10101 Renner Blvd
Lenexa, Kansas 66219
www.Employer Solutions.com

November 2017

Subject: Revisions to DOT workplace drug testing

On November 13, 2017, the U.S. Department of Transportation (DOT) published a final rule in the Federal Register that amends its drug testing program regulations effective **January 1, 2018**. This change harmonizes DOT regulations with Mandatory Guidelines established by U.S. Health & Human Services (HHS) for Federal drug-testing programs for urine testing.

Key changes include:

- DOT expands the drug test panel to include four Schedule II semi-synthetic opioids: hydrocodone, hydromorphone, oxycodone, and oxymorphone
- DOT adds MDA (methylenedioxyamphetamine) as an initial test analyte
- DOT removes MDEA (methylenedioxyethylamphetaime) for confirmatory testing
- **NOTE:** The lower pH cutoff, for both HHS and DOT mandated testing was raised, from 3 to 4 to identify an adulterated specimen on October 1, 2017. To ensure consistency, Quest Diagnostics changed this pH level for both Federally-mandated (other than NRC) and non-regulated urine testing on October 1, 2017.

A comprehensive summary of all DOT changes is available at.
www.transportation.gov/odapc/Part_40_Final_Rule_Summary_of_Changes

As a reminder, Federal CCF forms used for DOT drug testing will not change until after January 1, 2018. You can continue to use the old (2014) Federal without issue until June 30, 2018.

Rest assured that all of Quest Diagnostics drug testing laboratories will be ready on January 1, 2018. We are refining our collection and laboratory testing processes and updating our IT systems to comply with all DOT requirements. If you have any questions, please refer to the FAQs included with this letter or contact your Sales or Account Management representative.

Sincerely,

Bob McCormick
Vice President, Employer Solutions

Frequently Asked Questions

Revisions to U.S. Department of Transportation (DOT) & non-regulated drug testing

Q: When are the new DOT regulations effective?

A: The new regulations are effective January 1, 2018. We will transition all DOT clients to the upgraded, "future state" drug test panel on January 1, 2018.

Q: What are the new DOT drug testing regulations?

A: On November 13, 2017, the DOT published a final rule in the Federal Register that amends its drug testing program regulations effective January 1, 2018. This change harmonizes DOT regulations with Mandatory Guidelines established by U.S. Health & Human Services (HHS) for Federal drug-testing programs for urine testing. Key changes include:

- DOT expands the drug test panel to include four Schedule II semi-synthetic opioids: hydrocodone, hydromorphone, oxycodone, and oxymorphone
- DOT adds MDA (methylenedioxyamphetamine) as an initial test analyte
- DOT removes MDEA (methylenedioxyethylamphetaime) for confirmatory testing
- **NOTE:** The lower pH cutoff, for both HHS and DOT mandated testing was raised, from 3 to 4 to identify an adulterated specimen on October 1, 2017. To ensure consistency, Quest Diagnostics changed this pH level for both Federally-mandated (other than NRC) and non-regulated urine testing on October 1, 2017.

Part 40 Final Rule – DOT summary of changes:
https://www.transportation.gov/odapc/Part_40_Final_Rule_Summary_of_Changes

Part 40 Final Rule full text:
https://www.gpo.gov/fdsys/pkg/FR-2017-11-13/pdf/2017-24397.pdf

Subscribe to DOT ListServe:
https://www.transportation.gov/odapc/ListServe_Notices

Q: Will there be a new name for the 5-panel DOT test because it will include additional drugs?

A: The DOT still considers this a "5-panel" drug test because there are no new classes, or groups, of drugs. Because all of these drugs are opioids, the test will continue to be referred to as a "5-panel" test. Due to operational considerations, the laboratory testing for codeine, morphine, hydrocodone, hydromorphone, oxycodone, and oxymorphone will be broken out into three different groups in the reporting (*see the example on page 3*). **NOTE:** The order code will change with the new panel.

Q: What are the opiates added to the DOT drug testing panel?

A: All four substances — hydrocodone, hydromorphone, oxycodone, and oxymorphone — are classified as Schedule II semi-synthetic opioids under the Controlled Substance Act. They are prescribed to treat moderate to severe and chronic pain and have a high potential for abuse.

- According to the Drug Enforcement Administration (DEA), "hydrocodone is the most frequently prescribed opioid in the U.S." Additionally, the Quest Diagnostics Drug Testing Index™ data shows that hydrocodone continues to be one of the most detected opiates in the U.S. general workforce. It is commonly known as Vicodin®.
- Hydromorphone is both a stand-alone drug as well as a metabolite of hydrocodone. It is approximately 8 times more potent than morphine on a per milligram basis. A common brand name is Dilaudid®.
- Oxycodone is a "semi-synthetic narcotic analgesic and historically has been a popular drug of abuse among the narcotic abusing population" according to the DEA. It is commonly known as OxyContin®.
- Oxymorphone is both a stand-alone drug and a metabolite of oxycodone. Common trade names are Opana® and Numorphan®.

Q: What is the difference between the terms opiates and opioids?

A: The term opiate has historically meant a psychoactive substance found in or derived from the opium poppy and that share a number structural characteristics. Opioid is a more modern term and includes naturally occurring (e.g. morphine), semi-synthetic (e.g. oxycodone), and synthetic (e.g. fentanyl) substances as well as antagonists (e.g. naloxone) that interact (bind) with the opiate receptor in the body. In the context of the new DOT regulations, "opioids" refers to six specific opioid drugs included in the DOT panel.

