

Quest Diagnostics

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

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2/23/2010



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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 Matrices
 - ◆ Alternative Technologies
- Nov. 2004: DOT Interim Final Rule
- Aug. 2008: Revised DOT Rules (SVT)
- Nov. 2009: Proposed CCF
- Feb. 2010: Proposed DOT Rules Changes
- May 2010: Revised Mandatory Guidelines (Cutoff Changes, IITF)

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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

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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

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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

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Urine Cutoffs

- Industry Standard Cutoffs
- HHS-5 (aka "NIDA"-5)
- New Guidelines/Rules
 - ◆ SAMHSA/HHS-7?
 - ◆ MDMA & 6-MAM

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Drugs Tested

<u>CLASS</u>	<u>CUTOFF</u>
"Amphetamines" (New) ◆ Amp, Methamphetamine	1000/500 (500/250)
Cocaine (New) ◆ BE	300/150 (150/100)
Marijuana Metabolite	50/15
"Opiates" ◆ Codeine, Morphine	2000/2000
PCP	25/25

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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

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Other Regulatory Changes (Testing) (eff: 2010)

- Instrumented Initial Test Facility (IITF)
 - ◆ HHS/NLCP certified screening facility
 - ◆ Similar to certified lab through screening
 - ◆ Non-Negatives sent to full-service lab for screen/confirm
- New Analytes
 - ◆ MDMA (& MDA, MDEA)
 - ◆ Cutoffs – 500/250
 - ◆ Positivity (2007-2009) – 0.02% (2 per 10K) @ 250 ng/mL cutoff
 - ◆ 6-MAM
 - ◆ All specimens (not just positive morphine)
 - ◆ Cutoffs – 10/10

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Other Regulatory Changes (CCF) (Proposed)

- Copy-1
 - ◆ Testing Authority
 - ◆ New drugs (MDMA & 6-MAM)
 - ◆ Split Results
 - ◆ IITF chain of custody
 - ◆ Tamper-evident seal size
- Copy-2
 - ◆ MRO split/primary results

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Other Regulatory Changes (DOT) (Proposed)

- Conforming Rules ("Harmonization with HHS")
 - ◆ Definitions
 - ◆ Cutoffs/Analytes
 - ◆ IITF
- MRO Certification/Recertification
 - ◆ Approval of MRO certification boards
 - ◆ CEUs vs. Recertification

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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

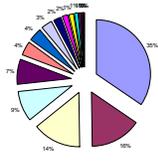
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Log-In (Accession)



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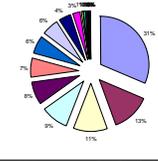
Fatal Flaws 2006-2009 (FMSS) (n~11K)



Insufficient quantity	Collector's Name and Signature Missing
Specimen leaked in transit	Donor ID on CDC form does not match specimen container
Tamper-evident Seal Broken	No CDC form received with specimen
No specimen received with CDC form	No tamper-evident seal on specimen container
Tamper-evident seal misapplied/missing	No Donor ID on specimen container
Generic Report message	Lab accident
Unauthorized changes on specimen container or CDC form	Wrong CCF Used
Collector signature missing	Temperature Outside Range at Collection Site

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Fatal Flaws 2006-2009 (GW) (n~48K)



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

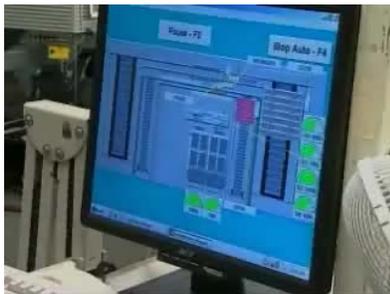
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Aliquot



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Urine Aliquoting



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Lab Testing Processes

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

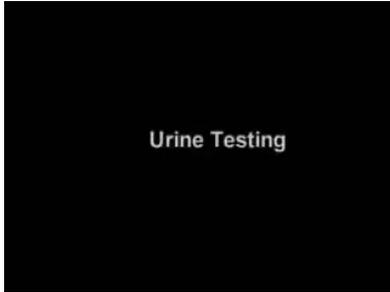


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Urine Screening



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Lab Testing Processes

- Screen: enzyme immunoassay (EIA)
 - ◆ TAT: < 24 hrs
- Re-aliquot if non-negative
- Extract
- Confirmation: GC(LC)/MS(/MS)
The "Gold Standard"
 - ◆ TAT: 48 - 72 hrs.



