Monitoring and Toxicology
National Behavioral Consortium
Phoenix, AZ
Tuesday, February 9, 2016

Christopher Hamilton, Ph.D., MPA

Monitoring Programs Director

Reliant Behavioral Health

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Toxicology

- Backgrounds
- Tests
- Your experience?

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Toxicology

Collection

- Mon-Sat Notifications
- Randomized Schedule
- Nationwide sites
- Observed Collection
- Chain of Custody
- Split sample

Transportation

- From collection to lab
- Chain of Custody

Screening and Analysis

- Screening cutoff
- Analysis
- Non-negative storage
- Available for retest

Medical Review

- MD or DO
- All non-negative
- Licensee follow-up
- Defensible

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Toxicology-Collection

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Toxicology-Notification

- Randomized schedule
- How will the individual know they need to test?
  - Interactive Voice Response (IVR)
  - Website
  - Application
  - On demand

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Toxicology- Specimen Collection

- Monitored or Observed (Department of Transportation)
- (i) As the observer, you must request the employee to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist; and lower clothing and underpants to show you, by turning around, that they do not have a prosthetic device. After you have determined that the employee does not have such a device, you may permit the employee to return clothing to its proper position for observed urination.
- (j) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to watch the urine go from the employee's body into the collection container.
- Other?

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Toxicology- Split Sample

- 15ml of the collected specimen
- Retained for same period of time as all accompanying non-negative tests
- Available for retest by a different approved lab

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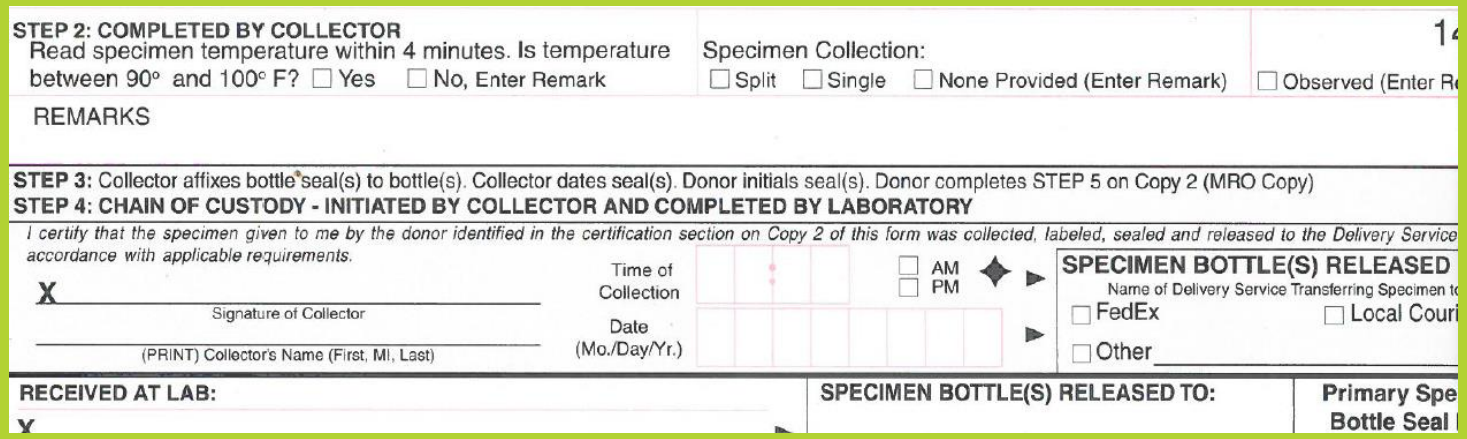
Toxicology- Chain of Custody

- Chain of custody. The procedure used to document the handling of the urine specimen from the time the employee gives the specimen to the collector until the specimen is destroyed.


