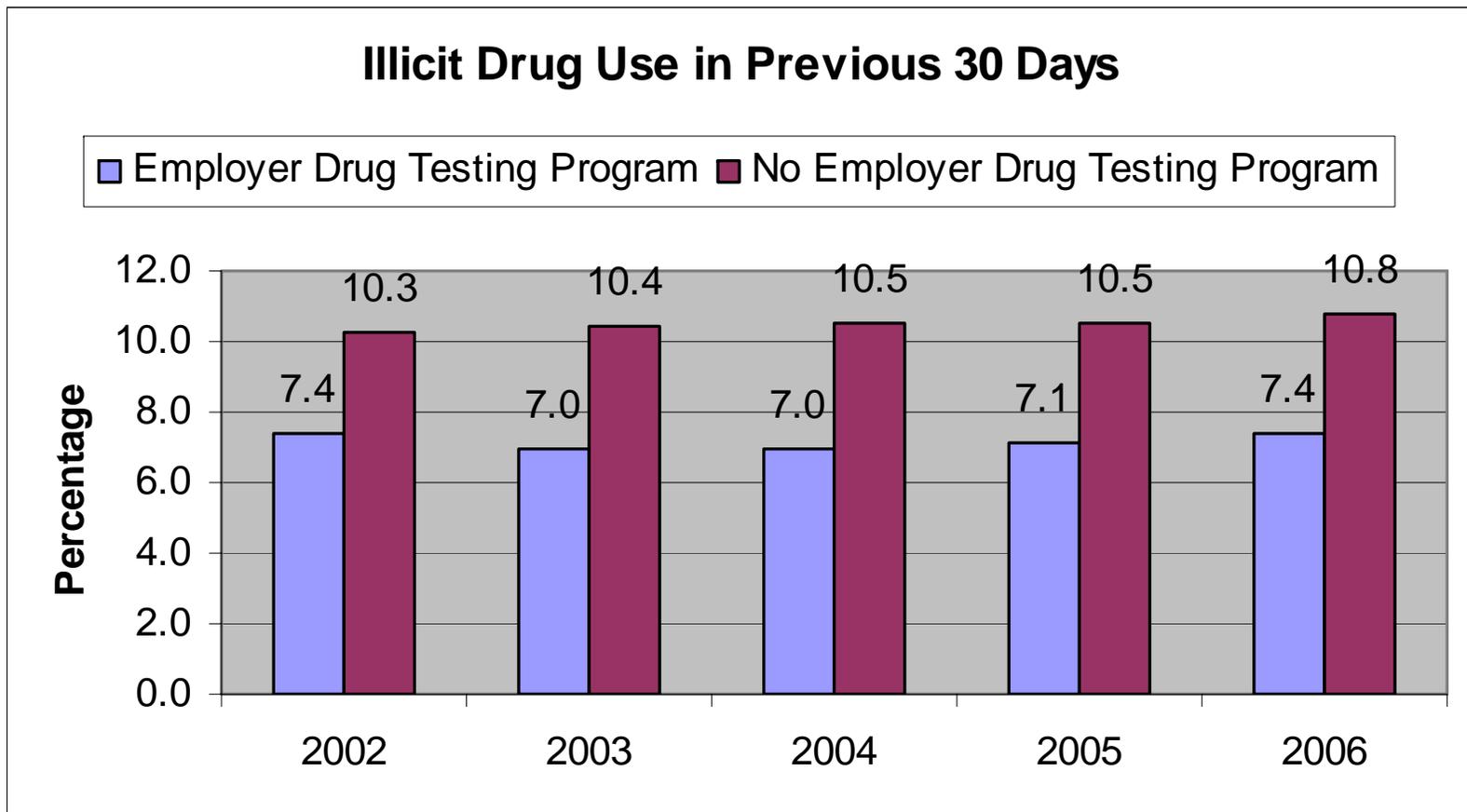
Random



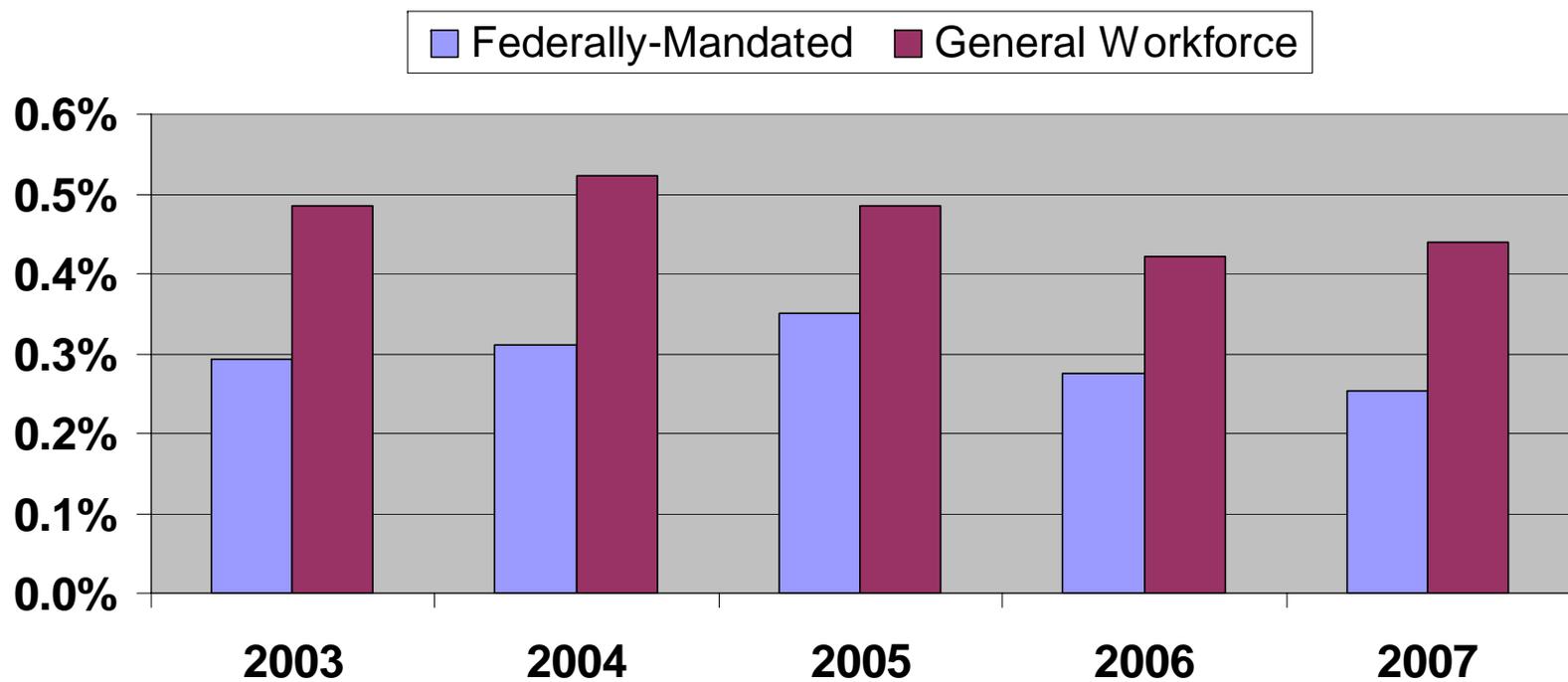
Percent of Specimens Tested by Testing Reason, 2001-2007

	FMSS (N=9.1 million)	GW (N=39 million)
Pre-Employment	46%	78%
Random	43%	10%
Other	11%	12%

