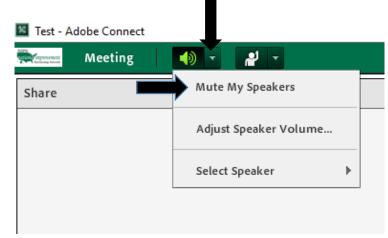
ICON Statewide Call February 10, 2020

What does it mean? Interpreting Drug Testing in the Patient Context

- (1) Upon arrival, please use the *Chat* box to provide your first **and** last name *and* your phone number (if you called in using your phone).
- (2) Please provide first **and** last names for those with you on the call.
- (3) Please include your practice or organization name.



Please remember to mute the phone line by dialing *6 (#6 to unmute) and/or mute the speakers on your computer.





What does it mean? Interpreting drug testing in the patient context.

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Disclosures

- Clayton Wilburn: I have no relevant financial relationships to disclose or conflicts of interest to resolve
- Adrienne Pahl: I have no relevant financial relationships to disclose or conflicts of interest to resolve
- Jill Warrington: I am on the Blue Cross Blue Shield Community Advisory Council in which I receive reimbursement for time/travel. I am employed by the University of Vermont Medical Center and the Larner College of Medicine, carry an unsalaried position as Chief Medical Officer at Aspenti Health with a minor stock option holding (value <\$1000).



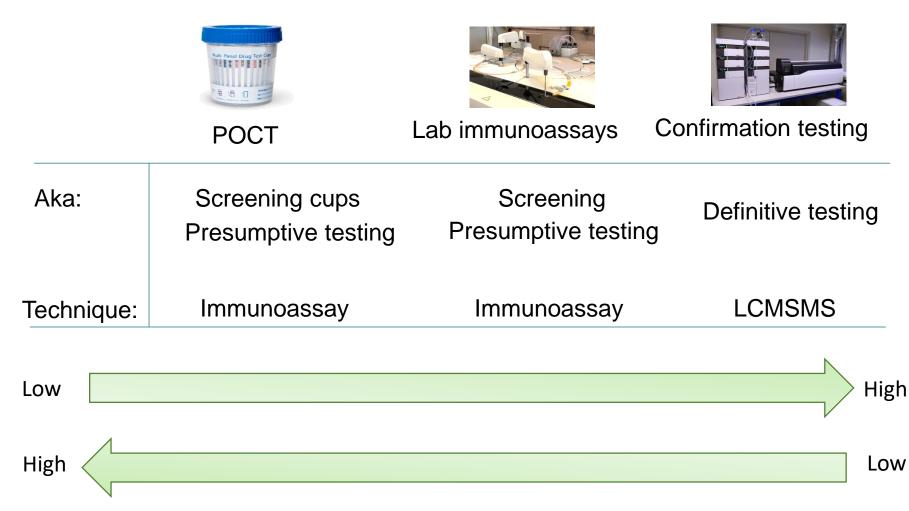
Objectives

- Use cases to demonstrate importance of the patient history and information gathered in the clinical encounter when determining:
 - Which screening tests to order
 - When to send confirmatory testing
 - How to interpret results





Traditional methods of testing





Diagnostic

Certainty

Speed &

Cost



Case 1- Megan

- 28yr old woman with a history of opioid use disorder, stable on prescribed MAT for 2 years. Transitioned from suboxone to buprenorphine when became pregnant.
- Second pregnancy, first child is 18 months old. Megan's partner is involved and also in recovery.
- Received regular prenatal care and continued meeting with her MAT provider and counselors throughout pregnancy. All routine urine screening tests obtained during pregnancy were positive for buprenorphine and negative for all other substances.
- Pregnancy uncomplicated except for breech position of the infant at 36 weeks, C-section is scheduled for 39 weeks



Delivery

- Megan presents to the birth center at 37 weeks 1 day in active labor and found to be 6cm dilated with fetus still in breech position.
- Urgent c-section is called and Megan is transferred quickly to the OR for delivery. An epidural and foley catheter are placed in the OR and the infant is delivered without complication.
- Several hours later, the nurse notices an admission order for a urine drug screen and sends a sample of urine from Megan's foley catheter bag.





