



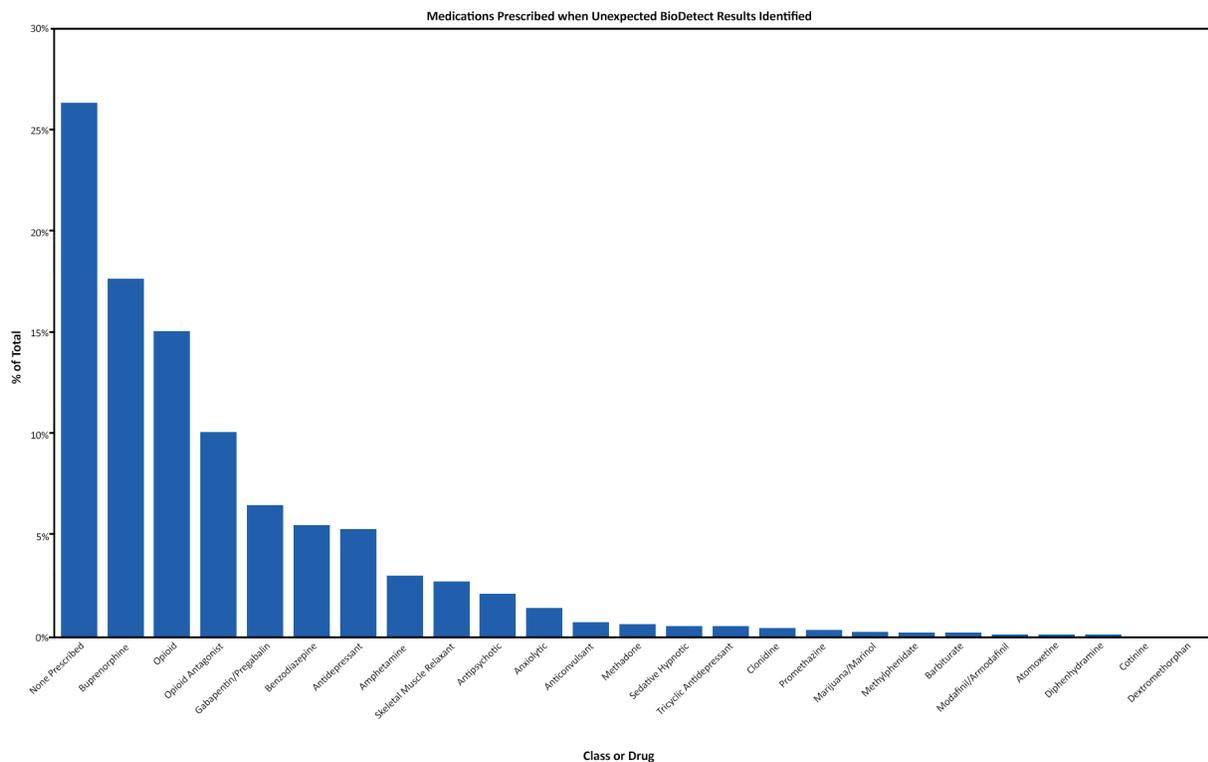
Clinical Update: May 2022

BIODETECT™: IDENTIFYING NON-URINE SUBSTANCES

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 have greater insight into an individual’s medication adherence.