STEP 2: COMPLETED BY COLLECTOR
Read specimen temperature within 4 minutes. Is temperature between 90° and 100° F? ☐ Yes ☐ No, Enter Remark

Specimen Collection: ☐ Split ☐ Single ☐ None Provided (Enter Remark) ☐ Observed (Enter R

REMARKS

STEP 3: Collector affixes bottle seal(s) to bottle(s). Collector dates seal(s). Donor initials seal(s). Donor completes STEP 5 on Copy 2 (MRO Copy)
STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AND COMPLETED BY LABORATORY

I certify that the specimen given to me by the donor identified in the certification section on Copy 2 of this form was collected, labeled, sealed and released to the Delivery Service in accordance with applicable requirements.

X _____ Signature of Collector

_____ (PRINT) Collector's Name (First, MI, Last)

Time of Collection ☐ AM ☐ PM

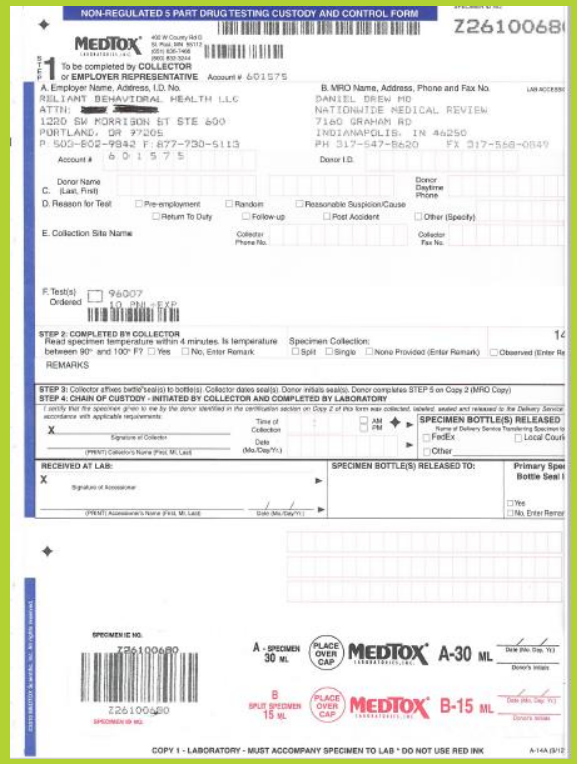
Date (Mo./Day/Yr.)

SPECIMEN BOTTLE(S) RELEASED
Name of Delivery Service Transferring Specimen t
☐ FedEx ☐ Local Couri
☐ Other _____

RECEIVED AT LAB:
X

SPECIMEN BOTTLE(S) RELEASED TO:

Primary Spe Bottle Seal



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Toxicology- Chain of Custody

- (2) Complete the chain of custody on the CCF (Step 4) by printing your name (note: you may pre-print your name), recording the time and date of the collection, signing the statement, and entering the name of the delivery service transferring the specimen to the laboratory,
- (3) Ensure that all copies of the CCF are legible and complete.
- (4) Remove Copy 5 of the CCF and give it to the **employee**.
- (5) Place the specimen bottles and Copy 1 of the CCF in the appropriate pouches of the **plastic bag**.
- (9) Send Copy 2 of the CCF to the **MRO** and Copy

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Transportation

Collection

- Mon-Sat Notifications
- Randomized Schedule
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Medical Review

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Toxicology- Transportation

- How will the specimen get to the lab?
- Out of country?

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Toxicology

Collection

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- Randomized Schedule
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Transportation

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Toxicology- Screening and Analysis Panels

- Consider: what substances to test for?
- Are you detecting substances of choice or availability?

