



Given that part of the agenda of the current CLIAC meeting is dedicated to the “Role of the Laboratory in the Opioid Crisis”, Evanostics, LLC appreciates the opportunity to make a statement about a product that has the potential to play a role in addressing key aspects of the Opioid Crisis.

Evanostics is developing a diagnostic system for presumptive testing of major drugs of abuse analytes and is intended for use in the clinical management of Opioid Use Disorder and chronic opioid pain patients. Our product will be a Point of Care (POC) system consisting of a small tabletop analyzer and proprietary test cartridge combining sample collection with highly sensitive multiplex assays. Our initial product will be a ten-test multiplex assay, including assays such as fentanyl, buprenorphine, methadone and heroin required on the front lines of detecting drug addiction and facilitating treatment. The system is designed to help drive medication compliance conversations between clinicians and patients at the POC and assist in the rapid triage of suspected overdose and/or opioid withdraw symptoms in urgent care settings. The product has the potential to be used in alternate sites such as physician offices, Telemedicine, clinics and multiple other primary care sites. In addition, the system could help facilitate widespread adoption of MAT treatment, a major goal of public health goal for its documented effectiveness in reducing opioid overdose deaths.

Traditional methods of drug testing, such as urine cup or strip testing, provide rapid results, but often lack sensitivity and specificity for critical assays such as fentanyl. On the other hand, some physicians are reluctant to perform in-office testing using traditional laboratory equipment and reagents as it does not offer patients real-time results. The expected benefits of lab quality results, comprehensive assay panel, unambiguous test results available for transfer to patient records and automated ease-of-use are unique to the Evanostics product.

Evanostics feels it is important to reveal the existence of this product so that it can potentially be included in discussions about clinical diagnostic tools to combat the Opioid crisis.

Evanostics would also appreciate the opportunity to be included in the discussion surrounding the Nontraditional Testing Workgroup, especially relating to models such as Telemedicine and Toxicology.

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