Urine drug screening results- Case 1

Component	Result	Reference Range
Amphetamine Screen	Negative	Negative
Barbiturate Screen	Negative	Negative
Benzodiazepine Screen	Negative	Negative
Buprenorphine Screen	Positive	Negative
Cocaine Screen	Negative	Negative
MDMA Screen	Negative	Negative
Methadone Screen	Negative	Negative
Methamphetamine Screen	Negative	Negative
Opiates Screen	Negative	Negative
Oxycodone Screen	Positive	Negative
Marijuana (THC) Screen	Negative	Negative





How to interpret these results?

Urine drug <u>screen</u> is positive for expected buprenorphine AND positive for oxycodone

- What do you do <u>first</u>?
 - Tell mother you know she has been using drugs and that she cannot breastfeed her baby
 - Don't say anything to mother and order confirmation testing
 - Have a conversation with mother and ask her about possible use





Case 1 discussion

• You sit down privately with Megan after all support people have left the room and ask her about her recovery and any recent drug use.

 Megan states she has been compliant with her MAT and has not been taking any non-prescribed drugs.

 You let Megan know her screening urine test was positive for oxycodone. She is very surprised and asks if it is possible her epidural caused this positive result.





Next steps

- How do you respond to Megan?
 - There is no way the epidural could cause this result, you are lying
 - I'm not sure if the epidural is related, but we can test via confirmatory testing





Next steps

- Confirmatory testing is ordered but will take several days to get the results. In the meantime, Megan wants to breastfeed her baby. What do you tell her?
 - You cannot breastfeed due to opioid use
 - You have to wait for confirmatory testing before you can breastfeed
 - It's ok to breastfeed the baby. The benefits of breastfeeding outweigh the risks of infant exposure to very small amounts of opiates passed in breastmilk





Confirmatory results

Component	Result	Reference Range
Buprenorphine, Quantitative	235 ng/mL	Not Detected
Norbuprenorphine, Quantitative	298 ng/mL	Not Detected
Fentanyl, Quantitative	3.5 ng/mL	Not Detected
Norfentanyl, Quantitative	10.0 ng/mL	Not Detected
Oxycodone, Quantitative	210 ng/mL	Not Detected

Negative for all other tested substances (not detected)





How would you interpret each result?

1. Buprenorphine and norbuprenorphine expected from MAT

- 2. Fentanyl and norfentanyl
 - Patient used fentanyl prior to going into labor
 - 2. A review of the epidural medication is warranted
 - 3. Fentanyl is a false positive related to known buprenorphine use





Fentanyl Screens

- Fentanyl is not included in routine opioid panels- must order separately
 - AND does not make opiate/oxycodone screens positive
- Carries high false-positive rate- recommend confirming all positives
 - Trazodone cross-reactivity commonly seen

- Detection window for use is up to 3 days
 - May be longer in transdermal (patch) use





Fentanyl and Epidural Anesthesia

Fentanyl and Sufentanil used for epidural analgesia in labor

- Both rapidly enter maternal/placental circulation
 - Concentrations approach low therapeutic dose
- Both found in fetal circulation at time of delivery
 - Lower level in fetus than maternal blood





Epidurals and Urine Drug Testing

 Fentanyl from an epidural can reach serum and urine concentrations high enough to test positive by screen and/or confirmation

Sufentanil has very low cross-reactivity with many fentanyl screens

- Fentanyl from an epidural can be detected in the infant
 - May be positive in umbilical cord testing but not in meconium testing





Case 1: MAR review

- A review of Megan's medication administration record demonstrates she received the following medications:
 - Epidural: fentanyl and bupivacaine

- Oral medications given in recovery room:
 - Acetaminophen 500mg
 - Ibuprofen 400mg
 - Oxycodone 5mg





Now how do you interpret the confirmatory results?

