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New FDA Approvals, Guidelines and Letters Address Zika Testing

After garnering Food and Drug Administration (FDA) approval, a diagnostic test for the Zika virus is being distributed to certified labs by the Centers for Disease Control and Prevention (CDC) in March.

The test, called the CDC Zika IgM Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA)—is regarded as the first FDA-approved commercial diagnostic test for Zika.

The CDC, which made an emergency use request for the test, is sharing it with labs in the Laboratory Response Network, a group of domestic and international labs that respond to public health emergencies. Hospitals and other providers seeking the tests for patients need to work through CDC and CDC-certified labs. But while this test got the green light by the FDA, the agency wrote other test-makers to challenge their Zika tests, seeking agency review of their design, validation and performance.

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State Laws, Industry Attention Needed to Advance Roadside Marijuana Testing for Drug-Impaired Driving

With the movement to legalize marijuana use for medical or recreational purposes gaining traction, states are calling for improved standards for marijuana testing, particularly as it relates to measuring drivers' drug-related impairment. But, the association between legal definitions of detection and the capabilities of tests to judge impairment is complex and not fully understood.

Medical marijuana is legal in 23 states in the U.S., while recreational use of the drug is legal in Alaska, Colorado, Oregon, Washington, and Washington, D.C. An additional 16 other states have decriminalized possession of small amounts of marijuana. This changing legal landscape, combined with recent studies assessing the prevalence of drivers with detectable drugs in their blood, indicate that an increasing number of drivers are using marijuana. But, local and state law enforcement departments don't have the necessary tools and standards to determine if drivers are impaired.

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New FDA Approvals, Guidelines and Letters Address Zika Testing, *from page 1*

Finally, on March 1, the FDA issued recommendations to reduce risk of Zika virus transmission by human cell and tissue products. And in mid-February the agency advised how to reduce risk of Zika virus transmission through blood transfusions. Here is an overview of the FDA activities regarding new tests and the agency's recent guidance.

New Zika Test by CDC Detects Antibodies

How the test works: The Zika MAC-ELISA, developed by the CDC, works by detecting antibodies the body, when infected, makes to fight the Zika virus. The test can detect antibodies in blood—immunoglobulin M (IgM)—beginning four to five days after onset of symptoms through about 12 weeks, the CDC said.

"Our assay is laboratory-developed test, performed by qPCR, to determine the presence of the virus. We are able to do this specifically without cross-reacting with other potential viruses such as dengue or West Nile."

— Eddie Moradian, PhD, CEO, MD Biosciences

Zika and its symptoms: Zika, a disease caused by the Zika virus, spreads to people primarily through the bite of an infected Aedes species mosquito, according to the CDC, which said sexual transmission is also possible. Diagnosis is challenging because about 80% of people show no signs of the disease, points out the FDA, adding that mild symptoms that may appear two to 12 days after a mosquito bite are low-grade fever, joint and muscle pain, headache and maculopapular rash. The virus has been linked by health care officials with microcephaly (causing an infant's head to be smaller than expected) in babies born to mothers with the infection.

Who needs Zika MAC-ELISA? The blood test is intended for people with a history of Zika symptoms or who have traveled to an area active with Zika, according to a CDC statement. It is being performed by labs experienced in high-complexity testing. Results, too, need to be carefully interpreted because false positives can occur in patients who had similar viruses such as dengue, CDC notes. Also, a false negative result may be reported when blood samples are collected before enough antibodies are available for measurement.

Other Zika Tests

Also, MD Biosciences Clinical and Diagnostic Services Laboratory announced in March a rapid assay to detect the Zika virus in human blood and urine samples. The nucleic acid test, with no relation to MAC–ELISA, is a diagnostic service by MD Biosciences of St. Paul, Minn. The company, after receiving a letter from the FDA, said it "will proceed with the Zika test services following clarification with the FDA regarding any pre-market approval requirements pertaining to this assay. Testing services will not be offered pending this clarification."