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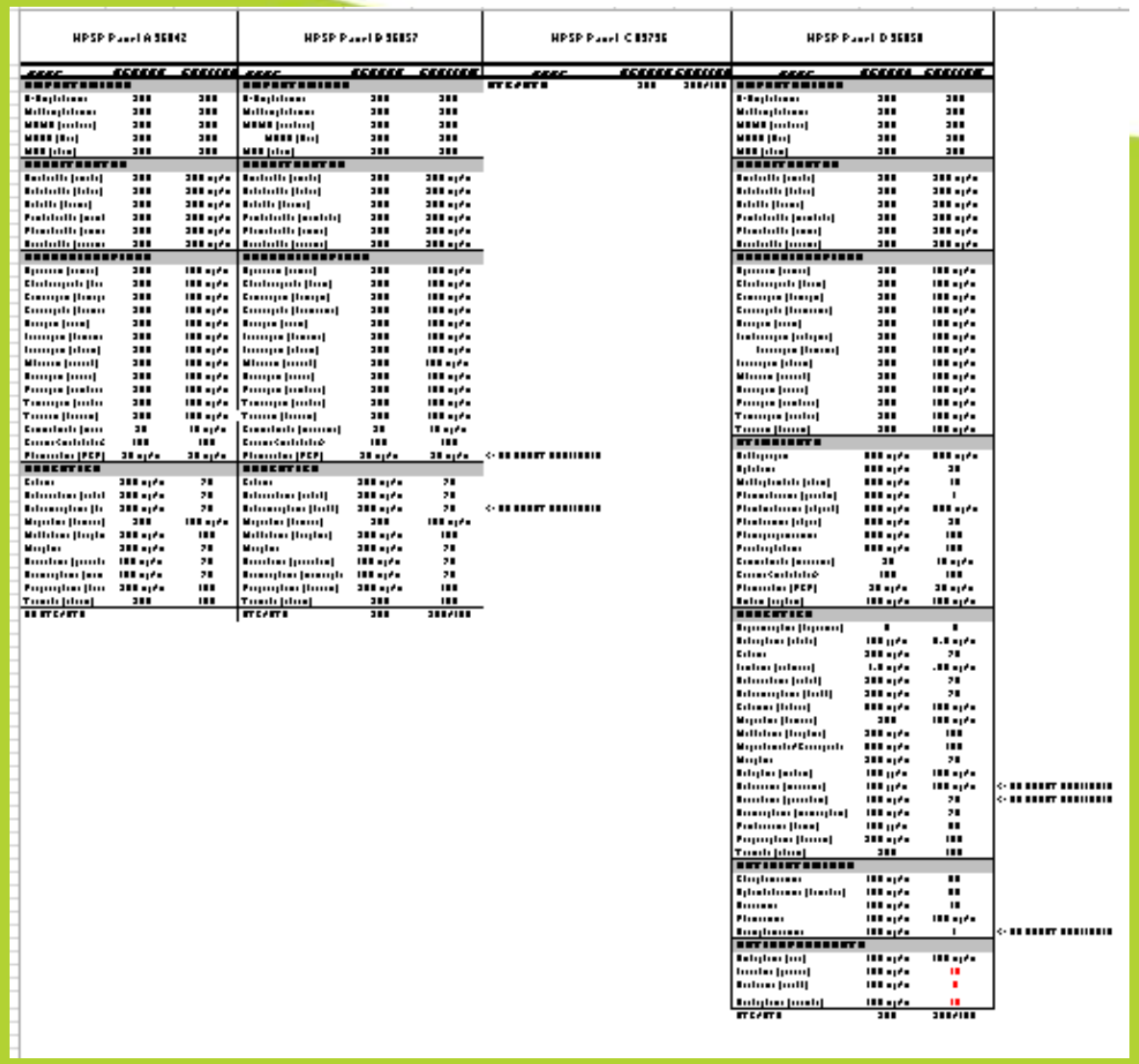
Toxicology- Screening and Analysis Panels