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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

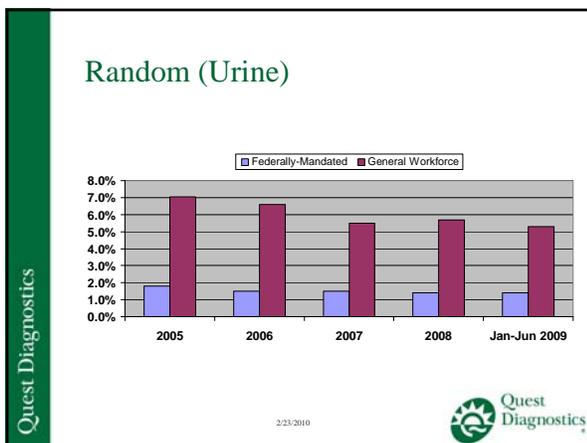
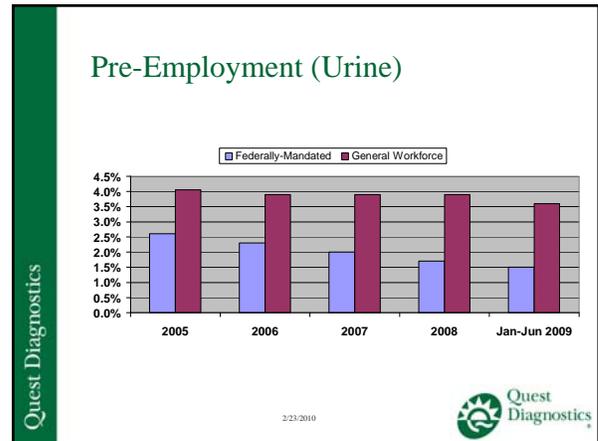
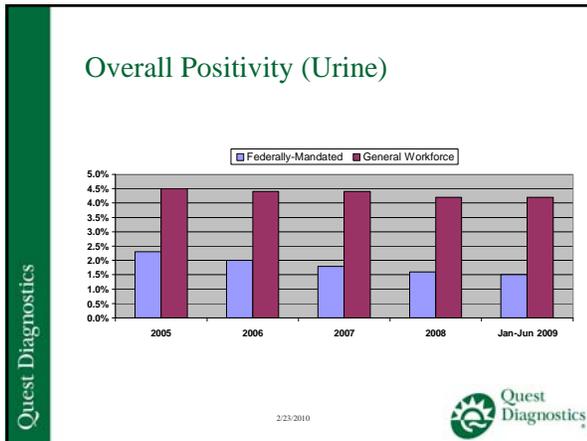
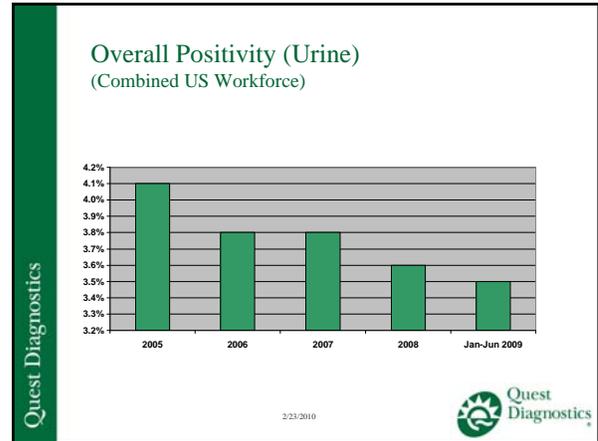
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Detection Window

