

Synthetic Substitution: Identifying Non-Urine Substances Amidst Medication Compliance Testing

Healthcare providers rely on medication compliance test results to assist in measuring compliance and establishing recent substance use. Providers must remain aware of specimen substitution attempts to avoid misuse and diversion going unidentified. Aegis has developed an expanded validity measure called BioDetect to assist with identification of substituted and synthetic urine specimens. Through the identification of unique markers expected in human urine, healthcare providers will have greater insight into patient's medication adherence.

Ongoing Trends in the Opioid Epidemic

The U.S. Opioid Epidemic has received a great deal of attention in recent history, and it has been well characterized in both peer-reviewed publications and by organizations like the U.S. Department of Health and Human Services (HHS). Data accumulated by HHS from 2019 showed that over 1 million individuals had an opioid use disorder in the past year, over 10 million individuals misused prescription opioids, and over 70,000 individuals died from drug overdose.¹ Though progress has been made over the past few years to curtail the epidemic, it has been stymied by the COVID-19 pandemic and has led to an unfortunate uptick in overdoses and hospitalizations secondary to opioid use.² Growing availability of novel psychoactive substances (NPS), including designer opioids, has further complicated this issue, as use of substances of varying concentrations and strengths can significantly increase the risk for overdose when taken in combination with prescription drugs. The Opioid Epidemic is particularly impactful on two populations: those requiring chronic opioid therapy to manage debilitating pain and those suffering from opioid use disorder. Identification of appropriate medication use, substance misuse, and medication diversion is of particular importance in each of these populations and is a key to both patient care and mitigation of risk for opioid overdose.

Identifying Medication Use and Misuse

Healthcare providers have a variety of tools at their disposal for identifying at-risk patients that are being treated for chronic pain, opioid use disorder, and substance use disorder. Objective monitoring of recent use of prescription or non-prescription substances through use of urine or oral fluid testing is key to identifying prescription adherence, unreported substance use, medication diversion, or sample adulteration. Studies on toxicology findings across a variety of patient populations that include both presumptive and definitive test methodologies have demonstrated a significant rate of unexpected test results.^{3,4,5,6,7,8,9} Unexpected results can assist providers in determining causes of non-adherence, improve continuity of care through identification of medications prescribed by other providers, and assist in patient risk stratification through identification of aberrant behaviors. Unfortunately, limitations in presumptive testing technologies (e.g., false positive, false negatives)^{10,11,12} or use of non-urine substances, such as sample substitution with synthetic urine, to mask aberrant behaviors may complicate interpretation of results. When the latter occurs, medication non-adherence and substance use may go unnoticed, and patients may be at risk for negative outcomes.¹³