1. Positive for buprenorphine and norbuprenorphine- known MAT

- 2. Positive for fentanyl and norfentanyl
 - Likely due to epidural medication

- 3. Positive for oxycodone
 - Can be explained by oxycodone given in recovery room





Case 1: Summary

- Mom was telling the truth!!
- Be careful not to jump to conclusions with positive screening tests or even confirmatory testing
- Before making decisions that may affect the mother-infant dyad including breastfeeding make sure to:
 - Speak with the patient first
 - Check the MAR
 - Speak with the lab to understand what the results mean





Case 2: Trudy

- 34yr old woman with a history of opioid-use disorder, started on methadone at 18 weeks of pregnancy. First pregnancy.
- Received regular prenatal care and meetings with her MAT provider and counselors throughout the remainder of her pregnancy.
- Routine urine screening tests obtained after starting methadone were negative for all other substances.
- Pregnancy uncomplicated and mother received education regarding routine monitoring of the baby after delivery for signs of neonatal abstinence syndrome related to her methadone maintenance





Delivery

• Trudy presents in labor at 40+2 weeks.

 A screening urine drug test was ordered and collected on arrival to the birth center.

- After 8 hours of active labor a healthy baby girl is born by vaginal delivery without complications
 - no maternal chorioamnionitis or fever during delivery





Urine drug screening results- Case 2

Component	Result	Reference Range
Amphetamine Screen	Negative	Negative
Barbiturate Screen	Negative	Negative
Benzodiazepine Screen	Negative	Negative
Buprenorphine Screen	Negative	Negative
Cocaine Screen	Negative	Negative
MDMA Screen	Negative	Negative
Methadone Screen	Positive Pos	Negative
Methamphetamine Screen	Negative	Negative
Opiates Screen	Negative	Negative
Oxycodone Screen	Negative	Negative
Marijuana (THC) Screen	Negative	Negative





Newborn evaluation

 4 hours after birth on routine assessment the infant is noted to have high tone, tremors, exaggerated moro, a high pitched cry and excessive suck

• The pediatrician is called to evaluate the infant. Vitals signs are reassuring against infection.

 After examining the baby, the pediatrician feels the infant is showing signs of withdrawal.





What can cause infant withdrawal symptoms?

- Medication assisted therapy (methadone, buprenorphine)
- Nicotine
- Anti-depressant/anti-anxiety medications (SSRIs, SNRIs)
- Prescribed or non-prescribed opioids
- Prescribed or non-prescribed benzodiazepines





Which cause withdrawal signs in the first 24hr after birth?

- Medication assisted therapy (methadone, buprenorphine)
- Nicotine
- Anti-depressant/anti-anxiety medications (SSRIs, SNRIs)
- Prescribed or non-prescribed opioids
- Prescribed or non-prescribed benzodiazepines





What do you do now?

Collect more information!

- 1. Ask mom are you:
 - Smoking, vaping or using other forms of nicotine
 - Taking an SSRI (Prozac, Zoloft, Celexa) or SNRI (Effexor)
 - Taking benzodiazepines (Valium, Ativan)
 - Taking any opioids (prescribed or not)
- 2. Check the MAR- did mom receive any medications during delivery that could affect the baby?





More information

- Mom states she is not
 - Smoking, vaping or using other forms of nicotine
 - Taking an SSRI (Prozac, Zoloft, Celexa) or SNRI (Effexor)
 - Taking benzodiazepines (Valium, Ativan)
 - Taking any opioids (prescribed or not)
- MAR: no epidural medications or intrapartum pain medications were given
- What is causing the baby's withdrawal symptoms?





Next steps

What drug tests could be ordered?

- Infant
 - Urine (must be first void)- too late
 - Meconium (must be first stool)- too late
 - Umbilical cord- stored in lab
- Mother
 - Urine- admission specimen saved at lab





Case 2: Further testing

- The infant's umbilical cord is sent for confirmatory drug testing
 - Includes a large panel of drugs and metabolites

 Mother's urine is sent for confirmatory testing with additional tests added including expanded number of opioids and metabolites

- Confirmatory Results- both specimens positive for
 - Methadone and EDDP
 - Tramadol





How do you interpret this unexpected result?