Grid for Self-help meetings, Testing Frequency and Panel Percentages		
Self Help meetings	**Testing Frequency**	**Panel Percentages**
Year One – 3-4 (determine if they completed 90/90 following treatment). Decrease to 3 meetings after completion of IOP.	36 minimum- any increase other than non-compliance has to go to the PAC for review.	**Alcohol diagnosis** with **no** concern of drug use, 40 % panel A, 15% panel B, 35% panel C, and 10% panel D. **Any drug use concern**: 90 % panel B and 10% panel D. Acupuncturists see below.
Year Two – 2-3 based on compliance, includes low creatinine, dilutes, missed calls, the more incidents the higher the number of self-help meetings required.	24 minimum- any increase other than non-compliance has to go to the PAC for review	Unless circumstances change keep panel %, the same. A change would include that there is new information available that a new drug of abuse has been introduced.
Year Three – 2-3 same as above may not want to lower frequency if areas of non-compliance exist.	18 minimum- any increase other than non-compliance has to go to the PAC for review	See above
Year Four – 2 minimum. 3 if non-compliance reports or no other supports in place.	18 minimum- any increase other than non-compliance has to go to the PAC for review	See above
Year Five- same as year four	18 minimum- any increase other than non-compliance has to go to the PAC for review. (12 minimum if precedent from previous program.)	See above
If the licensee experiences a relapse in years one or two of the program, the testing will be increased to a minimum of 48 tests per year. If the licensee experiences a relapse in year three or beyond, the testing will be increased to a minimum of 24 tests per year.		

	Panel A 87610	Panel B 96123	Panel C 87606	Panel D 96130
Primary Alcohol Employed *	40%	15%	35%	10%
Primary Alcohol Not Employed*	53%	7%	35%	5%
Any Drug Concern Employed*	X	90%	X	10%
Any Drug Concern Unemployed*	50%	45%	X	5%
Acupuncturist *	90%	10%	X	X
Acupuncturist Unemployed*	95%	5%	X	X

*** The grid applies to most licensees in all boards, but ultimate discretion is left to the monitoring programs' medical director.**

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Toxicology- Screening and Analysis Panels

NARCOTICS			
Buprenorphine (buprenex)	5	5	
Butorphanol (stadol)	150 pg/ml	0.5 ng/ml	
Codeine	300 ng/ml	75	
Fentanyl (sublimaze)	1.0 ng/ml	.05 ng/ml	
Hydrocodone (lortab)	300 ng/ml	75	
Hydromorphone (dilaudid)	300 ng/ml	75	
Ketamine (ketalar)	500 ng/ml	100 ng/ml	
Meperidine (demerol)	200	100 ng/ml	
Methadone (dolophine)	300 ng/ml	100	
Meprobamate/Carisoprodol	500 ng/ml	100	
Morphine	300 ng/ml	75	
Nalbuphine (nubain)	150 pg/ml	100 ng/ml	
Naltrexone (naloxone)	150 pg/ml	100 ng/ml	<-
Oxycodone (percodan)	100 ng/ml	75	<-
Oxymorphone (numorphan)	100 ng/ml	75	
Pentazocine (talwin)	150 pg/ml	50	
Propoxyphene (darvon)	300 ng/ml	100	
Tramadol (ultram)	200	100	

ANTIHISTAMINES			
Chlorpheniramine	100 ng/ml	50	
Diphenhydramine (benadryl)	100 ng/ml	50	
Doxylamine	100 ng/ml	10	
Pheniramine	100 ng/ml	100 ng/ml	
Brompheniramine	100 ng/ml	1	<

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Cutoff Levels for Screening and Confirmation by Substance

- Screening- uses immunoassay technology
- Confirmation- uses gas chromatography mass spectrum (GC/MS) analysis
- Levels low enough to detect
- Confirmation lower than screening
- Samples screened first, then confirmed unless . . . .

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Screening

- Immunoassay interference
- Wrong color
- High nitrite levels
- Includes validity testing- 49CFR Part 40, Section 40.89

(a) Specimen validity testing is the evaluation of the specimen to determine if it is consistent with normal human urine. The purpose of validity testing is to determine whether certain adulterants or foreign substances were added to the urine, if the urine was diluted, or if the specimen was substituted.