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

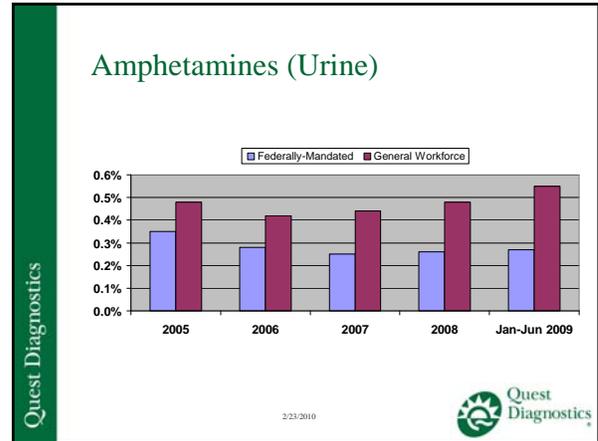
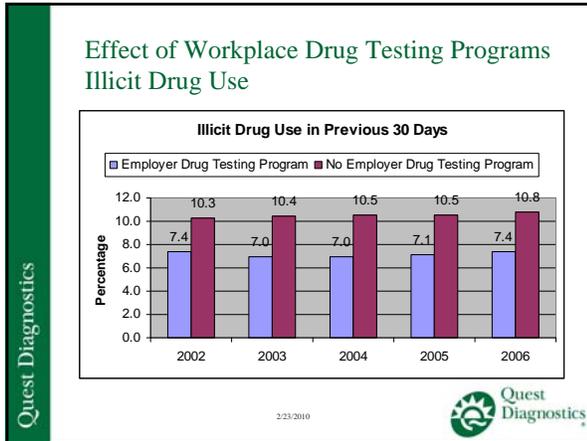
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Percent of Urine Specimens Tested by Testing Reason, 2004-2008

	FMSS (N=10.5 million)	GW (N=31.4 million)
Pre-Employment	46%	76%
Random	44%	11%
Post-Accident	4%	6%
Other	7%	7%