Effect of Workplace Drug Testing Programs Illicit Drug Use



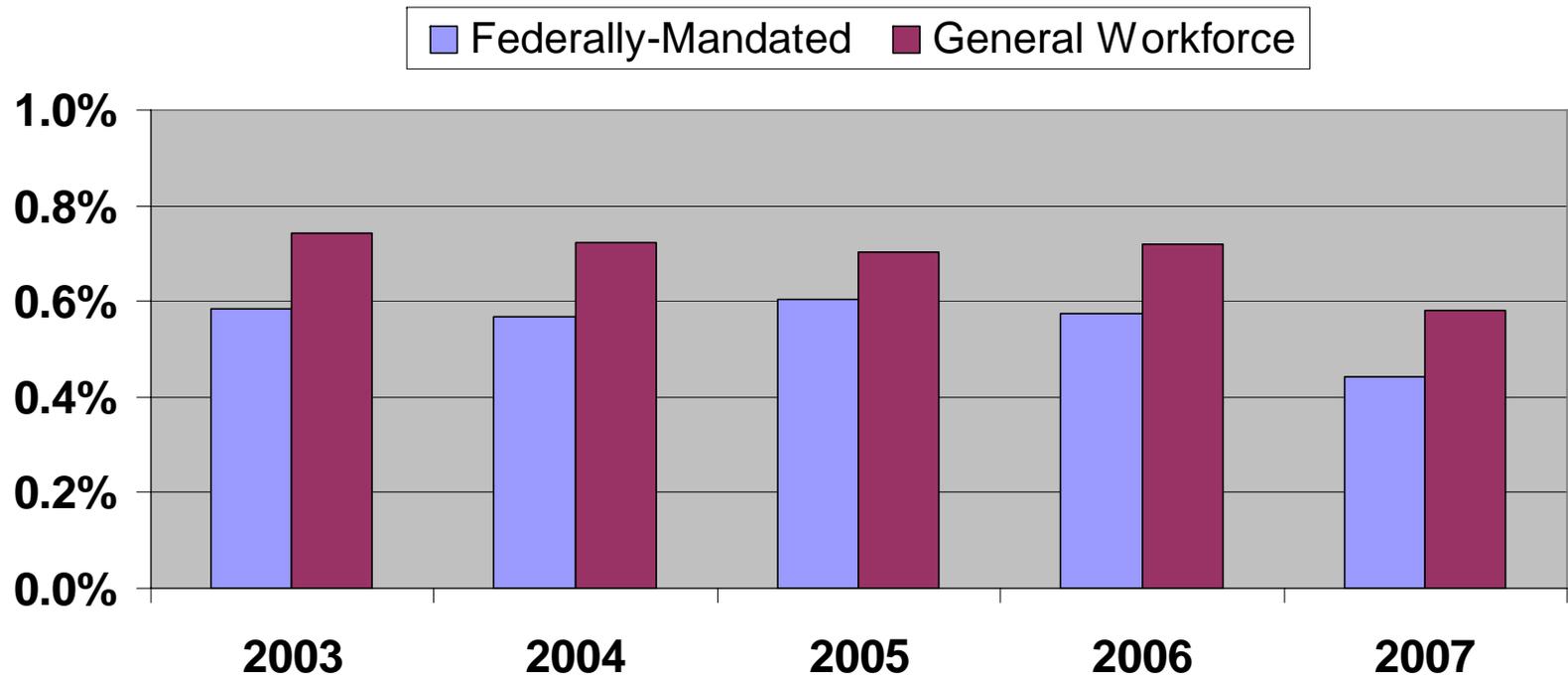
Amphetamines



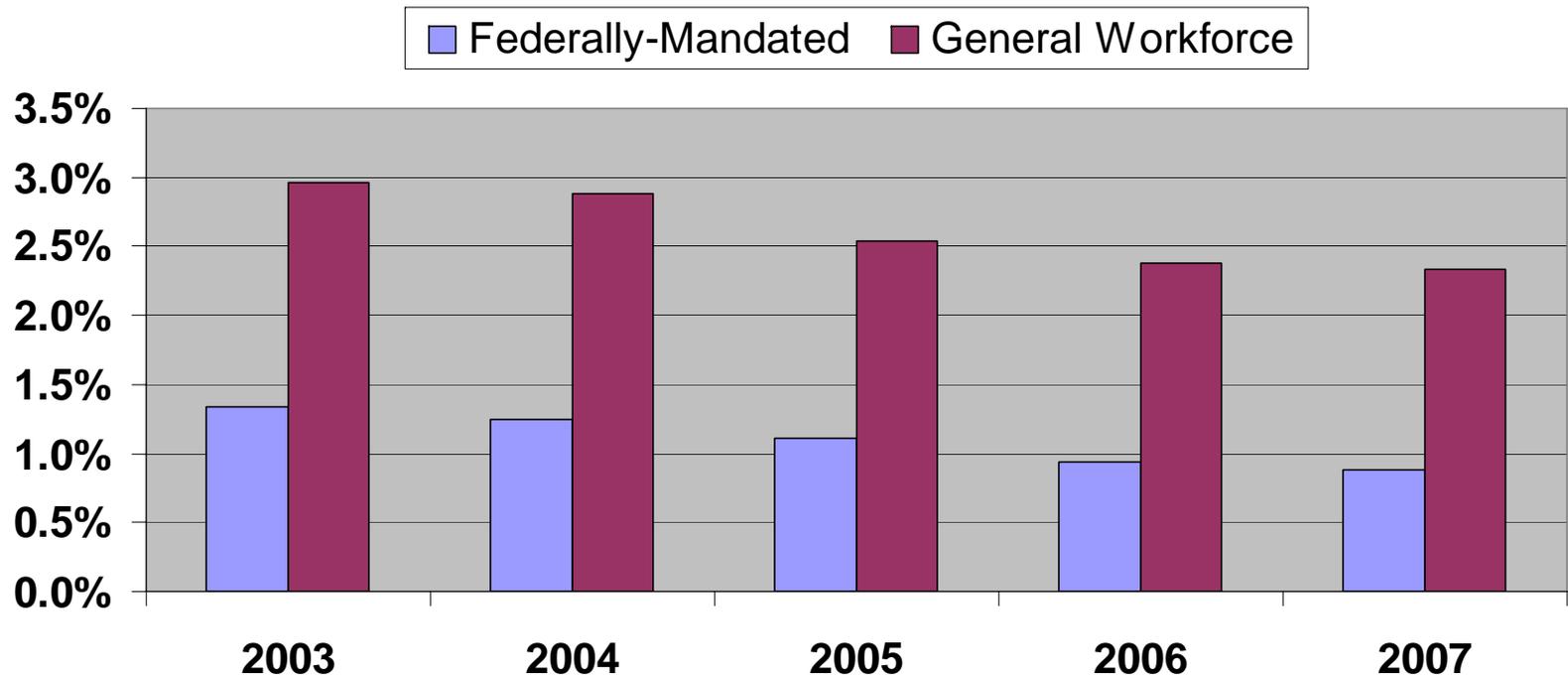
Amphetamine Class Positivity

Type	Drug	2003	2004	2005	2006	2007
FMSS	Amphetamine	0.22%	0.24%	0.44%	0.31%	0.21%
FMSS	Methamphetamine	0.22%	0.23%	0.40%	0.25%	0.13%
GW	Amphetamine	0.41%	0.45%	0.44%	0.38%	0.40%
GW	Methamphetamine	0.32%	0.33%	0.28%	0.18%	0.14%