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Cutoff Levels for Screening and Confirmation by Substance

- If screened out. Samples are confirmed to the lowest levels of detection. . .

TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
MEDTOX PROPANEL 58			
DRUGS OF ABUSE SCREEN 96128			
DRUG TEST RESULT	INVALID		
INVALID - OXIDANT ACTIVITY = > = 200 MCG/ML NITRITE EQUIVALENTS			
REMARKS			
INVALID RESULT: IMMUNOASSAY INTERFERENCE			

DRUG TEST RESULT	INVALID	
REMARKS		
INVALID RESULT: IMMUNOASSAY INTERFERENCE		
ETHYL GLUCURONIDE	NR	ng/ml
AMPHETAMINES	NR	ng/ml
MDMA	NR	ng/ml
BARBITURATES	NR	ng/ml
BENZODIAZEPINES	NR	ng/ml
COCAINE METABOLITE	NR	ng/ml
OPIATES	NR	ng/ml
OXYCODONE	NR	ng/ml
PHENCYCLIDINE (PCP)	NR	ng/ml

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Results

- Negative
- Positive
- Non-Negative Pending MRO Review
- Rejected/Cancelled by Lab

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Dilutes

- Dilute = creatinine is less than 20 mg/dl **and** specific gravity is less than 1.003
- Low Creatinine = creatinine is less than or = to 15 mg/dl
- Closer specific gravity is to 1.0000 the less likely it could have come from a human
- Test sample to the lowest level of detection

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Normalization of EtG/EtS

- Normalizing the values adjusts for the distorting effect of concentration (which can, in some cases, be significant). When urine is more concentrated all the values are skewed upward and when urine is more dilute the values are skewed downward. A calculation to adjust values to a creatinine of 100 “normalizes” and standardizes the results. (Skipper. Dupont, & Baxter)

	Value	Normalized
EtG Value	650	4063
EtS Value	471	2944
Creatinine	16	100

	Value	Normalized
EtG Value	650	351
EtS Value	471	255
Creatinine	185	100

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Exercise. . .
What is happening here?

Date Collected	Creatinine	Specific Gravity
9/22/2015	6.9	1.002
9/24/2015	6.6	1.0013
10/7/2015	9.5	1.0011
10/13/2015	11.8	1.0011
10/19/2015	OK	OK

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Substance Use

Date Collected	Creatinine	Specific Gravity	MRO Report
9/22/2015	6.9	1.002	10/16/15 (Morphine 419 ng/ml)
9/24/2015	6.6	1.0013	None
10/7/2015	9.5	1.0011	10/13/2015 Positive (Morphine 2272 ng/ml)
10/13/2015	11.8	1.0011	10/23/2015 Dilute Negative (Morphine 92ng/ml)
10/19/2015	OK	OK	10/22/2015- Positive-Verified Buprenorphine 23ng/ml

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Toxicology Grid

11/10/2015	No Call		
11/6/2015	No Show		
11/2/2015	No Show		
10/28/2015	No Show		
10/23/2015	No Show		
10/19/2015	Non-Negative Pending MRO Review	Non-Negative; Positive; Positive for - DRUG TEST RESULT; Positive for - BUPRENORPHINE	Positive
10/13/2015	Non-Negative Pending MRO Review	Dilute; Positive for - CREATININE = 11.8; Positive for - CREATININE; Positive for - SPECIFIC GRAVITY	Negative
10/7/2015	Non-Negative Pending MRO Review	Non-Negative; Dilute; Positive; Positive for - DRUG TEST RESULT; Positive for - OPIATES; Positive for - CREATININE = 9.5; Positive for - CREATININE; Positive for - SPECIFIC GRAVITY	Positive Non Contact
10/3/2015	No Call		
9/24/2015	Negative	Dilute; Positive for - CREATININE = 6.6; Positive for - CREATININE; Positive for - SPECIFIC GRAVITY	
9/22/2015	Non-Negative Pending MRO Review	Dilute; Positive for - SPECIFIC GRAVITY	Positive Non Contact
9/11/2015	Rejected / Cancelled by Lab	Non-Negative; Rejected	
9/2/2015	Negative	Dilute; Positive for - CREATININE = 5.4; Positive for - CREATININE; Positive for - SPECIFIC GRAVITY	
8/26/2015	Negative		
8/17/2015	Negative		