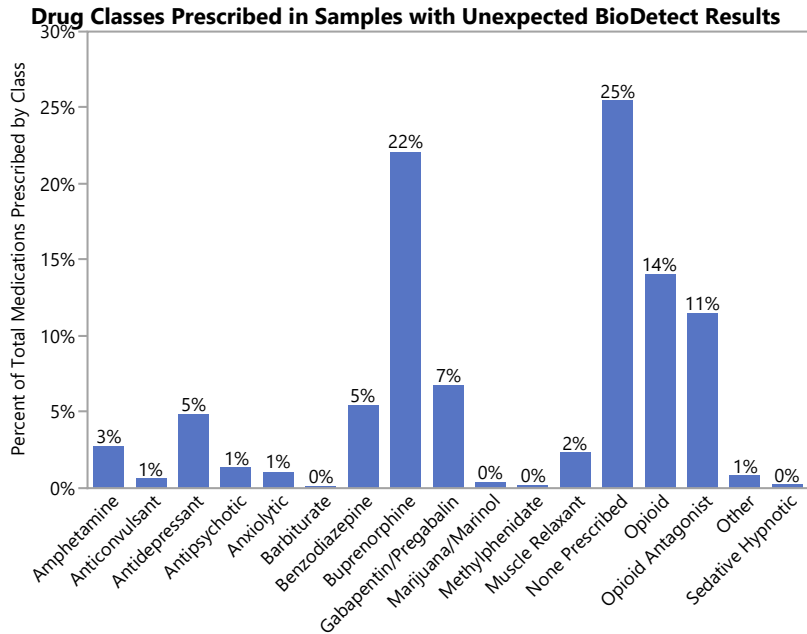
Overview Of The Synthetic Urine Market

Individuals utilize many techniques to adulterate a urine specimen and mask substance use and medication diversion from healthcare providers. Methods including dilution with assorted fluids or the addition of various chemicals, such as oxidative/reductive substances or detergents, are most often discovered using common specimen validity testing.¹⁴ Synthetic urine, also known as "fake urine,"¹⁵ is a booming business. Products used to assist with urine substitution are widely available for purchase on the internet. For example, a 3oz premixed urine kit with two heat pads and heat activator powder is available for \$100, and it can be purchased in addition to a practice kit for \$35 and a leg belt that can be used to hide the synthetic urine sample for \$24.95.¹⁶ There are stash undies for \$24.95, stash leg straps for \$19.95, and synthetic urine belts for \$34.95.¹⁷ Synthetic urine can be purchased for a wide range of prices and in a variety of volumes (\$15.50 for 10 mL¹⁸ to \$360 for 5.3 gallons of synthetic urine concentrate).¹⁹ These products are even available for purchase on seemingly reputable sites such as E-bay²⁰ and Amazon²¹. Directions are often included that explain everything from "how to use fake pee,"²² to tricks for "how to keep it the same warmth as pee,"²³ and "how to pass self-administered urine tests."¹⁵ Synthetic urine has become alarmingly accessible, and its use by patients can create significant difficulties for providers when attempting to accurately assess recent prescription or non-prescription drug use.

BioDetect Testing at Aegis

Aegis has recently enhanced testing with unique specimen validity markers to assist with identification of samples that are not consistent with routinely analyzed human urines. Individuals in various treatment settings may rely on urine substitution as one of several different methods of adulteration to "pass" a urine drug test. Individuals may substitute a specimen to hide the use of non-prescribed substances or may spike a prescribed drug into the substituted specimen in an attempt to appear compliant with prescribed medications. Synthetic urine is one mechanism of substitution. Synthetic urine is typically manufactured to include creatinine, specific gravity, appropriate pH, and other specimen validity parameters in the samples.²⁴ This can create difficulty for providers, who are utilizing routine specimen validity testing while monitoring patients, to adequately identify aberrant patient behaviors. Aegis's BioDetect test includes unique markers that are expected to be present in routinely analyzed human urine. Thus, when an authentic urine specimen is provided, it is expected that the components of the BioDetect test will be present. BioDetect testing is included on all urine samples to improve a provider's ability to identify

samples that are not consistent with routinely analyzed human urine. Similar to routine specimen validity testing, this is performed at no cost to patients or providers. To date, BioDetect testing has been included in over 200,000 urine samples with ~0.7% of samples reporting with unexpected results. The chart below demonstrates the frequency of prescribed medication by class in samples with unexpected BioDetect Results.



Aegis has a long history of developing clinically innovative testing solutions that give providers insight to make better treatment decisions. BioDetect was developed to identify samples that are not consistent with routinely analyzed human urine. Using BioDetect to identify these specimens provides clinically relevant information to the healthcare provider seeking to make more informed treatment decisions and improve patient outcomes. Manufacturers of synthetic urine are bolstering techniques to “beat” a drug test, including supplementing products with creatinine in order to pass routine specimen validity testing. At-risk patients receiving treatment for chronic pain, opioid use disorder, or substance use disorder may seek to mask non-prescription drug use or medication diversion through urine sample substitution. Aegis continues to provide clinicians greater insight regarding potential substitution to mitigate risk and make treatment decisions with greater confidence.

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