"Our assay is laboratory-developed test, performed by qPCR, to determine the presence of the virus. We are able to do this specifically without cross-reacting with other potential viruses such as dengue or West Nile," Eddie Moradian, PhD, chief executive officer of MD Biosciences, told *National Intelligence Report*. The FDA issued a letter to MD Biosciences, Inc. indicating the test "appears to meet the definition of a device" under section 201(h) of the Federal Food, Drug, and Cosmetic Act and should be subject to premarket clearance, approval or Emergency Use Authorization. The letter added that "it is particularly important for the FDA to review information related to your Zika Virus RNA by RT-PCR Assay's design, validation and performance characteristics."

> *"[G]iven what we know about the virus at this point, ... we must address the potential risk of Zika virus transmission by human cells and tissues."*
>
> — Peter Marks, MD, PhD

The FDA has issued similar letters regarding other tests: to First Diagnostic Corporation for its ATFirst's One Step Zika Antibody Test and to Texas Children's Hospital and Houston Methodist Hospital for their Zika Direct Test intended as a rapid diagnostic test. The FDA states in those letters as well the need for the agency to review the "design, validation, and performance characteristics of those tests."

FDA Urges Caution in Donations of Human Cells and Tissues

FDA is intent on reducing risk of transmitting the Zika virus from human cells, tissues and cellular and tissue-based products (HCT/Ps) The agency released March 1 recommendations for handling these donations from living and deceased donors.

"[G]iven what we know about the virus at this point, ... we must address the potential risk of Zika virus transmission by human cells and tissues," said Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research in a statement.

The FDA said people should be considered ineligible for donating HCT/Ps if they were: 1) diagnosed with the Zika virus infection; 2) were in an area with active Zika virus transmission; or 3) had sex with a male with either of those risk factors within the past six months.

As to donations of HCT/Ps from deceased, the FDA advises they not be accepted when the donor had the Zika virus within six months of death.

The FDA points out in its guidance document that HCT/Ps with the highest potential for transmission of the Zika virus are those recovered from living donors. For example, the virus was detected in two men's semen 62 days and 10 weeks, respectively, after onset of symptoms.

FDA Addresses Blood Transfusions

Blood transfusions and risk of Zika virus have also garnered FDA attention. In mid-February, the agency issued recommendations on how to reduce risk in the U.S. The agency said then there are no reports to date of Zika virus in the U.S. blood supply, but the risk exists given how the Zika virus and others like it spread.

Blood establishments, in areas with active Zika virus transmission, need to obtain whole blood and blood components for transfusion from areas of the U.S. without active transmission. Collection and preparation of platelets and plasmas can continue as long as FDA-approved pathogen-reduction device is used.

For those blood facilities in areas without Zika virus transmission, FDA noted importance of deferral of donors at risk of Zika virus for four weeks.

Takeaway: After an emergency request by the CDC, the FDA has approved use of a new tool to diagnose Zika virus. FDA has also promulgated guidelines for reducing risk of Zika virus transmission by human cell and tissues donations and blood transfusions. G2

Cybersecurity and Social Media Lead Compliance Concerns for Health Care Compliance and IT Professionals

In 2014, the Federal Bureau of Investigation warned that the health care industry wasn't prepared for cyber risks. Last year, *National Intelligence Report* reported on a May 2015 Ponemon Institute study that revealed health care-related criminal attacks on data increased 125 per cent since 2010 and were "the leading cause of data breach" in health care, yet most organizations still weren't prepared to respond to this threat to patient information. The authors of the Ponemon report also estimated that such breaches cost the health care industry $6 billion annually, with average costs per breach for individual health care organizations hitting about $2.1 million.