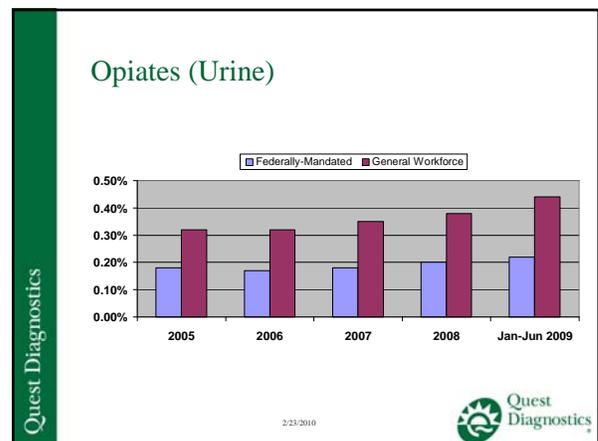
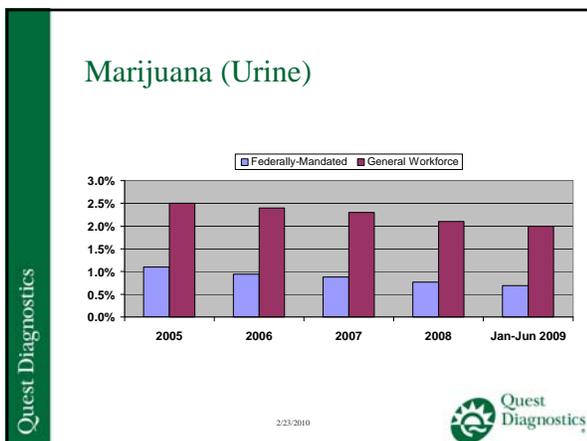
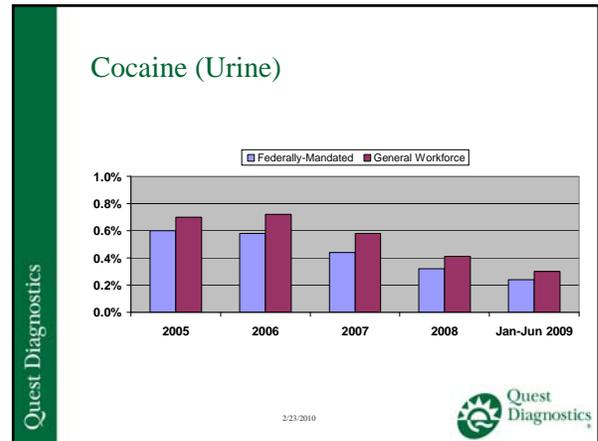
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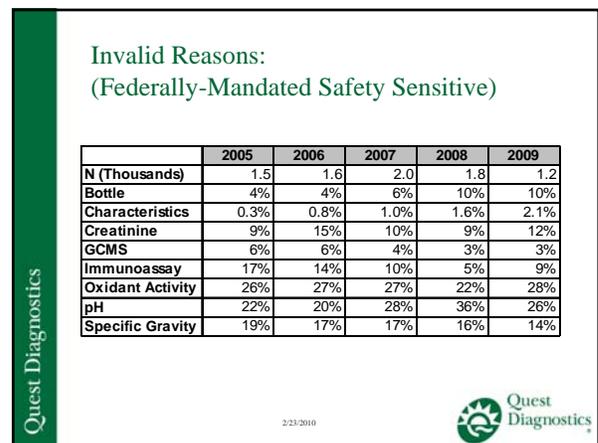
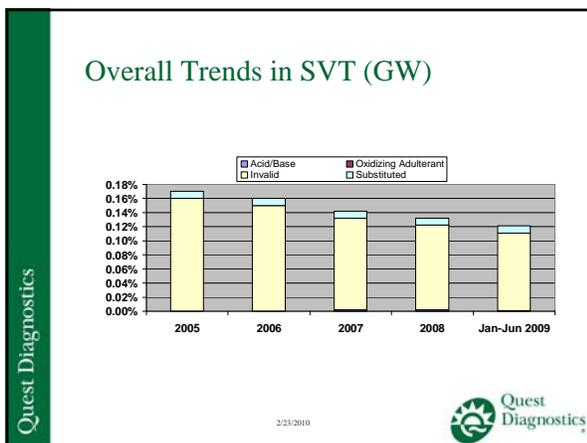
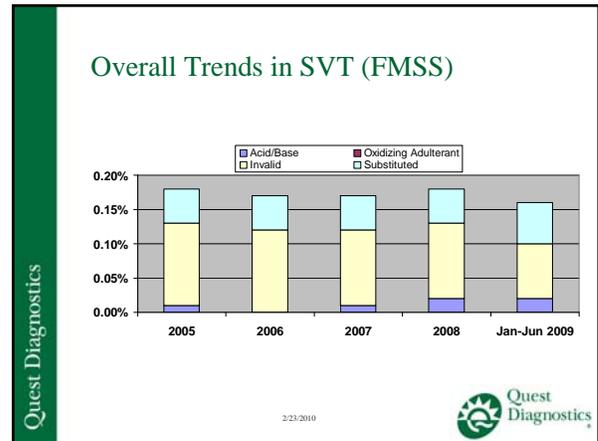
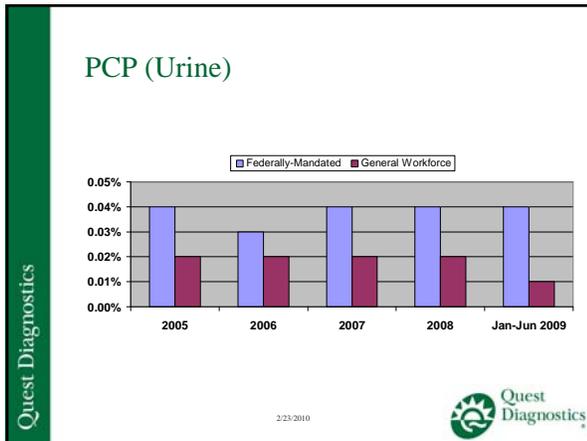
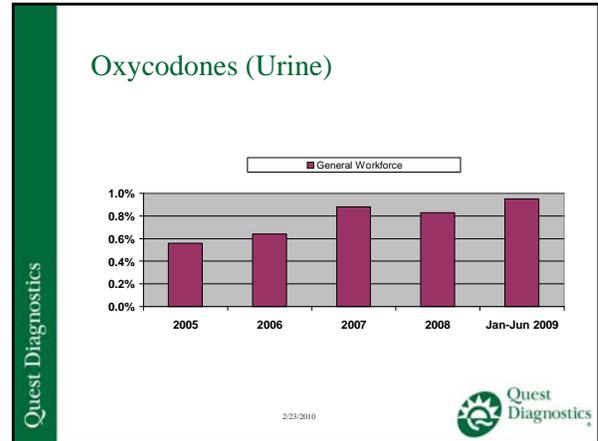
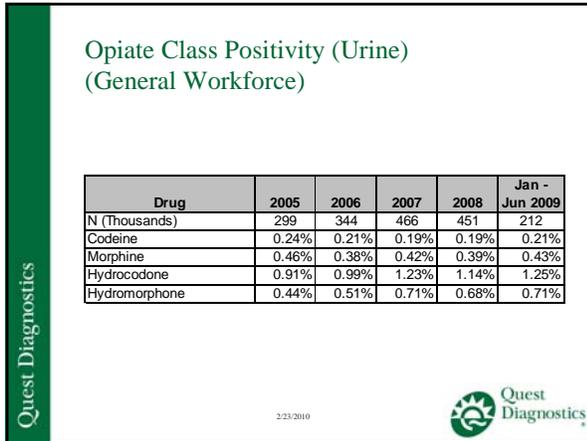


