January 8th, 2021

Submitted via regulations.gov.

RE: Docket No. NHTSA-2020-0102 A notice by the National Highway Safety Administration's "Request for Information: Impaired Driving Technologies"

Thank you for the opportunity to provide comment on impaired driving technologies. I am writing on behalf of Evanostics. Evanostics is a medical device company located in Silicon Valley. Evanostics platform is a complete testing system consisting of a small benchtop analyzer and a single-use test cartridge that collects oral fluid and performs multiplexed fluorescence immunoassays for multiple analytes in 15 mins. One of the many applications of the platform is drug and alcohol testing to detect driving under the influence.

Technology

Using its proprietary technology, Evanostics has developed a platform which can simultaneously detect small amounts of multiple antigens and produce lab-quality results within 15 minutes. The components of the platform are a benchtop analyzer and a single-use cartridge with a photonic biosensor chip.

TEST CARTRIDGE WITH TWO SIMULTANEOUS ORAL FLUID COLLECTIONS

SMALL DESKTOP ANALYZER
1. Electronic results transfer to patient medical record
2. Touchscreen operation

Collection 1
For Screening Test

Collection 2
For Confirmation Test

Opiate Class
Oxycodone
Fentanyl
Heroin
Methadone
Buprenorphine
Benzodiazepines
Amphetamines
Cocaine
THC (marijuana)
Alcohol

PHOTONIC BIOCHIP SENSOR
1. Comprehensive test menu

Benchtop analyzer: The automated, small-footprint analyzer produces lab-quality results in minutes. Instrument size is 17x12x11 inches and weight is around 20 lbs. The instrument can be battery operated and can be placed in the police officer's car to test for drugs and alcohol

onsite. The future versions of the analyzer will have a smaller footprint making it easier to carry around and test for impaired driving.

Cartridge: The cartridge collects two saliva samples simultaneously. The collection is as simple as using a thermometer. One specimen is used for point of care analysis and the other can be send to laboratory for confirmation if needed. Kinetic assays are performed using automated fluid handling. No sample preparation is required therefore minimal training is needed to run the test. The cartridge can also be adapted to collect other bodily fluids.

Photonic biosensor chip: Distinct binding reactions occur in predefined locations on the chip, enabling the system to quickly perform multiple, simultaneous tests with a small volume of saliva. Up to 32 simultaneous tests can be performed using a small amount of saliva (<1 mL)

The Problem

While traditionally driving under the influence involved alcohol, nowadays more and more people are being arrested for driving under the influence of drugs. According to NHTSA drunk driving is on the decline while drugged driving is on the rise. This shift comes as the number of states decriminalizing recreational marijuana as well as medical marijuana continues to grow. Law enforcement, traffic safety professionals, criminal justice professionals, and social advocates have worked together to address alcohol-impaired driving for decades, dramatically reducing its prevalence and saving tens of thousands of lives. Unfortunately, far less time and resources have been devoted to an equally significant and related problem: driving under the influence of drugs (DUID).

In fact, the National Highway Traffic Safety Administration (NHTSA) did not test biological samples from drivers for drugs during the National Roadside Survey (NRS) until 2007 when data showed that 16.3 percent of weekend nighttime drivers tested positive for drugs; marijuana accounted for almost half of the positives. To put this in perspective, 12.4 percent of weekend nighttime drivers tested positive for alcohol, and less than 2.2 percent of weekend drivers tested above the legal limit (0.08) for alcohol [1].

Opportunity in Oral Fluid

Urine is the most common method to test for drugs. However, urine sample collection has limitations for onsite testing:
- Easy to adulterate.
- Observed collection of urine is not feasible onsite.
- The window of detection time of drugs after use in urine is 2-4 days. Therefore, there is no relationship between drug concentration and impairment.

The window of detection time of drugs after use in blood is within minutes to hours. Therefore, blood is a better indicator of drug concentration and impairment. However, blood has its own limitations for onsite testing:

- The collection of blood is invasive.

- Trained personnel need to be present to conduct the test.

The results of the 2007 National Roadside Survey of Alcohol and Drug Use by Drivers showed a 97 percent agreement between blood and oral fluid when collected simultaneously and tested for drugs, indicating that oral fluid is a viable alternative to blood for the detection of drugs in drivers [1].

Oral fluid is ideal for onsite testing for drugs and alcohol for impaired driving because:

- Noninvasive oral fluid collection is ideal for onsite collection.
- Observed collection decreases the risk of adulteration of the sample.
- The window of detection time of drugs after use in oral fluid is within minutes to hours. Therefore, oral fluid is a better indicator than urine of drug concentration and impairment.