> *"Based on our field research, healthcare organizations are struggling to deal with a variety of threats, but they are pessimistic about their ability to mitigate risks, vulnerabilities and attacks."*
>
> — Larry Ponemon

Just last month, the Ponemon Institute released results of a study, *The State of Cybersecurity in Healthcare Organizations in 2016*, which indicates 48 per cent of health care organizations surveyed have had a cyber incident in the past year that involved exposure or loss of patient information. The Ponemon Institute—a research firm focused on privacy and information management—worked with ESET, a security software developer, on the study which surveyed 535 IT and IT security professionals in small to medium sized health care organizations. "Based on our field research, healthcare organizations are struggling to deal with a variety of threats, but they are pessimistic about their ability to mitigate risks, vulnerabilities and attacks," reported Larry Ponemon, chairman and founder of the Ponemon Institute, in a statement announcing the organization's latest study.

Thus, it shouldn't be surprising that cybersecurity is a top compliance concern among compliance professionals, according to a survey conducted by Health Care Compliance Association (HCCA) and the Society of Corporate Compliance and Ethics (SCCE). In January 2016, HCCA and SCCE surveyed 900 individuals, suggesting 38 potential compliance issues and asking them to pick no more than 10 in answer to the question: "What are the hot topics in compliance you will be focusing on in 2016?" Those surveyed included compliance professionals from many different sectors, including health care.

The results revealed that cybersecurity and cybercrime were the top concern from survey respondents overall. For health care respondents cybersecurity and cybercrime ranked second, behind another internet-related issue—social media compliance risks. The SCCE and HCCA report on the survey reveals the top five responses identified by respondents overall and grouped by employer type. For health care companies other issues making the top five were: "More effective internal investigations," False Claims Act enforcement, and "Creating/Maintaining an ethical culture." For small entities, nonprofits and privately held businesses, cybersecurity and social media compliance risks were most frequently cited issues. Respondents at larger and publicly traded companies, however, placed cybersecurity risks behind third party risks and leveraging compliance to increase efficiency and effectiveness.

These results coincide with data reported by the Ponemon Institute last month. In that study, 81 per cent of organizations surveyed identified patient medical records as the biggest target for hackers and others seeking unauthorized access. The top

threats reported by surveyed entities were system failures, cyber attacks and unsecure medical devices. More than half of those surveyed reported that new technologies relevant to mobile health and big data and cloud storage increased risk to patient information. Other risks of concern included employee negligence and business associate relationships.

Takeaway: Cybersecurity continues to be a significant concern for both IT and health care compliance professionals. G2

AACC Weighs in on Regulation of Laboratory Developed Tests

Another industry trade group has chimed in on the issue of the U.S. Food and Drug Administration's (FDA) intent to regulate laboratory developed tests (LDTs).

The American Association of Clinical Chemistry (AACC) issued a position paper urging the FDA to give up its effort to regulate LDTs and instead strengthen the existing CLIA regulations.

The FDA has proposed regulating LDTs in recent years, raising concerns that the complexity of the tests could put patients in danger if they are not properly interpreted. It has issued proposed guidelines for regulation over the objection of virtually all the laboratory sector.

"Clinical labs have one of the lowest error rates in healthcare, showing that CLIA has done an excellent job of regulating labs so that clinicians get the quality test results they need to make critical decisions about patient treatment."

— Janet B. Kreizman, CEO, AACC

In its position paper, the AACC made the following recommendations:

- LDTs should be defined as new or significantly modified tests for which the modification alters the clinical claims
- CLIA should be updated to require laboratories to demonstrate that LDTs are clinically valid for use in medical decisions
- The Centers for Medicare & Medicaid Services (CMS) should credential third-party organizations to review a laboratory's clinical validation data for LDTs
- CMS and deemed accrediting organizations should include on inspection teams individuals with expertise to evaluate LDTs

The AACC's position is similar to that of other trade groups in the laboratory space, including the American Clinical Laboratory Association. However, the AACC has gone the farthest in terms of articulating a specific alternative to the FDA regulating LDTs.

"Clinical labs have one of the lowest error rates in healthcare, showing that CLIA has done an excellent job of regulating labs so that clinicians get the quality test results they need to make critical decisions about patient treatment," said AACC Chief Executive Officer Janet B. Kreizman in a statement. "AACC urges Congress and CMS to update the already rigorous CLIA framework, as we firmly believe this is the most effective way to improve oversight of laboratory-developed tests while still fostering innovation and enabling labs to meet the changing needs of patients."