Q: Has Quest Diagnostics made any recent changes to its opiates panel?

A: Yes. We began using a new reagent/assay in April 2017 that is more sensitive and specific for detecting hydrocodone, and hydromorphone in our semi-synthetic opiates immunoassay screening (initial) test. We now use the Thermo Scientific™ DRI® Hydrocodone Assay with a 300 ng/mL cutoff to screen for hydrocodone and hydromorphone in these urine drug test specimens. This enhancement offers a greater ability to detect these specific opiates. We continually fine-tune our lab processes to reflect the latest science, technology, and regulations.

Q: What is MDA?

A: MDA is short for methylenedioxyamphetamine, an amphetamine-like designer drug.

Q: What is MDEA?

A: MDEA is short for 3,4-methylenedioxyethylamphetamine, an illicit substance chemically similar to MDMA (ecstasy). There are very few drug tests that test positive for MDEA according to workplace drug testing data.

Q: Why was the pH cutoff changed in the new regulations?

A: The new DOT guidelines changed the lower pH cutoff from 3 to 4 to better identify an adulterated urine drug test specimen that is not consistent with normal human urine.

Q: Will all Quest Diagnostics collection sites be trained on the new DOT shy bladder rules?

A: Yes. Collectors at every Quest Diagnostics drug testing collection site are trained and well-versed in the latest DOT policies and procedures. These new rules clarified and emphasized that the collector should discard any initial urine collection specimen that was questionable (e.g. due to temperature or suspected tampering) when a shy bladder (the inability to urinate) event develops during the subsequent direct observation collection. We comply with the DOT's Urine Specimen Collection Guidelines, which include strict protocols for how to handle shy bladder when conducting a DOT urine drug test. We will continue to follow the steps outlined in new regulations.

Q: Will the d,l-isomer (D&L) change in the new DOT regulations?

A: Medical Review Officers (MROs) will be authorized to request d,l-isomer testing of both amphetamine and methamphetamine.

Q: Will the test panel codes change for DOT testing?

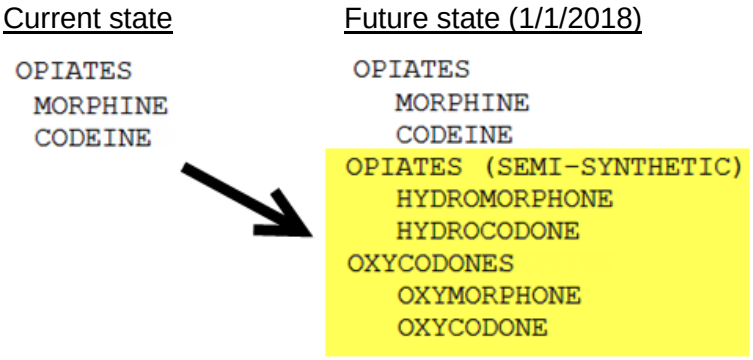
A: Yes, the order codes for both DOT and DOT look-alike testing will change due the changes in test analytes (components).

Q: Will my DOT look-alike drug test panel change on January 1, 2018?

A: No, not automatically. This new regulation only impacts automatic changes made to the DOT drug testing on January 1, 2018. If you would like your non-regulated panel, or DOT look-alike panel, to mirror the new DOT drug test panel, please contact your Sales or Account Management representative to make these changes.

Q: Will results reporting for the DOT and DOT look-alike panels change for clients using the new panel?

A: Yes. As a part of these changes, we will report hydrocodone and hydromorphone under a new header class called "opiates (semi-synthetic)." Added to the panel will be an oxycodones 100 ng/mL screen header class with oxycodone and oxymorphone reporting under that class. See a reporting example below:



Q: When will the Federal Custody and Control Form (CCF) change to mirror the changes made with the new DOT regulations?

A: Federal CCF forms used for DOT drug testing will not change until after January 1, 2018. (We expect the new Federal CCF to be available in early 2018.) Customers can continue to use the old (2014) Federal without issue until June 30, 2018.

Q: Can I use electronic Custody and Control Forms (eCCF) for DOT drug testing?

A: Yes and we encourage you to do so. The eCCF process helps to bear the administrative burden and the online form is available today, at no additional cost. Benefits of eCCF include fewer data-entry and legibility issues, less paper to manage, and improved overall efficiency. Get started with eCCF.

Q: Will I need to make changes or updates to my IT systems?

A: Yes. An EDI (Electronic data interchange) notification will be sent on Friday, December 1, 2017. Clients with DOT drug testing accounts will receive information that outlines the IT changes needed to implement the new regulation changes by January 1, 2018. The packet will also include examples of positive and negative drug test results to help ensure a seamless transition. For any technical questions, please contact us at DGXLENESImplementation@QuestDiagnostics.com.

Q: Will Quest Diagnostics implement a price change associated with this upgraded prescription opiates panel?

A: Adding more drugs to the panel and thereby increasing the volume of confirmatory testing will both incur additional expenses. That said, until our laboratories have data around the scope of the impacts, a pricing change would be premature. Our intent is to evaluate positivity data, assay consumption, instrument and personnel utilization, and other potential impacts associated with these Federal regulation changes before making any decisions that will impact the prices of our testing. We anticipate taking the first quarter of 2018 to conduct this analysis, after which time we will be better informed as to the fees we will pass along associated with this upgraded panel.

Q: Whom should I contact with questions about DOT drug testing?

A: Contact your Sales or Account Management representative for more information or contact our National Customer Support Center at www.EmployerSolutions.com/Support or 1.800.877.7484.