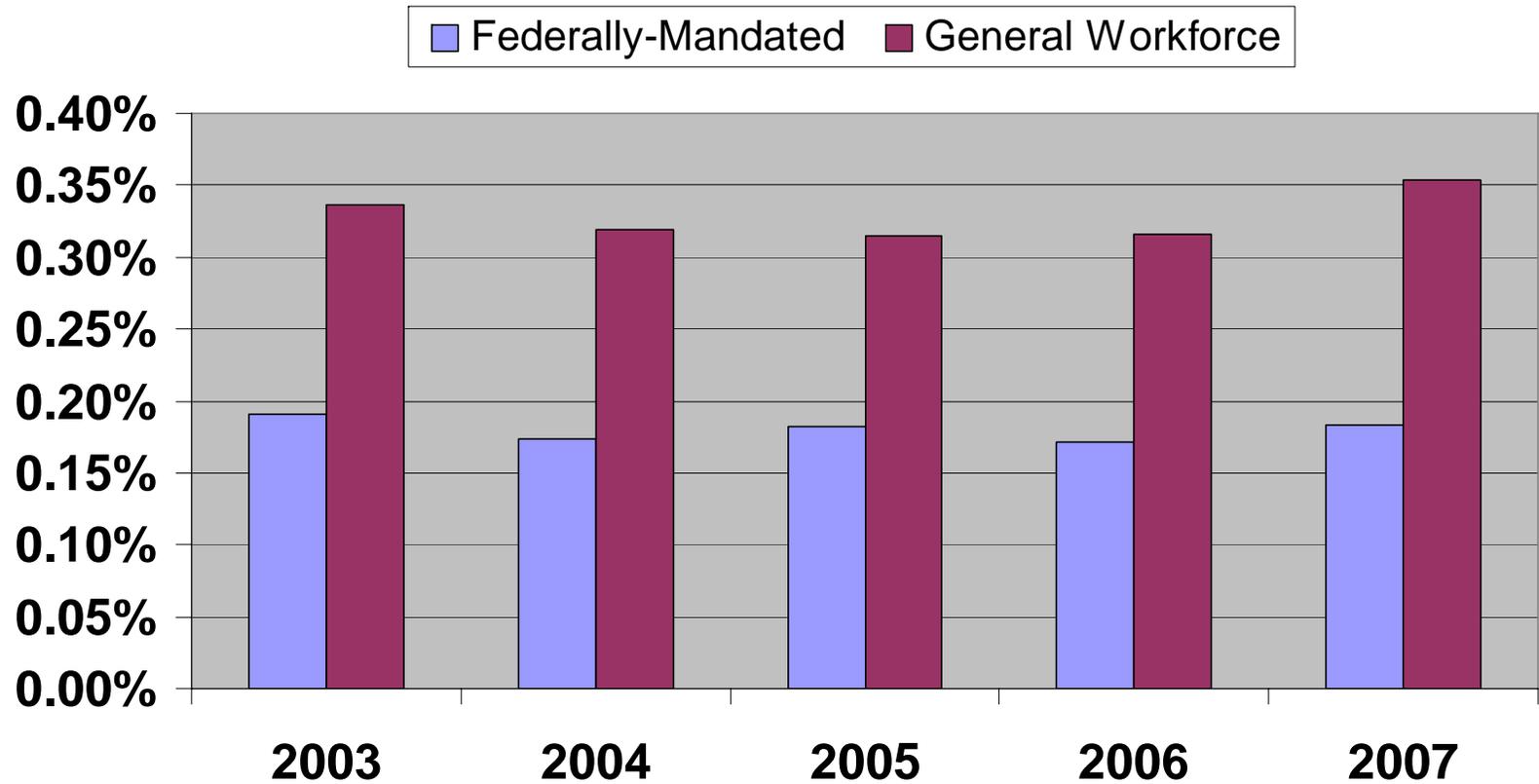
Cocaine



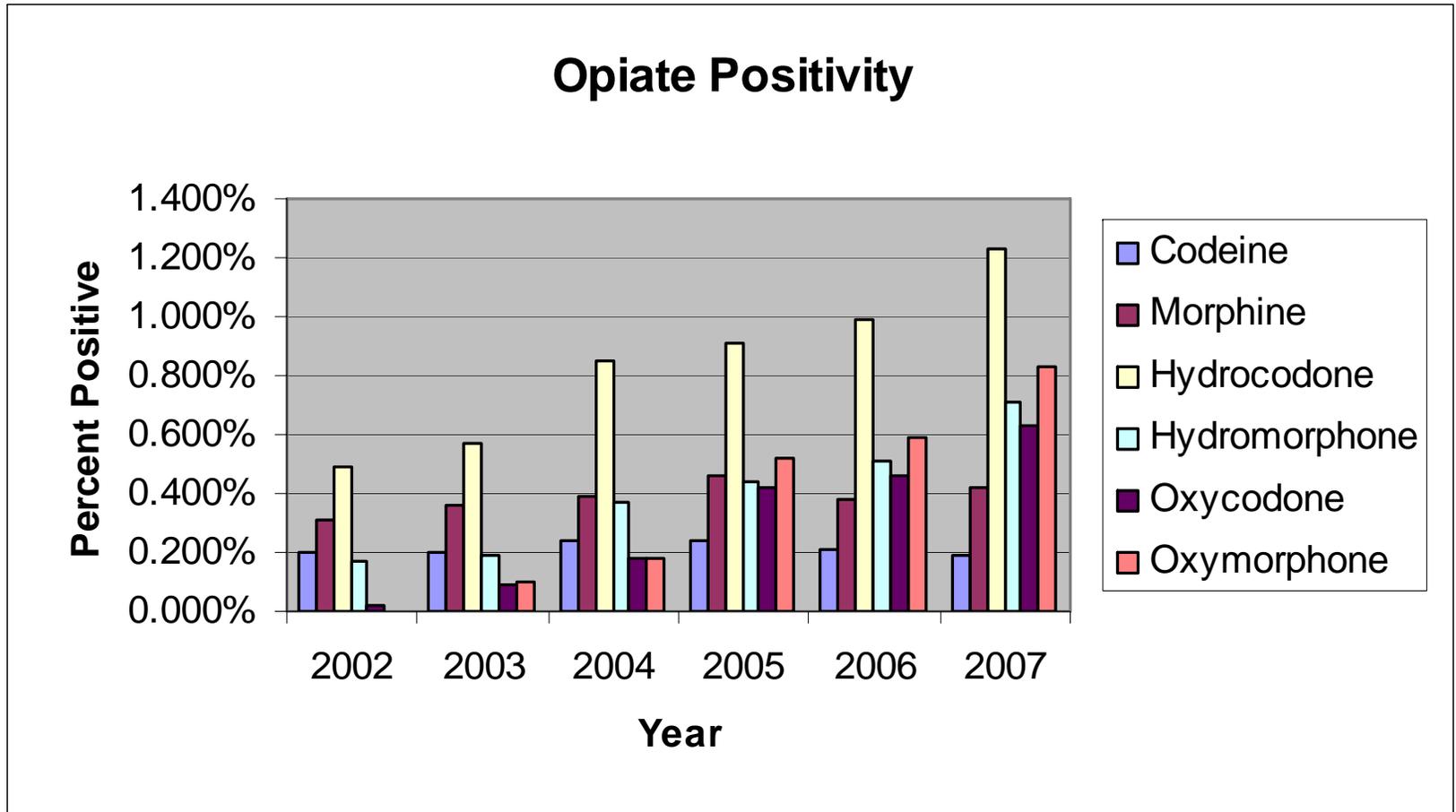
Marijuana



Opiates



“Expanded” Opiate Positivity (GW – 300/300)¹



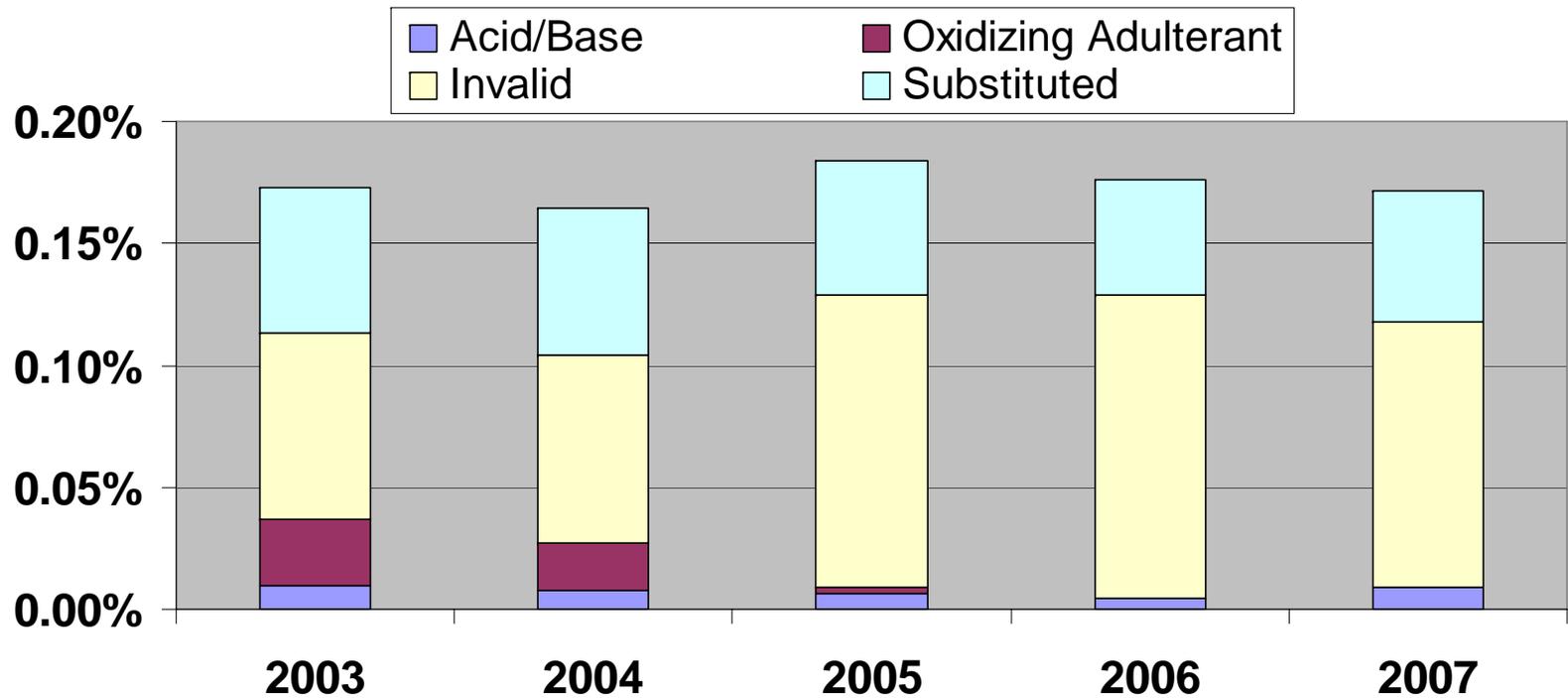
¹ Jul-Dec 2005 Oxycodone specific screen & cutoffs 100/100 (N ~175K)

Jan-Dec 2006 Oxycodone specific screen & cutoffs 100/100 (N~390K)

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Overall Trends in SVT (FMSS)

(7/2001-12/2007)



Invalid Reasons: FMSS

	2004	2005	2006	2007
N (Thousands)	1.0	1.5	1.6	2.0