Takeaway: The AACC is joining the chorus of laboratory groups objecting to the regulation of laboratory developed tests by the FDA, but has issued an extensive alternative. G2

DOJ Report Reveals Fraud and Abuse Recoveries Declined in Fiscal Year 2015

The Department of Justice (DOJ) and Department of Health and Human Services (HHS) released their annual report regarding the achievements of the Health Care Fraud and Abuse Control (HCFAC) Program for Fiscal Year 2015 and it indicates the government recovered $2.4 billion in judgments, settlements and administrative penalties from fraud cases.

Overall, since the HCFAC program's launch in 1997, the government has recovered $29.4 billion for the Medicare Trust Fund. Recoveries in any one year are the culmination of efforts that span more than one fiscal year.

A press release announcing the report touts that recovery as a return on investment of $6.10 for every dollar spent over the last three years. Impressive numbers, yet not quite as impressive as 2014's—when the government reported $3.3 billion in recoveries and estimated a $7.70 return per dollar spent over the prior three years. The recovery in 2015 is also lower than that of 2013 which recorded $4.3 billion recovered and estimated $8 return for each dollar spent over the prior three years.

Overall, since the HCFAC program's launch in 1997, the government has recovered $29.4 billion for the Medicare Trust Fund. Recoveries in any one year are the culmination of efforts that span more than one fiscal year. This year's report indicates that for 2015, the government "won or negotiated over $1.9 billion in health care fraud judgments and settlements." That's down from the $2.3 billion reported as won or negotiated in Fiscal Year 2014 and $2.6 billion won or negotiated in Fiscal Year 2013. Note, however, that enforcement efforts don't appear to be waning. In its 2017 Budget Request, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) is requesting a total budget of $419 million to oversee the administration of the HHS programs—that includes $334 million for oversight of Medicare and Medicaid and the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative.

This year's report touts the achievements of state-of-the-art fraud detection technology including Centers for Medicare & Medicaid Services' Fraud Prevention System (FPS), enhanced provider screening and enrollment and the Health Care Fraud Prevention Partnership (HFPP). The FPS uses predictive analytics to spot suspicious billing patterns before claims are paid and the government credits the program with assisting in saving up to $820 million since 2011. The HFPP is a joint effort between the government and private insurers, states and associations to prevent health care fraud. Finally, the report also praises the payoff of involving beneficiaries in the fight against fraud through the Senior Medicare Patrol. However, that program experienced a decline between 2013 and 2014 with regard to recoveries attributable to its efforts. (See *National Intelligence Report*, Aug. 20, 2015, p. 4)

Takeaway: Despite robust enforcement and big settlements announced last year, the DOJ reports fewer dollars recovered than in prior years. G2

State Laws, Industry Attention Needed to Advance Roadside Marijuana Testing, *Continued from bottom of p. 1*

In response to growing drug use, states have implemented piecemeal regulation for impairment testing. According to the Governors Highway Safety Association (GHSA):

- Nine states have zero tolerance for delta-9-tetrahydrocannabinol (THC), the psychoactive ingredient in cannabis or metabolites.
- Three states have zero tolerance for THC but no restriction on metabolites.
- Five states have specific per se limits for THC (Pennsylvania, 1 ng; Nevada and Ohio, 2 ng; Montana and Washington, 5 ng).
- Colorado has a reasonable inference law for THC.
- The majority of states, including Oregon, have no marijuana-specific laws and rely on police officers' observations.

Forty percent of fatally injured drivers test positive for drugs and 22 percent of all drivers tested in the National Highway Traffic Safety Administration's (NHTSA) 2013-2014 National Roadside Survey of Alcohol and Drug Use by Drivers would test positive for at least one drug. In both studies, marijuana is the most common drug detected, but testing only detected the presence of THC, not the quantity of the drug. Also, both surveys found the presence of marijuana increasing in frequency, but again, could not link the presence of the drug to either impairment or the cause of the fatal crash.