BioDetect™ Testing at Aegis

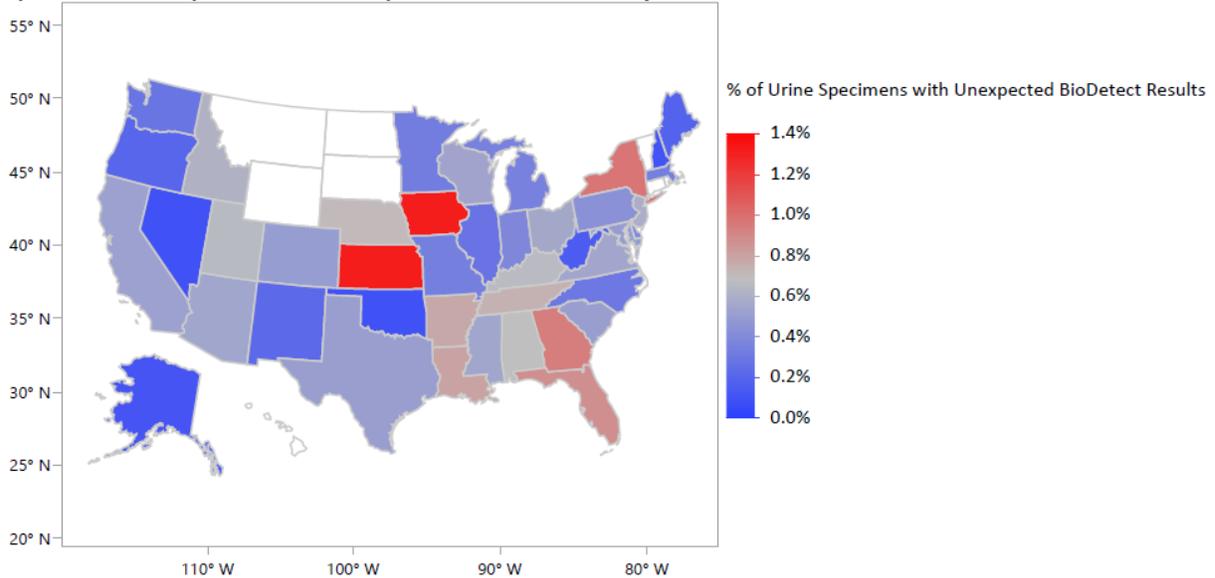
Individuals may substitute a specimen to mask the use of non-prescribed substances or may spike a prescribed drug into the substituted specimen in an attempt to appear compliant with prescribed medications. This can create difficulty for providers, who are utilizing routine specimen validity testing, to adequately identify aberrant behaviors. Synthetic urine is one mechanism of substitution and is typically manufactured to include creatinine, specific gravity, appropriate pH, or other specimen validity parameters in the samples.¹ 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. The chart below demonstrates the frequency of prescribed medication by class in samples with unexpected BioDetect™ Results at Aegis. The data includes a total of 836,785 urine samples collected from February 2021 to March 2022, with 4,871 (0.6%) samples reporting with unexpected BioDetect™ results.





The following illustration categorizes the same data set by the percent of urine specimens with Unexpected BioDetect™ Results by state. States with overall low sample volume were excluded.

Proportion of Urine Specimens with Unexpected BioDetect Results by State



Individuals in various treatment settings may rely on urine substitution as one of several different methods of adulteration to “pass” a urine drug test. 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 an individual receiving treatment may be at risk for negative outcomes.² BioDetect™ provides information to identify aberrant behaviors to both guide risk stratification and determine causes of non-adherence.³

Pain Management

The results below represent an Aegis urine sample in a pain management setting that reflect noncompliance with prescribed medications. The sample has concomitant unexpected BioDetect™ results demonstrating inconsistency with routinely analyzed human urine informing the provider that the drug results cannot be applied to objectively assess medication compliance. The unexpected BioDetect™ results provide direction to identify diversion or substance use and to determine causes of non-adherence.³ The Opioid Epidemic is particularly impactful on those requiring chronic opioid therapy to manage debilitating pain, where medication non-adherence and substance use may go unnoticed, and individuals receiving treatment may be at risk for negative outcomes.² Data accumulated by the U.S. Department of Health and Human Services (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.⁴ 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.⁵ 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. As providers navigate this landscape, identification of sample substitution or synthetic urine is of particular importance to guide their treatment decisions.



Medication(s) Prescribed

Alprazolam, Amphetamine, Gabapentin, Hydromorphone, Tramadol

Medication Compliance

| Drug and/or Metabolites | Result Interpretation | Result | Comment |
|-------------------------|-----------------------|------------|--|
| Tramadol | NON-COMPLIANT | <100 ng/mL | Test result indicates patient may not be taking drug prescribed. |
| Hydromorphone | NON-COMPLIANT | <100 ng/mL | Test result indicates patient may not be taking drug prescribed. |
| Gabapentin | NON-COMPLIANT | <5 mcg/mL | Test result indicates patient may not be taking drug prescribed. |
| Alprazolam | NON-COMPLIANT | <50 ng/mL | Test result indicates patient may not be taking drug prescribed. |
| Amphetamine | NON-COMPLIANT | <250 ng/mL | Test result indicates patient may not be taking drug prescribed. |

| Result | Comment |
|--------------|--|
| Not Expected | Please contact the Clinical Team at 1-877-552-3232 for more information. |