- These are false positives
- These are true positives

- Why were the screening urine tests during pregnancy and at delivery negative?
 - Standard opioid screening tests do not include tramadol.
 - The levels were below the limit of detection of the lab's opiate screening assay.
 - Mom has tampered with her urine samples

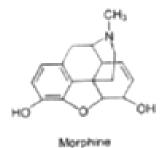


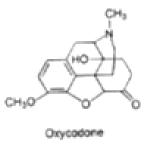


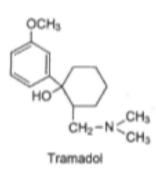
Not All Opioid Tests are Created Equal

 Opioids are a class of drugs with similar effects but different structures

- Opioid Drug Screen antibodies are designed against one structure
 - Slight differences in structure can lead to negative results
- Cross-reactivity of one opioid to a particular opioid screen differs between manufacturers











Opioid Screen General Rules of Thumb

- Standard Opiate Screen:
 - Detects well: Morphine, Codeine, 6-MAM
 - Detects ok: Hydrocodone, Hydromorphone, Heroin
 - Does not detect: Oxycodone, Oxymorphone, Methadone, Buprenorphine, Tramadol, Tapentadol, Fentanyl
- Standard Oxycodone Screen:
 - Detects well: Oxycodone, Oxymorphone
 - Does not detect: All others





Opioid Screen General Rules of Thumb

- The following Opioids are their own test/order:
 - Methadone
 - Buprenorphine
 - Fentanyl
 - Tramadol
 - Tapentadol
 - 6-MAM
 - Propoxyphene





Be Mindful of Panels

- Opioid Panels are lab specific
 - Common terms include Extended, Comprehensive, Complete
 - But that does not mean they are
 - Always verify the individual drugs covered in a panel
 - Make sure you speak with your lab to interpret results correctly

- Judicious use of testing- think before your order
 - All panels and additional tests are associated with a cost
 - A panel may be appropriate in some cases, but not in others





Case 2: Follow-up discussion

 You sit down privately with Trudy after all support people have left the room and ask her about her recovery and any recent drug use.

 The baby is now 3 days old and is doing well without any signs of withdrawal.

• You let Trudy know her confirmatory urine test and the infant's umbilical cord were positive for tramadol. She breaks down crying and admits to taking this medication.





Case 2: Summary

A negative screening test can be falsely reassuring!

- Make sure to take the signs and symptoms of the infant into consideration as well as the timing of symptom development
 - Long acting opioids will cause signs of infant withdrawal 50% of the time, but the symptoms generally present after 2-3 days
 - Short acting opioids, nicotine, SSRIs and benzodiazepines can all cause symptoms in the 1^{st} day of life





Case 3- Serena

- 38yr old woman with a history of opioid use disorder, presented for prenatal care at 24 weeks and was started on methadone immediately.
- She is now 32 weeks pregnant and presents for her routine prenatal visit.
- Routine urine screening tests obtained after starting methadone were negative for all other substances.

You collect a urine specimen today for testing





Urine drug screening results- Case 3

Component	Result	Reference Range
Amphetamine Screen	Negative	Negative
Barbiturate Screen	Negative	Negative
Benzodiazepine Screen	Negative	Negative
Buprenorphine Screen	Negative	Negative
Cocaine Screen	Negative	Negative
MDMA Screen	Negative	Negative
Methadone Screen	Positive Pos	Negative
Methamphetamine Screen	Negative	Negative
Opiates Screen	Positive Pos	Negative
Oxycodone Screen	Negative	Negative
Marijuana (THC) Screen	Negative	Negative





Case 3: Confirmatory Results

Component	Result	Reference Range
Morphine, Quantitative	5,000 ng/mL	Not Detected
6-MAM, Quantitative	Not Detected	Not Detected
Codeine, Quantitative	25 ng/mL	Not Detected
Hydromorphone, Quantitative	492 ng/mL	Not Detected
Hydrocodone, Quantitative	Not Detected	Not Detected
Methadone, Quantitative	911 ng/mL	Not Detected
EDDP, Quantitative	1913 ng/mL	Not Detected