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Testing Frequency

- “The frequency of testing may initially be more than once a week and later reduced to several times a month” (National Council of State Boards of Nursing, 2011, p. 201).
- “PHP’s conduct random drug and alcohol tests for five years or more, with participants tested on average twice per month-typically four times or more a month at the start and after prolonged abstinence, typically once a month” (DuPont & Skipper, 2012, p. 74).

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Testing Frequency Continued

- HPSP:
  - Year 1= Minimum of 36 tests
  - Year 2= Minimum of 24 tests
  - Year 3, 4, and beyond= minimum of 18 annual tests
- Deterrent?
- Detection window sufficient?

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Reading Reports

General Information	Date Collected	Date Received	Date Reported
	01/20/2016 16:20	01/23/2016	01/27/2016 3:10PM

TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
MEDTOX PROPANEL 58			
DRUGS OF ABUSE SCREEN 96128			
DRUG TEST RESULT	POSITIVE		
ETHYL GLUCURONIDE	NEGATIVE	ng/ml	
AMPHETAMINES	NEGATIVE	ng/ml	
MDMA	NEGATIVE	ng/ml	
BARBITURATES	NEGATIVE	ng/ml	
BENZODIAZEPINES	NEGATIVE	ng/ml	
COCAINE METABOLITE	NEGATIVE	ng/ml	
OPIATES	NEGATIVE	ng/ml	
OXYCODONE	+++POSITIVE+++	ng/ml	
PHENCYCLIDINE (PCP)	NEGATIVE	ng/ml	
MARIJUANA METABOLITE (THC)	NEGATIVE	ng/ml	

	16:20		3:10PM
TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
OXYCODONE CONFIRMATION			
OXYMORPHONE	116	ng/ml	

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Collected at 5412283100 MEDTOX collection site #25364

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Reading Reports Continued

TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
MEDTOX PROPANEL 58			
DRUGS OF ABUSE SCREEN 96128			
DRUG TEST RESULT	POSITIVE		
DRUG TEST RESULT	INVALID		
REMARKS			
INVALID RESULT: IMMUNOASSAY INTERFERENCE			
ETHYL GLUCURONIDE	NR	ng/ml	
AMPHETAMINES	NR	ng/ml	
MDMA	NR	ng/ml	
BARBITURATES	NR	ng/ml	
BENZODIAZEPINES	NR	ng/ml	
COCAINE METABOLITE	NR	ng/ml	
OPIATES	NR	ng/ml	
OXYCODONE	NR	ng/ml	
PHENCYCLIDINE (PCP)	NR	ng/ml	
MARIJUANA METABOLITE (THC)	+++POSITIVE+++	ng/ml	
METHADONE	NR	ng/ml	
PROPOXYPHENE	NR	ng/ml	
BUPRENORPHINE	NR	ng/ml	
CREATININE	40.2	mg/dl	> = 20
NITRITES	NEGATIVE	mcg/ml	< 200
Certified by: ELLINGSON,JOYCE			
ANTIHISTAMINES	NEGATIVE		
NARCOTICS/OPIATES	NEGATIVE		

General Information	Date Collected	Date Received	Date Reported
15043387	12/15/2015 10:25	12/17/2015	12/22/2015 4:20PM

TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
CARBOXY-THC, GC/MS CONFIRMATION			
CARBOXY-THC	16	ng/ml	