Amphetamine Class Positivity (Urine)

Type	Drug	2005	2006	2007	2008	Jan - Jun 2009
FMSS	Amphetamine	0.28%	0.22%	0.21%	0.22%	0.24%
FMSS	Methamphetamine	0.25%	0.17%	0.13%	0.11%	0.11%
GW	Amphetamine	0.44%	0.38%	0.40%	0.45%	0.52%
GW	Methamphetamine	0.28%	0.18%	0.14%	0.11%	0.10%

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Invalid Reasons: (General Workforce)

	2005	2006	2007	2008	2009
N (Thousands)	9.2	9.2	8.5	6.7	5.1
Bottle	0.8%	1.6%	2.2%	3.7%	3.5%
Characteristics	0.3%	0.7%	1.2%	2.1%	1.2%
Creatinine	7%	12%	8%	7%	10%
GCMS	6%	5%	7%	9%	8%
Immunoassay	16%	16%	14%	13%	22%
Oxidant Activity	23%	18%	19%	15%	15%
pH	19%	20%	23%	21%	18%
Specific Gravity	32%	30%	31%	33%	25%

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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

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Hair Collection Procedure (2/3)

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

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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

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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

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Hair Specimen Validity Testing

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

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Hair Cutoffs

- No Industry Standard Cutoffs

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Drugs Tested

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

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Lab Receiving Process

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

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Hair Cutting



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Lab Testing Processes

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



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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.



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Lab Certification Process

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

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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

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ORAL - FLUID

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Oral-Fluid Collection Device



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The image shows two boxes of Intercept Oral Specimen Collection Devices and a single applicator wand. The boxes are white with blue and red text. The applicator wand is white with a blue tip.