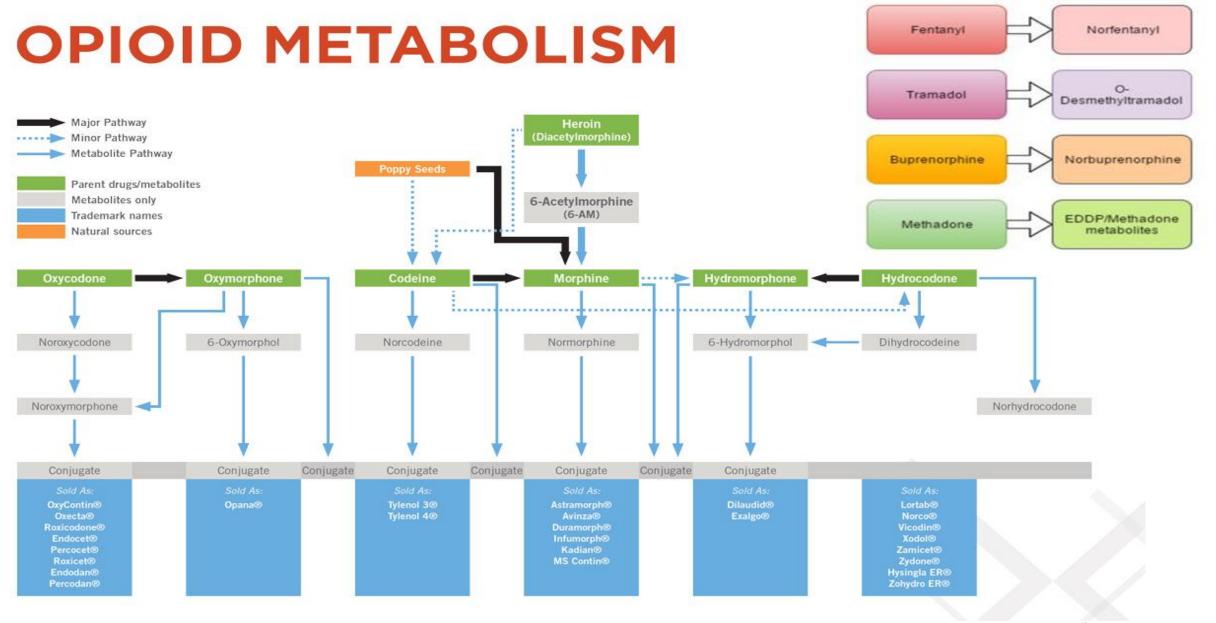
How Would You Interpret?

- A. Patient is taking Morphine, Codeine, and Methadone
- B. Patient is taking Morphine, Hydromorphone, and Methadone
- C. Patient is taking Morphine, Codeine, Hydromorphone, and Methadone

D. Patient is taking Morphine and Methadone





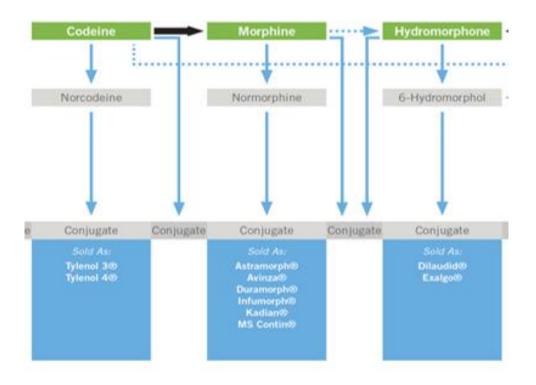






How is it all Explained?

- Hydromorphone is minor metabolite of morphine
 - Comprises ≤10% of total morphine
- Codeine is trace impurity in morphine production
 - Estimated range of 0.04-0.5%







Case 3: discussion

 You call Serena in and let her know her urine confirmatory testing is positive for morphine (and it's metabolites).

 Serena admits to using MS Contin she obtained without a prescription for her chronic back pain.

 After discussing your concerns around using this non-prescribed opiate medication, you offer Serena a referral to the pain clinic which she accepts.





Case 4- Melissa

- 21yr old woman presents to her first prenatal visit at 8 weeks. She is very excited and nervous.
- You screen for substance use with a paper questionnaire and Melissa reports quitting marijuana 3 months ago. She then states she is using CBD oil for her nausea and vomiting.
- After discussing the possible negative effects of all substances on fetal development Melissa starts crying and states her boyfriend still smokes marijuana around her and worries it may have hurt the baby. She asks you to test her "for all drugs" to be sure her baby is ok.