Bottle	8%	4%	4%	6%
Characteristics	0.6%	0.3%	0.8%	1.0%
Creatinine	17%	9%	15%	10%
GCMS	11%	6%	6%	4%
Immunoassay	19%	17%	14%	10%
Oxidant Activity	12%	26%	27%	27%
pH	32%	22%	20%	28%
Specific Gravity	6%	19%	17%	17%

Invalid Reasons: GW

	2004	2005	2006	2007
N (Thousands)	5.6	9.2	9.3	8.6
Bottle	1.6%	0.8%	1.5%	2.2%
Characteristics	0.9%	0.3%	0.7%	1.2%
Creatinine	12%	7%	12%	8%
GCMS	15%	6%	6%	7%
Immunoassay	22%	16%	16%	14%
Oxidant Activity	13%	23%	18%	19%
pH	33%	19%	20%	22%
Specific Gravity	8%	32%	30%	31%

HAIR

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Hair Collection Procedure (1/3)

- Open sample collection kit and remove contents & fold foil into a 'V' shape
- Grasp a lock of hair from crown of the head and hold away from scalp
 - ◆ When laid flat across finger, there should be ~1 cm in width.
- Cut as close to scalp as possible
- Total collected: ~100 mg

Hair Collection Procedure (2/3)

- Pinch foil closed and fold tightly around hair
- Place hair in specimen container (identification envelope)
- Seal envelope
- Complete CCF