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

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Oral Fluid Collection Procedure (2/3)

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

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Oral-Fluid Collection



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The image shows a woman with curly hair, wearing a pink long-sleeved shirt, sitting at a desk. She is holding a small white device (the collection pad) and looking at it. There is a computer monitor and some papers on the desk.

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

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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

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Cutoffs

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

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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

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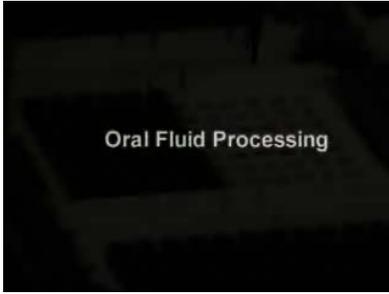
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Oral-Fluid Aliquoting



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Lab Testing Processes

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



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Lab Certification Process

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

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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

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Comparison of Specimen Types

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Hair and Urine in Drugs of Abuse Testing

- Hair
 - ◆ Can detect repeated use of a drug over approximately three (3) months (based on testing proximal 1.5" head hair)
- Urine
 - ◆ Can find a single use of a drug in the past one (1) to three (3) days
- Oral-Fluid
 - ◆ Can find a single use of a drug in the past one (1) to two (2) days

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Paired (Simultaneously Collected) Hair and Urine Specimens

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Objectives

- Compare positive prevalence rates for paired hair and urine specimens
- Review "concordance" between simultaneously collected hair and urine specimens