Urine drug screening results- Case 4

Component	Result	Reference Range
Amphetamine Screen	Negative	Negative
Barbiturate Screen	Negative	Negative
Benzodiazepine Screen	Negative	Negative
Buprenorphine Screen	Negative	Negative
Cocaine Screen	Negative	Negative
MDMA Screen	Negative	Negative
Methadone Screen	Negative	Negative
Methamphetamine Screen	Negative	Negative
Opiates Screen	Negative	Negative
Oxycodone Screen	Negative	Negative
Marijuana (THC) Screen	Positive Pos	Negative





What could cause the positive result?

- A. Use of full spectrum CBD oil for nausea
- B. Secondhand smoke of boyfriend
- C. Old use of marijuana prior to pregnancy
- D. Recent use of marijuana





What could cause the positive THC result?

YES

MAYBE*

NO

D. Recent use

A. Use of full spectrum CBD oil for nausea

C. Old use prior to pregnancy **

B. Secondhand smoke

*(but not likely)

**reports quit
3 months ago



Clinical factors that impact detection of use

Body Mass Index

- THC is lipophilic
- Increased BMI will prolong THC detection

Patterns of use

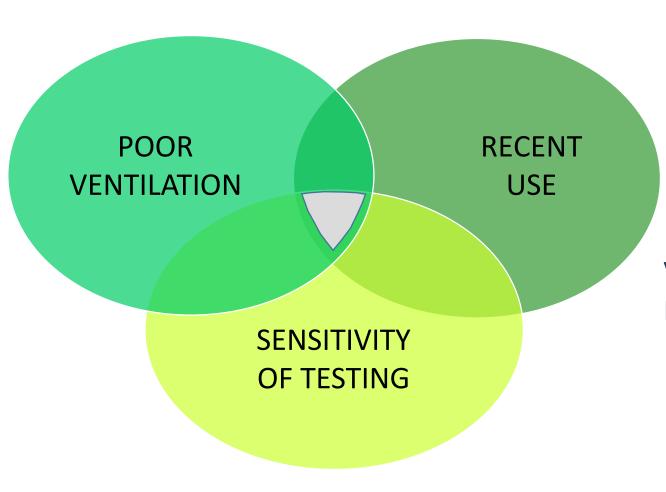
- Dose
- Mechanism of consumption
- Timing of use
- Regularity of use

Frequency of use	Detection window (days) at 3 ng/ml
Single use	3 days
Moderate (4 x/week)	5 days
Heavy (daily)	10 days
Chronic heavy use	30 -60 days





Secondhand smoke





Very specific conditions are necessary to Detect secondhand smoke:

- Visible smoke
- Testing sensitivity <20ng/ml
- Testing in <24 hours





CBD oil

- CBD itself is not detected by immunoassay or confirmation testing
- Trace THC levels can be found in CBD, since contents are not FDA-regulated.
- CBD products are legally allowed up to 0.3% THC content.
- Generally need at a minimum of >1000-2000 mg/day to be detected

What about hemp-containing foods?

 While trace THC can be present, clinical laboratory cutoffs are generally too high to detect it in hemp food products





Case 4: Confirmatory testing

- All tested substances were negative other than THC
 - THC level was 156 ng/mL
- What is the source?
 - Gather more information





Case 4: Follow-up discussion

- You sit down privately with Melissa and ask again about any recent marijuana use.
- You let Melissa know her confirmatory urine test was positive for THC and it is unlikely from passive breathing of her boyfriend's smoke or from the CBD oil. Also with quitting 3 months ago, this is unlikely from use prior to pregnancy.
- Melissa then states she recently smoked marijuana with her boyfriend when she had severe nausea and was unable to drink or eat but felt too guilty and afraid she had harmed her baby to tell you.





Case 4: Summary

 Although it is important to consider all possible sources of THC, the most common explanation for positive urine drug screening is still use.

• Be mindful to provide information on the risks of substance use during pregnancy in a patient-centered, non-judgmental way to maintain trust and allow women to feel safe disclosing use.





Case 5: Jen

• 22 year old woman presents for her first prenatal visit at 6 weeks. This is her first pregnancy.