Test Results to Define Impairment

GHSA's report, *Drug-Impaired Driving: A Guide for What States Can Do*, makes recommendations for both state and federal action against drug-impaired driving, including continued research on the effects of drugged driving laws and the level of impairment produced by different concentrations of the most commonly used drugs. This lack of a clear link between impairment and drug concentrations in the body makes it difficult to define drug impairment, which, in turn, challenges efforts to enforce drug-impaired driving laws and standardize testing.

NHTSA wrote in a 2015 publication "specific drug concentration levels cannot be reliably equated with a specific degree of driver impairment."

Many long for the marijuana analogy to a blood alcohol level, but evidence suggests this may be impossible. Compared to alcohol, defining and identifying impairment due to drugs is more complicated. In experimental settings, marijuana has been shown to impair psychomotor skills and cognitive functions associated with driving, including vigilance, time and distance perception, lane tracking, motor coordination, divided attention tasks, and reaction time. However, detection of the drug's presence in the body, its concentration, and its impairing effects are not well understood and can vary by person due to frequency of use and individual differences in metabolism.

The height of intoxication and related impairment doesn't occur when blood THC levels peak. Experts say that a few hours after smoking marijuana, a user could still be intoxicated, yet pass a drug-related driving test because only small traces of THC would be in the blood. With edible marijuana, blood THC levels would be even lower, even when the user is still high. In contrast, frequent users have so much THC built up in body fat (THC is fat soluble, as opposed to alcohol, which is

water soluble), it would leach out of body fat into blood for weeks reaching moderate levels, even when users are not actively high.

"An accurate, reliable, and inexpensive oral fluid test device that could be used at the roadside would be very useful. It should be quick and easy to use and should detect the most common drugs that impair drivers."

— GHSA's Drug-Impaired Driving: A Guide for What States Can Do

Steps to Improve Testing

Additional recommendations from GHSA's *Drug-Impaired Driving: A Guide for What States Can Do* focus on efforts to improve testing, including testing all fatally injured drivers, standardizing testing protocols and procedures for roadside testing and laboratory testing, and validating roadside testing devices. These efforts, GHSA says, will need to be informed by further research on the effects of drugs on driving; the effectiveness of drugged driving per se laws; the accuracy, reliability and cost-effectiveness of drug detection tests; and the feasibility of establishing national standards for various controlled substances involved in drug-impaired driving.

"An accurate, reliable, and inexpensive oral fluid test device that could be used at the roadside would be very useful. It should be quick and easy to use and should detect the most common drugs that impair drivers," writes GHSA in its report. "If an oral fluid test were of evidential quality for some drugs it might reduce the need for blood tests. Research is needed to continue refining, evaluating, and eventually establishing standards for oral fluid test devices. Continuing research is [also] needed to determine if a useful marijuana breath test device can be developed."

Additionally, there are calls to establish national drug testing best practices that will include threshold concentrations, in addition to drug presence. National standards for toxicology testing would also include identifying the circumstances under which tests should be conducted, a minimum set of drugs for which to test, and cutoff values for reporting the results.

Internationally, roadside drug testing is catching on in Australia and the United Kingdom, despite remaining uncertainties if detected drugs are actually affecting driving abilities. Experts say oral fluid testing is advantageous because improved timing of sample collection can provide results that more accurately reflect the driver's drug levels while driving. In addition to a lack of timeliness, current testing is plagued by inconsistent usage, expense and laboratory backlogs that often prevent results from being available in time for court appearances.

Takeaway: Roadside testing for marijuana is needed at a time when driving under the influence is increasing. Yet, development of these tests and adoption is hampered by non uniform testing standards and legal thresholds, as well as the current inability to differentiate the presence of a drug from impairment. Yet, officials are hopeful that a quick, noninvasive, and inexpensive roadside test can be developed soon. G2

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