Specimen Validity Testing

| Tested For | Comment | Result | Normal Range |
|------------|---------|------------|----------------|
| Creatinine | NORMAL | 76.5 mg/dL | 20 – 370 mg/dL |
| pH | NORMAL | 7.17 | 4.5 - 9.0 |

Opioid Use Disorder (OUD)/Substance Use Disorder (SUD)

The Aegis report below illustrates a urine sample collected at an SUD clinic with both unexpected BioDetect™ results and noncompliance of prescribed buprenorphine and naloxone. The individual that submitted this sample may have substituted the specimen in an effort to mask the presence of another ingested substance. Without BioDetect™, the possibility of relapse in addition to noncompliance may not have been considered and the risk for negative outcomes may have been missed. Due to the inclusion of the BioDetect™ testing on this sample, the provider had additional information to guide risk stratification and to consider possible referral for additional treatment. Identification of appropriate medication use, substance misuse, and medication diversion is of particular importance and is a key to both effective care and mitigation of risk for overdose. The rate of increase in adults in the US with substance use disorder is startling as it doubled from 20.4 million people in 2019 to 40 million people in 2020.⁶

Medication(s) Prescribed

Buprenorphine, Naloxone

Medication Compliance

| Drug and/or Metabolites | Result Interpretation | Result | Comment |
|-------------------------|-----------------------|-----------|--|
| Naloxone | NOT PRESENT | <10 ng/mL | Test result indicates patient may not be taking drug prescribed. |
| Buprenorphine | NOT PRESENT | <1 ng/mL | Test result indicates patient may not be taking drug prescribed. |

| Result | Comment |
|--------------|--|
| Not Expected | Please contact the Clinical Team at 1-877-552-3232 for more information. |



Specimen Validity Testing

| Tested For | Comment | Result | Normal Range |
|------------|---------|------------|----------------|
| Creatinine | NORMAL | 66.3 mg/dL | 20 – 370 mg/dL |
| pH | NORMAL | 7.15 | 4.5 - 9.0 |



Behavioral Health

Many individuals with mental illness fail to take their medication because of their lack of awareness of their illness or due to side effects of the prescribed therapy. The noncompliance to prescription medications represented below on the Aegis urine sample in addition to the unexpected BioDetect™ results is alarming. Substitution of the urine sample may mask self-medication with a non-prescribed substance, diversion, or use of illicit substances, and if not recognized, could cause serious harm. Action can be taken to provide assistance to the individual that submitted the sample and the relationship between this individual and the provider can be enhanced when the results are used to improve communication.⁷ Mental illness is becoming more prevalent as 53 million adults in the US experienced any mental illness (AMI) in 2020⁶ compared to 45 million adults in 2016⁸, and 32.8% of American adults had at least one major depressive episode in 2020 compared to 7.8% of adults in 2019.⁹ The information offered by BioDetect™ allows providers to appropriately assess and treat each individual specifically in the behavioral health setting.

Medication(s) Prescribed

Duloxetine, Hydroxyzine, Quetiapine

Medication Compliance

| Drug and/or Metabolites | Result Interpretation | Result | Comment |
|-------------------------|-----------------------|-----------|--|
| Duloxetine | Inconsistent | <5 ng/mL | Test result indicates patient may not be taking drug prescribed. |
| Quetiapine | Inconsistent | <10 ng/mL | Test result indicates patient may not be taking drug prescribed. |
| Hydroxyzine | Inconsistent | <50 ng/mL | Test result indicates patient may not be taking drug prescribed. |

| Result | Comment |
|--------------|--|
| Not Expected | Please contact the Clinical Team at 1-877-552-3232 for more information. |

Specimen Validity Testing

| Tested For | Comment | Result | Normal Range |
|------------|---------|----------|----------------|
| Creatinine | NORMAL | 50 mg/dL | 20 – 370 mg/dL |
| pH | NORMAL | 7.91 | 4.5 - 9.0 |

BioDetect™ Testing at Aegis

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 treatment 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. Synthetic urine has become alarmingly accessible and at-risk individuals receiving treatment for chronic pain, opioid use disorder, substance use disorder, or behavior health 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.

NOTICE: The information above is intended as a resource for health care providers. Providers should use their independent medical judgment based on the clinical needs of the patient when making determinations of who to test, what medications to test, testing frequency, and the type of testing to conduct.



References:

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