 Fitness is very important to her and she just finished a triathlon this past weekend. She asks about safe ways to continue exercise during pregnancy.

She shares a concern that her friend gave her an energy drink right before
the race yesterday and was worried about its contents harming the baby
after reading on her pregnancy app that the baby's brain was developing
now.





Questions about Energy Drinks



- 1. What are the contents of energy drinks?
 - Top 10 most popular drinks contain caffeine, amino acids and sweeteners
 - Ephedra (ma huang) and synephrine (bitter orange extract) are occasionally found
- 2. Are any of the ingredients harmful to fetal development?
- 3. If you were to order a urine drug test, would it be positive?
 - If so, what drug class might be positive?





Questions about Energy Drinks

- 1. What are the contents of energy drinks?
- 2. Are any of the ingredients harmful to fetal development?
 - Caffeine can negatively affect vascularization of the placenta
 - Minimal studies on ephedrine and synephrine in early pregnancy but known to cause increased fetal heart rate and fetal acidosis at delivery

3. If you were to order a urine drug test, would it be positive?





Questions about Energy Drinks

- 1. What are the contents of energy drinks?
- 2. Are any of the ingredients harmful to fetal development?
 - Caffeine can negatively affect vascularization of the placenta
 - Minimal studies on ephedrine and synephrine in early pregnancy but known to cause increased fetal heart rate and fetal acidosis at delivery

- 3. If you were to order a urine drug test, would it be positive?
 - Maybe- ephedrine and synephrine can cause positive amphetamine screen





False positives in amphetamine testing

Generally considered the test with the most false positives of any urine drug test*

Examples include: Phentermine MDA

Ephedrine MDEA Synephrine MDMA

Pseudoephdrine Erythro-dihydro buproprion

Phenylephrine Hydroxy-buproprion

Trazodone metabolite Ranitidine Fenofibrate Labetalol

Tranylcypromine Dimethylamylamine (DMAA)

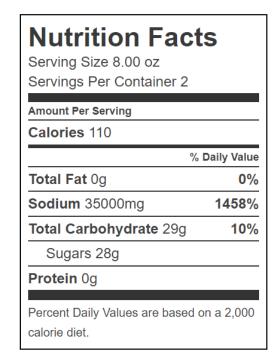
^{*} Likely exception is fentanyl immunoassay





Case 5: discussion

- Jen reports drinking Monster Mango Loco.
- What is in this energy drink?
 - Caffeine- 152mg
 - B vitamins
 - Sucralose
 - Salt





Consume Responsibly:

Not Recommended for children, people sensitive to caffeine, pregnant women or women who are nursing.

Case 5 Summary

 You reassure Jen that the energy drink she used did not contain ephedrine and synephrine but recommend she avoid the excess caffeine contained in many energy drinks. Electrolyte water or sports drinks would be better alternatives.

 Good reminder to ask about all over the counter medications, supplements and performance enhancing drinks.





Case 6: Linda

- 32-year old woman with a history of alcoholism presents at 20 weeks of pregnancy for regular prenatal care. Pregnancy has been uncomplicated except low weight gain.
- She reports all has been going well except for new urinary frequency and burning for 2 days.
- She has trouble answering your questions today and appears jittery.
- You disclose you are concerned she has relapsed with her alcohol use disorder and ask her if she would provide a sample for testing. Linda denies alcohol use and consents to urine testing.



What test to order?

- Your office point of care urine drug test does not include alcohol.
- You log-in to the EHR and notice several options for alcohol testing.
 - A. Breath alcohol testing (Breathalyzer)
 - B. Urine ethanol screening
 - C. Urine ethanol confirmatory testing
 - D. Urine ethyl glucuronide (EtG) screening
 - E. Urine ethyl sulfate (EtS) confirmatory testing
- You decide to call the lab to ask what test to order





Assessing alcohol metabolites

Two fundamental considerations:

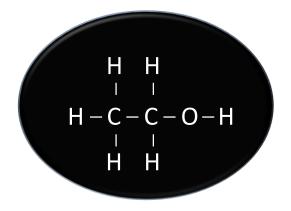
- 1. For "alcohol": there are three "drugs" that you are looking for and they differ by how long it's been since consumption (window of detection)
- 2. Stability of these drugs alters how we can interpret the test