Hair Collection



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Hair Collection Procedure (3/3)

- Place envelope & CCF in COC bag for transport to lab
- Specimen sent by Overnight Courier Collection
Time: 5-10 minutes
- Not considered Biohazardous

Hair Collection Issues

- 90-day window requires ~4 cm hair length (closest to scalp)
- “Sparse” hair - May collect from 2-3 separate locations
- Bald/”Crew-Cut”: May collect from alternative body sites
 - ◆ Site must be noted on CCF

Hair Specimen Validity Testing

- Observed Collection - Adulteration more difficult
- No lab tests for hair specimen validity

Hair Cutoffs

- No Industry Standard Cutoffs

Drugs Tested

<u>CLASS</u>	<u>CUTOFF</u>
<p>“Amphetamines”</p> <ul style="list-style-type: none"> ◆ Amp, Methamphetamine, MDMA 	300/300
<p>“Cocaines”</p> <ul style="list-style-type: none"> ◆ Cocaine, BE, CE 	300/300
Marijuana Metabolite	1.0/0.1
<p>“Opiates”</p> <ul style="list-style-type: none"> ◆ Codeine, Morphine, 6-MAM 	500/500
PCP	300/300

Lab Receiving Process

- Pre-Sort
 - ◆ Specimen type
 - ◆ Regulated vs. non-regulated
- Accession
 - ◆ Verify specimen identification
 - ◆ Verify specimen integrity
 - ◆ Label
- Aliquot for screen
 - ◆ Extract

Hair Cutting



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Lab Testing Processes

- Screen: enzyme immunoassay (ELISA)
 - ◆ TAT: < 24 hrs



ELISA Screening

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Lab Testing Processes

- **Screen: enzyme immunoassay (ELISA)**
 - ◆ TAT: < 24 hrs

- Re-aliquot if non-negative

- Extract

- Confirmation:
GC(LC)/MS(/MS)
The “Gold Standard”
 - ◆ TAT: 48 - 72 hrs.



Lab Certification Process

- Review chain of custody
 - ◆ External – CCF
 - ◆ Internal – Specimen & Aliquot
- Review analytical data
- Report results

Detection Window

- Longer Detection Window than Urine - up to 90-days
- Detection times are dependent on Cutoff
- Will not reliably detect:
 - ◆ Single use
 - ◆ Use in first week of abuse

ORAL - FLUID

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Oral-Fluid Collection Device



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Oral Fluid Collection Procedure (1/3)

- Nothing by mouth for 10 minutes
- Donor places collection pad between lower cheek and gums - gently rub until moist
- Pad remains in mouth for 3 minutes - Collects ~0.4 mL
- Donor places pad in specimen vial which contains buffer

Oral Fluid Collection Procedure (2/3)

- Donor snaps off applicator wand
- Donor places cap on specimen vial
- Vial sealed
- CCF completed

Oral-Fluid Collection



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Oral Fluid Collection Procedure (3/3)

- Vial & CCF placed in COC bag for transport to lab
- Specimen sent by Overnight Courier
- Collection Time: 5-10 minutes
- Not considered Biohazardous

Specimen Validity Testing

- Observed Collection - Adulteration more difficult
- IgG measured as indicator of Specimen Validity - Common practice in Insurance Industry to validate that *Human* saliva collected

Cutoffs

- No Industry Standard Cutoffs
- Collection device has ~X3 Dilution - Cutoffs are *not* directly comparable between different oral-fluid collection/testing devices!