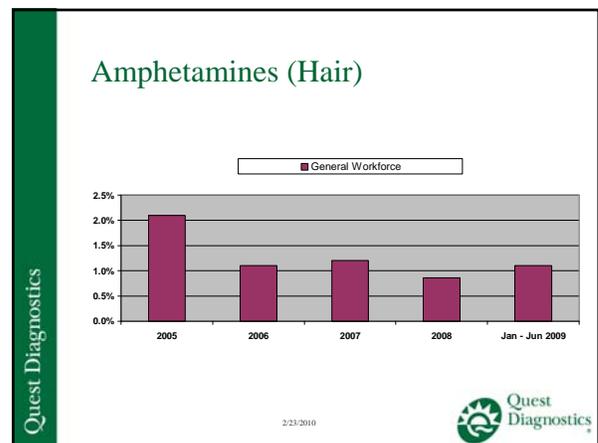
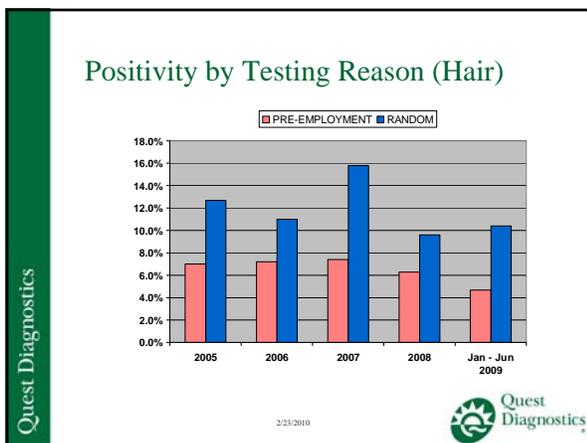
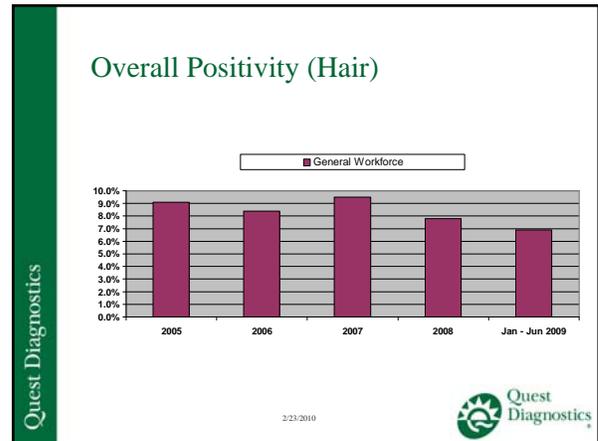
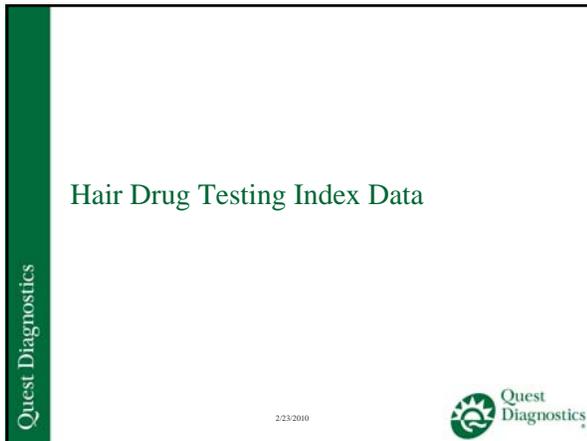
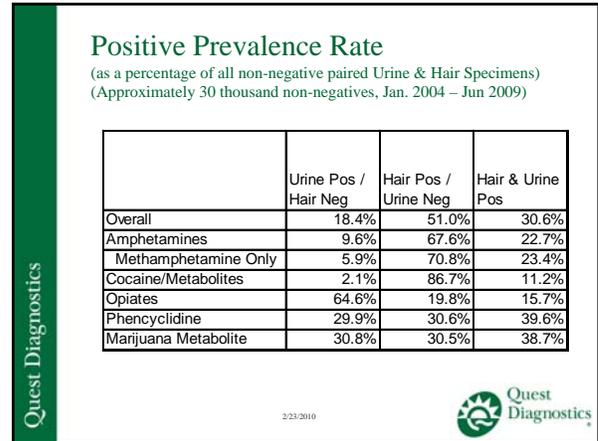
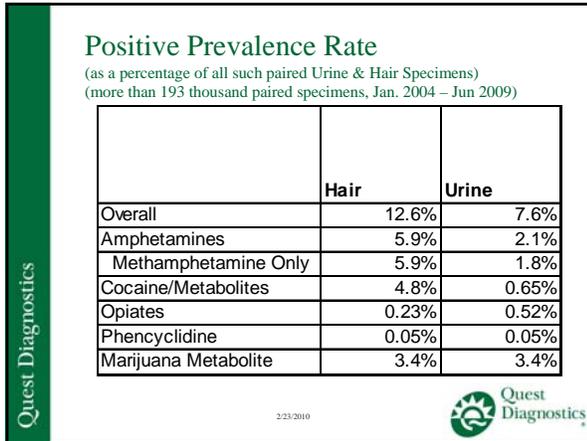
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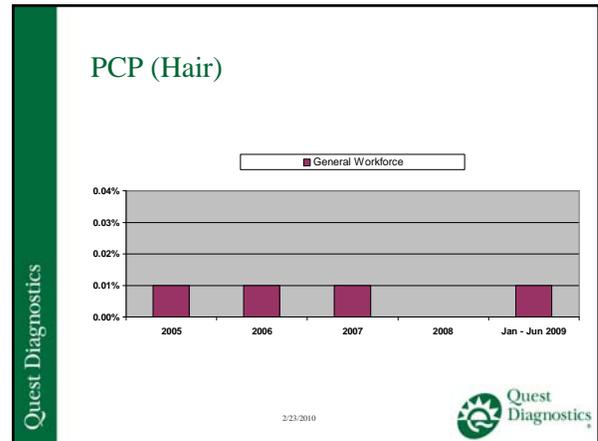
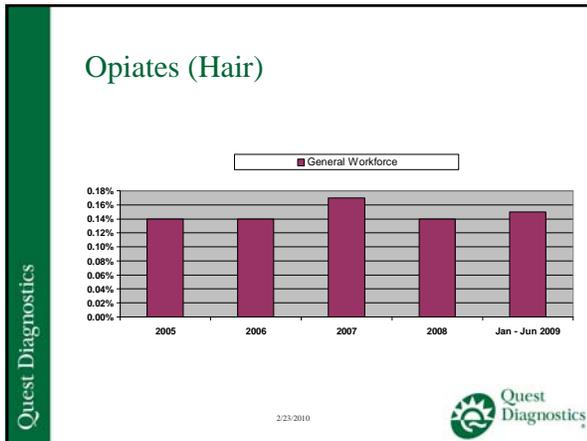
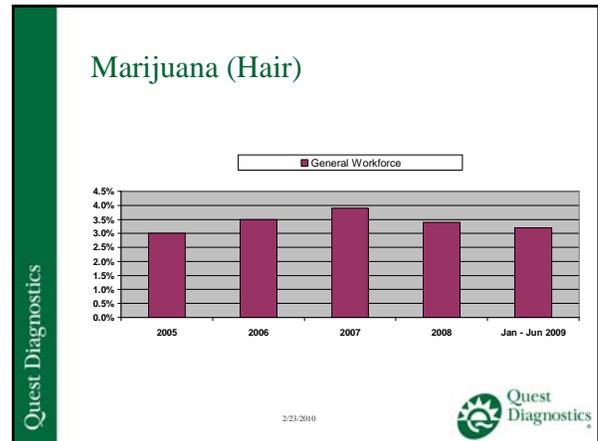
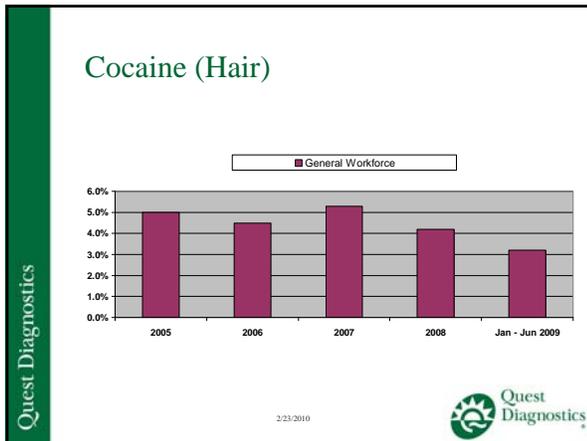
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Specimen Demographics