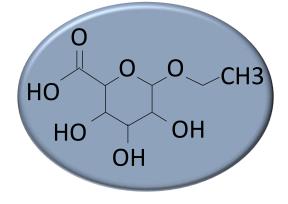
Window of detection

Ethanol



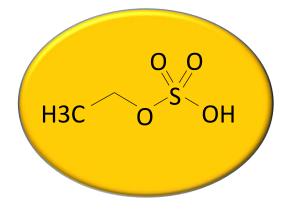
<8-10 hours

Ethyl Glucuronide (EtG)



2 – 96 hours

Ethyl Sulfate (EtS)



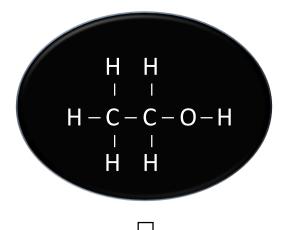
Up to 96 hours



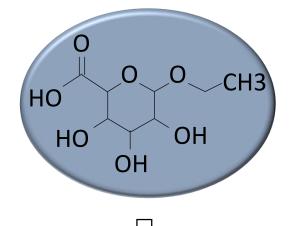


Stability

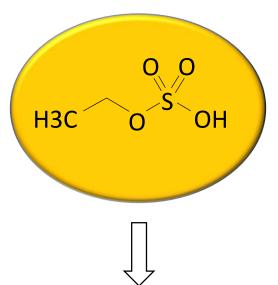
Ethanol



Volatile in specimen cup Sugars can ferment *in vitro* Ethyl Glucuronide (EtG)



Bacterial degradation Bacteria can also generate Ethyl Sulfate (EtS)



Relatively stable





Alcohol testing

- Options for alcohol testing:
 - A. Breath alcohol testing (Breathalyzer)
 - B. Urine ethanol screening
 - C. Urine ethanol confirmatory testing

D. Urine ethyl glucuronide (EtG) screening

E. Urine ethyl sulfate (EtS) confirmatory testing

If no signs of inebriation, generally no need to look for ethanol by either breathalyzer or by any laboratory test.

Linda has urinary symptoms and may have an UTI. The presence of bacteria in the urine can confound testing for Ethyl Glucuronide (EtG), so testing for Ethyl Sulfate (EtS) is the best choice.





Case 6: Follow-up

- Linda's urine confirmatory testing returns negative for EtS.
- Her urine culture returns positive for UTI
- Labs collected on the day of her visit demonstrated hypoglycemia, which may explain her jitteriness.
- You discuss the negative result with Linda and ask about food access to which she reports significant food insecurity and averaging 1 meal per day.



Case 6 Summary

 Alcohol testing can be confusing, talk to the lab and consider the clinical presentation and possible confounding factors before ordering

- Although substance use or relapse should be considered as a cause of behavior changes or physical symptoms in women with prior substance use disorder, other etiologies must be evaluated as well.
 - Do not make assumptions!





Summary

- Discussed the complexities that influence result interpretation including:
 - Epidural Analgesia with Fentanyl and Sufentanil
 - Differences in Detection between Opioid Tests and Panels
 - Interpreting Complex Opioid Metabolism
 - Potential confounders for THC testing
 - Energy drinks and urine drug testing
 - Complexities of alcohol testing

Any test result must be considered in the context of the patient to provide the best care





Laboratory related questions?

- Clayton Wilburn: 802-847-2700 or clayton.wilburn@uvmhealth.org
- Jill Warrington: 802-863-4105 or jwarrington@aspenti.com





ICON Statewide Conference Improving Care for Opioid-Exposed Newborns

Save the Date April 7, 2020

Moving Forward Together: Creating a Culture of Collaboration and Inclusion

University of Vermont, Davis Center, Grand Maple Ballroom

This year's topics will include:

- Prenatal education & trauma informed care
- Microaggressions and implications in practice
- New: Anne Johnston, MD Memorial Lecture: Honoring her legacy
 - Keynote speaker Hendrée Jones, PhD