** FINAL REPORT **

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Toxicology Grid

Scheduled Test Date	Result	Non-Negative Reason(s)	MRO Result
1/14/2016	Negative		
1/6/2016	Negative		
12/24/2015	Non-Negative Pending MRO Review	Non-Negative; Positive; Positive for - DRUG TEST RESULT; Positive for - MARIJUANA METABOLITE (THC)	Positive
12/15/2015	Non-Negative Pending MRO Review	Non-Negative; Invalid; Positive; Positive for - DRUG TEST RESULT; Positive for - MARIJUANA METABOLITE (THC)	Positive
11/12/2015	Negative		
10/23/2015	Negative		
10/15/2015	Negative		
9/14/2015	Non-Negative Pending MRO Review	Non-Negative; Invalid	
9/2/2015	Negative		
8/25/2015	Negative		
8/19/2015	Negative		
7/31/2015	Negative		

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Reading Reports- Phosphatidlethanol (Peth)

	17:30		9:36AM
TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
PHOSPHATIDYLETHANOL (PEth)	169 (H)	ng/mL	NEGATIVE

Analyzed compound: PEth 16:0/18:1.
1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoethanol.

Analysis performed by Liquid Chromatograpy with
Tandem Mass Spectrometry (LC/MS/MS)

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Reading Reports- Phosphatidlethanol (Peth)

	16:40		6:14AM
TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
PHOSPHATIDYLETHANOL (PEth)	NEGATIVE	ng/mL	NEGATIVE

Analyzed compound: PEth 16:0/18:1.
1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoethanol

Toxicology- Medical Review Officer (MRO)

Collection

- Mon-Sat Notifications
- Randomized Schedule
- Nationwide sites
- Observed Collection
- Chain of Custody
- Split sample

Transportation

- From collection to lab
- Chain of Custody

Screening and Analysis

- Screening cutoff
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Medical Review

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The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) define an MRO as a licensed physician holding either a Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree who has:

- Knowledge regarding the pharmacology and toxicology of illicit drugs;
- Training in the collection procedures used to collect Federal agency specimens; the interpretation of test results reported by laboratories; chain of custody, reporting, and recordkeeping requirements for Federal agency specimens; the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; and procedures for interpretation, review, and reporting of results as specified by the Federal agency or agencies for which the individual may serve as MRO; and

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The HHS Mandatory Guidelines MRO Continued

- Satisfactorily passed an examination administered by an HHS-approved organization (i.e., a nationally recognized entity that certifies MROs or a subspecialty board for physicians performing a review of Federal employee drug test results). HHS publishes an annual list of approved organizations in the Federal Register.

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MRO Responsibilities:

- Review all specimens reported as positive, adulterated, substituted, invalid, or rejected for testing, and report the verified result to the Federal agency;
- Ensure that specimens reported as negative or as negative and dilute are properly reviewed (i.e., at least 5% personally and the remainder by staff under the MRO's direct, personal supervision) and reported to the Federal agency;
- Review the results of all Federal agency blind samples and perform the initial investigation into discrepant results;
- Discuss potential invalid results with the laboratory to determine whether further testing at another HHS-certified laboratory is warranted;

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MRO Responsibilities continued:

- Conduct or facilitate a medical evaluation of the donor when a collector reports that the donor was unable to provide a urine specimen;
- Perform an initial investigation of problems identified in the drug testing process and notify the appropriate regulatory authority of findings;
- Monitor the frequency of errors and notify responsible parties to take corrective action to prevent recurrence; and
- Maintain records and confidentiality of drug test information.

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Reading Reports- Medical Review Officer

Results of Tests: Positive-Verified

Substance(s): Buprenorphine / 23 ng/ml

MRO Comments: REVISED REPORT: Donor called this MRO Office 10/22/15

MRO Verified Date: 10/22/2015 06:44:39 PM

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Reading Reports-
Medical Review Officer

Results of Tests: Positive-Non Contact

Substance(s): Opiate / Morphine: 2272 ng/ml

Lab Comments: DILUTE SPECIMEN
MRO Comments: A Valid contact telephone number was not provided this MRO Office., OBSERVED COLLECTION
MRO Report Date: 10/13/2015 07:00:17 PM

This test is VALID and is to become a part of the donor's record! The specimen was found to be DILUTE, which usually means the donor was over-hydrated; but sometimes suggests an attempt to invalidate the test. Please contact our office if you have questions regarding the management of dilute reports.