Our solution

Evanostics' product combines an oral-fluid collection with a digital point-of-care test to detect 10 drug classes from a single collection in 15 minutes. Two simultaneous samples are collected, one for point of care analysis and then other can be send for confirmation testing to a laboratory if needed. The product can multiplex up to 32 test targets including alcohol. This product has been field-tested for usability in a pain and addiction management clinic, and the beta design is ready.

Product Attributes	
Detection Technology Description	Immunodiagnostics
POC CLIA-waived	Easy to use, 3-steps from collection > reporting. Aims to be CLIA waived. Can be performed by a minimally skilled operator and does not require sample preparation
Time-to-Result	15 min from collection to reporting
Benchtop	Instrument size is 17x12x11 inches. Weight is around 20 lbs. Next version will have a smaller footprint
Portable	Easy to carry; powered with AC power or battery
Touchscreen Interface	Intuitive GUI
Results Reporting	POS, NEG, INVALID. The test results are algorithm based and are objective
Temperature limitations	TBD
Multiplex	The current design of photonic biosensor chip contains 32 wells can accommodate at least 10 distinct assays. Currently there are 10 drug classes with low cutoffs including fentanyl. Alcohol can be added to the test menu if needed

Dual collection	Collection device with dual collection in 5 mins. One sample is used for the rapid test and the other sample is for laboratory confirmation test as needed.
Vehicle integration feasibility	The instrument is portable and can be placed in the police car
Maintenance	Simple if any - 12months. We have automated calibration tools to verify performance after maintenance
Bar Code Scanning	QR code for Patient ID and Cartridge ID
System Connectivity	After each test, the results are automatically uploaded on the cloud.
Part life in the automobile environment	TBD
Cost of the unit	Instrument = 0$ Each test = 30$

Competitive advantage

Highly Multiplexed: The system is currently multiplexed for 10 drug classes. It can be multiplexed for up to 32 test targets including alcohol with a small sample of saliva(<1mL).

Two simultaneous sample are collected, one sample is for the point of care test and the other is for confirmation test if needed. The cartridge is designed to ensure that the confirmation sample is ready to be shipped if needed. No additional shipment preparation is needed.

Comprehensive test menu with low cutoffs: Lower cutoff than any of its competitors in oral fluid testing. The only product to have Fentanyl on its test menu. The cutoff levels can be changed according to the changing government regulation on impairment. The current cutoffs are listed below.

Drug class	Cutoff(ng/ml)
THC	5
BZO	1
BUP	4
FEN	0.25
6AM	2
COC	15
MOR	30
OXYC	30
MET	25
MTD	10

Future Proof: The test menu can be modified to the add new drugs as and when needed. The test menu can be modified to a cutoff required by the law.

Minimal training required to conduct the test; therefore, it can be used onsite.

Fast turnaround: Results in 15 minutes

Technology Readiness Level (TRL)

The product has application in multiple markets.

- Pain and addiction management clinics – TRL 7
- DUI – TRL 6

A field trial has been conducted with the product in pain and addiction management clinic. Therefore, it is at TRL 7. We plan to do a field trial for the DUI in June 2021.

The field trial in pain and addiction management clinics was a success. The field trial was done with N= 50 patients. The users were happy because the test was easy to perform and was a hassle-free experience. The results were accurate with over 95% specificity and 90% sensitivity. We aim to do multiple field trials and validation studies to launch the product for DUI in 2022.

Product launch

The product will be ready for DUI in Q3 of 2022.

Conclusion

Evanostics product can test for alcohol and 10 classes of drugs with a small sample of oral fluid (<1mL) in 15 minutes. The small benchtop analyzer can be placed in the police car and testing for DUI can be performed onsite. The product can be an integral tool for police officers for easy, reliable, and fast onsite testing to remove ambiguity in identifying impaired drivers. We are prepared to assist NHSTA with any additional information, if needed. Please contact Ashutosh Shastry, PhD, President & CEO of Evanostics, with any questions via email at ashastry@evanostics.com or phone at 650-308-4154.

Bibliography

[1] J. H. Lacey, T. K. Baker, D. F. Holden, R. B. Voas, E. Romano, . A. Ramirez, K. Brainard, C. Moore, P. Torres and A. Berning , "2007 National Roadside Survey of Alcohol and Drug Use by Drivers:," National Highway Traffic Safety Administration , Washington, DC , 2009.