- Source
 - ◆ Routine random, paired hair and urine specimens submitted for drugs of abuse testing (N~193K)
 - ◆ Workplace, Criminal Justice, Family/Social Services
 - ◆ Specimens tested Jan 2004 – Jun 2009
- Testing Reason
 - ◆ Pre-Employment – 73%
 - ◆ Random – 12%
 - ◆ Other – 15%

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Hair and Urine Drug Testing

- Both hair and urine have tracked sharp downward trends in cocaine and methamphetamine positives from 2005 to first-half of 2009
- Positive prevalence rates for some (not all) analytes are higher in hair than urine – Hair data shows a dramatically higher level of positives for cocaine and methamphetamine
- Both specimens detect some positives that the other does not
- Urine and hair testing are complementary and together, provide a more complete picture of an individual's drug use

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Oral-Fluid and Urine Drug Testing Index Data

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Oral-Fluid vs. Urine

(January 2005 – December 2009)

	Oral-Fluid	Urine GW
N (Millions)	~4.6	~40
Positive	4.1%	4.4%
BY DRUG		
Amphetamines	0.17%	0.48%
Methamphetamine	0.24%	N/A
Cocaine	0.82%	0.58%
Marijuana	2.5%	2.3%
Opiates	0.60%	0.35%
PCP	0.02%	0.02%

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Oral-Fluid and Urine Drug Testing

- 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
- Oral-fluid and urine provide insights into an individual's recent drug use

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Questions ?

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