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Reading Reports-
Medical Review Officer

Results of these tests: **Negative**

MRO Comments: SAFETY WARNING: As per regulation 40.327 (a) (2) employer is hereby notified of a potential safety hazard by reason of the nature of the medication prescribed, Hydrocodone last filled 12/17/15.

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Alternative Testing

- PEth
- Hair/Nail
- Breath

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Case Study

- Licensee on SoberLink with two daily scheduled tests. 6 AM and 10PM. Licensee had a three hour window for each test.
- For 6 AM test, licensee could test 5:45 AM until 8:59:59 AM.
- For 10PM test. Licensee had until 12:59:59 to test.
- 5:45 AM until 12:59:59 AM to test = 19 hour and 15 minute window.

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Case Study Continued

- Three missed tests and three late tests in one week.
- 3 hours 15 minutes to find time to test.
- Follow-up PEth was a high positive.
- Licensee had a long history of dilute urines.

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Reading Reports Recap

TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
MEDTOX PROPANEL 58			
DRUGS OF ABUSE SCREEN 96128			
DRUG TEST RESULT	POSITIVE		
DRUG TEST RESULT	INVALID		
REMARKS			
INVALID RESULT: IMMUNOASSAY INTERFERENCE			
ETHYL GLUCURONIDE	NR	ng/ml	
AMPHETAMINES	NR	ng/ml	
MDMA	NR	ng/ml	
BARBITURATES	NR	ng/ml	
BENZODIAZEPINES	NR	ng/ml	
COCAINE METABOLITE	NR	ng/ml	
OPIATES	NR	ng/ml	
OXYCODONE	NR	ng/ml	
PHENCYCLIDINE (PCP)	NR	ng/ml	
MARIJUANA METABOLITE (THC)	+++POSITIVE+++	ng/ml	
METHADONE	NR	ng/ml	
PROPOXYPHENE	NR	ng/ml	
BUPRENORPHINE	NR	ng/ml	
CREATININE	40.2	mg/dl	> = 20
NITRITES	NEGATIVE	mcg/ml	< 200
Certified by: ELLINGSON,JOYCE			
ANTIHISTAMINES	NEGATIVE		
NARCOTICS/OPIATES	NEGATIVE		

General Information	Date Collected	Date Received	Date Reported
15043387	12/15/2015 10:25	12/17/2015	12/22/2015 4:20PM

TEST(S) REQUESTED	RESULTS	UNITS	THERAPEUTIC RANGE
CARBOXY-THC, GC/MS CONFIRMATION			
CARBOXY-THC	16	ng/ml	

** FINAL REPORT **

RBH
Reliant Behavioral Health
MONITORING

Reading Reports MRO

Results of Tests: Positive-Verified

Substance(s): Marijuana / 16 ng/ml

Lab Comments: INVALID RESULT

MRO Comments: This positive result is valid even though the laboratory reported an invalid result for all other drugs in the requested test panel.

MRO Report Date: 12/23/2015 12:47:40 PM

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Reading Reports Split Sample

Tests Requested

ZU-THCA-C Cannabinoids GC/MS Confirm **Sample** POSITIVE

Test	Result	Quantitation	Screen Cutoff	Confirm
CANNABINOIDS	POSITIVE			
Carboxy-THC GC/MS	POSITIVE	16 ng/mL		3 ng/mL
VALIDITY CREATININE/SPGR	Normal			
Creatinine Urine		43.7 mg/dL		

Certification

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Questions?

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Thank You!

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