

## Capturing the Truth – Quality-Driven Laboratory Results to Improve Patient Outcomes

Each day clinical drug test results play a pivotal role in patient diagnosis and treatment. Patients, their families and physicians depend on these results with the expectation that the data presented are complete, quality-driven, accurate, and reliable. These words are frequently used to describe a test but what do they really mean? Does the result represent the truth, the entire “picture”; i.e., exactly what you needed when the test was requested? When reviewing and interpreting a laboratory report, it is important to understand that not all labs are equal in the quality of data they report. Quality measures must be in place to mitigate false negatives and false positives; the test must be complete and clinically relevant; and objective tools should be utilized to provide enhanced specimen validity testing to help physicians recognize if the sample submitted has potentially been substituted.

When considering all testing options and pathways, it is important to critically evaluate the differences between testing methods and how the results could impact clinical decisions. Presumptive testing methods frequently report the presence of a medication in a class-based manner, while definitive testing is specific to the ingested substance. The determination of testing method used for a specimen may be guided by asking the following questions: What do I need to identify for this patient, and will the testing method that I select provide me with the appropriate information to make an adequate treatment decision? In scenarios where the risk of substance use has been determined by the physician to be low, presumptive testing, indicative of use of a class of medications, may be adequate for decision-making. However, if there are concerns about use of a substance outside of what is being prescribed and class-based presumptive identification does not provide the specificity needed, then definitive testing is necessary. For example, presumptive testing for benzodiazepines in patients with risk for substance use may provide information about the presence of this class of medications, but is unable to identify the specific compound ingested, the quantitative values for parent drugs and metabolites, or ingestion of non-prescription substances such as designer benzodiazepines. Providers must evaluate the limitations of testing methods and consider how patient management may change based on the type of test selected and the results received.

When comparing laboratories, it is important to understand that not all definitive testing methods are equal. Perhaps the name of the assay and the check box selected to request the test looks similar but the name may not necessarily reflect the breadth and depth of the offering. Recall the situation mentioned above related to benzodiazepine results. If a provider determines that definitive testing is necessary for patient assessment, is the test menu that is available sufficient for identifying substance use? If the definitive testing is following an unexpected presumptive positive for benzodiazepines, and it is not inclusive of designer benzodiazepines – which along with many other novel psychoactive substances are becoming increasingly available – then it is possible that use of a dangerous substance may go undetected. Therefore, the patient report would go out negative and in this situation would be misleading to the physician and could potentially result in great harm to the patient. The breadth of the test menu should be critically evaluated and considered alongside the quality of data presented. Unfortunately, in today’s world where novel compounds are ravaging the United States and leaving in their wake patients suffering from addiction and increased morbidity, a comprehensive “up-to-date” test menu can be the difference between having an opportunity to treat and help a patient recover versus a human tragedy.

It is also important to recognize that analytical methods are not all developed equally. “Plug and play” methods often do not account for interferences observed in highly complex specimens. In order for a laboratory test to add meaningful clinical information, high-functioning method development coupled with ongoing quality measures must be in place. Methods must be developed with attention to detail, robustness, and the wherewithal to know that ongoing evaluation through quality controls, internal standards, internal audits, and external audits from accrediting bodies are necessary for a lab and the requesting physician, to know with confidence that valuable data is being reported.

Aegis recognizes the need for quality care. We are committed to offering a test menu that is responsive to the needs of patients and the clinicians who care for them. Most critically, we are willing to invest the necessary resources to update and stay abreast of the tsunami of synthetic and novel compounds ravaging our community. We recognize the importance of updated test offerings and that a single missed novel psychoactive substance could potentially result in devastating consequences. We are alert to sample substitution. We have implemented an enhanced specimen validity test method called BioDetect™. This one-of-a-kind test, performed on every urine sample submitted to our laboratory, alerts physicians that approximately 1 of every 200 specimens submitted are not consistent with routinely analyzed human urine, indicating potential sample substitution.

Aegis is taking action. We engage with and support people – patients, clinicians, and families – we do not want anyone to need to second-guess if test results include the proper analytes or to have any doubt whether method quality was paramount when developing the test. The opioid epidemic needs support from all areas. Measures must be taken to ensure that the lab results received do not remain a substantial obstacle to improving the quality and effectiveness of needed treatment and support. Together, we can make real strides in limiting and potentially ending the nation’s overdose death and drug epidemic. Now is the time to take action, before it’s too late.

### References:

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