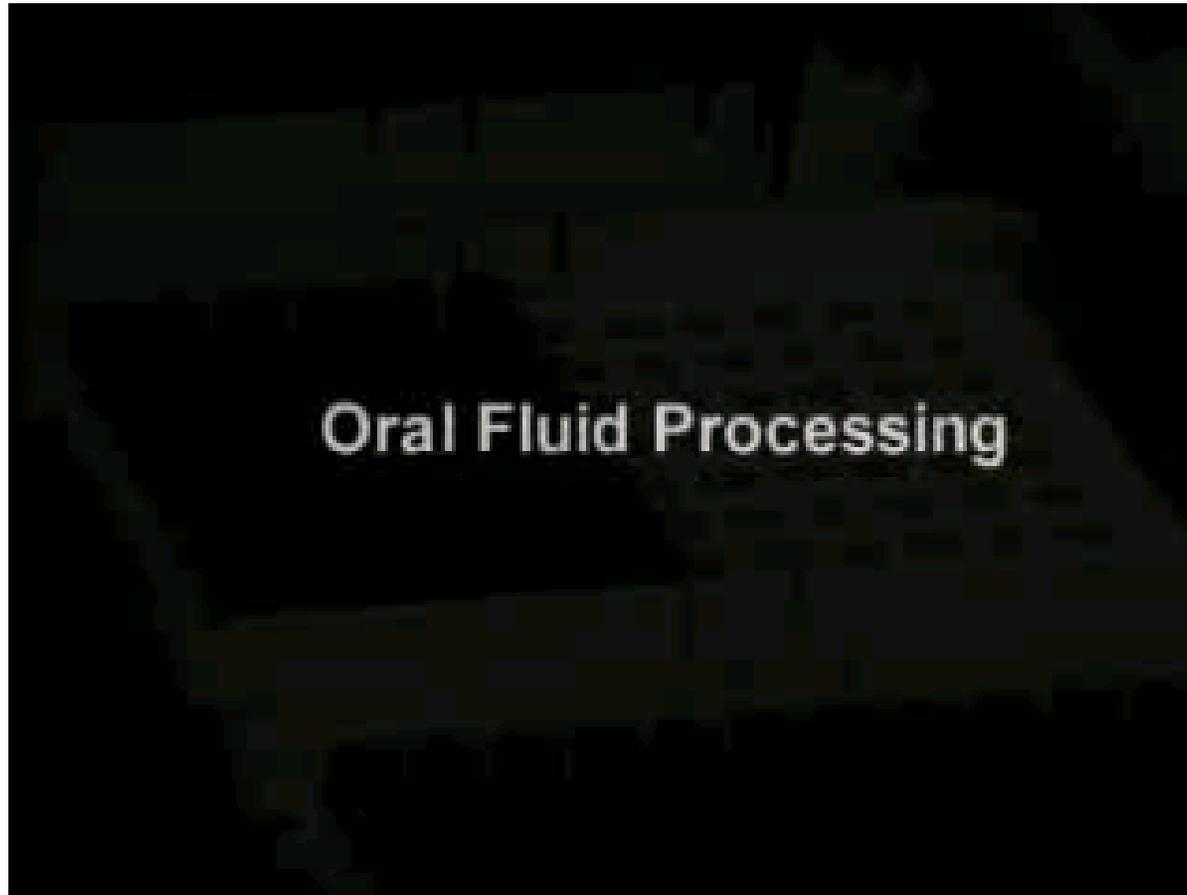
Drugs Tested

<u>CLASS</u>	<u>CUTOFF</u>
Amphetamine	100/40
Methamphetamine	40/40
◆ Methamphetamine, MDMA, MDA	
Cocaine Metab.	5/2
Marijuana (Parent)	1.0/0.5
“Opiates”	10/10
◆ Cod, Mor, HyCod, HyMor, 6-MAM	
PCP	1.0/0.5

Lab Receiving Process

- Pre-Sort
 - ◆ Specimen type
 - ◆ Regulated vs. non-regulated
- Accession
 - ◆ Verify specimen identification
 - ◆ Verify specimen integrity
 - ◆ Label
- Aliquot for screen

Oral-Fluid Aliquotting



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Lab Testing Processes

- Screen: enzyme immunoassay (ELISA)
 - ◆ TAT: < 24 hrs

- Re-aliquot if non-negative

- Extract

- Confirmation:
GC(LC)/MS(/MS)
The “Gold Standard”
 - ◆ TAT: 48 - 72 hrs.



Lab Certification Process

- Review chain of custody
 - ◆ External – CCF
 - ◆ Internal – Specimen & Aliquot
- Review analytical data
- Report results

Detection Window

- Shorter Detection Window than Urine
- Detection times are dependent on Cutoff
- Concentration in Oral Fluid is generally related to blood concentration - Indicator of *Recent* Use

Comparison of Specimen Types

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Matrix Comparison – Detection Time

Matrix	Detection window	Advantages
Urine	1-3 days	Good detection times, easy to collect, current workplace standard but adulteration potential
Hair	45-90 days	Difficult to adulterate, good detection time but more expensive and hair length may be an issue
Oral Fluid	24-36 hours	Easy to collect and difficult to adulterate but shorter detection time

Oral-Fluid vs. Urine

(January 2005 – December 2007)

	Oral-Fluid	Urine GW
N (Millions)	3	20
Positive	4.0%	4.4%
BY DRUG		
Amphetamines	0.16%	0.46%
Methamphetamine	0.29%	N/A
Cocaine	0.96%	0.68%
Marijuana	2.39%	2.42%
Opiates	0.50%	0.33%
PCP	0.02%	0.02%

Current Trends

- Oral Fluid vs. Urine
 - ◆ Similar positive prevalence rates
 - ◆ Cocaine positivity ~50% higher in oral-fluid
- Hair vs. Urine
 - ◆ Overall positive prevalence rates ~2x higher in hair
 - ◆ Most dramatic differences:
 - ◆ cocaine and methamphetamine

Questions ?

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