Ortho Clinical Diagnostics

Ortho Clinical Diagnostics Expands Drugs of Abuse and Therapeutic Drug Assay Menus in Collaboration With Thermo Fisher Scientific

October 8, 2019

New Microtip Partnership Assays (MPAs) help detect the use of fentanyl and tricyclic antidepressants (TCA)



Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, in collaboration with Thermo Fisher Scientific, has expanded the menus on MicroTip-capable VITROS® Systems to enable testing for fentanyl, a commonly abused opioid, and tricyclic antidepressant (TCA), which has a narrow safe therapeutic range.

The Thermo Scientific DRI Fentanyl[1] Assay has excellent sensitivity of 100 percent and cross-reacts with various analogs of fentanyl.

Fentanyl is a synthetic opiate analgesic that is prescribed for chronic pain management and is a potentially deadly drug when abused because it is 50 to 100 times stronger than morphine. The U.S. Drug Enforcement Agency (DEA) has called fentanyl "the most prevalent and the most significant synthetic opioid threat to the United States."[2] From 2014-2015, the DEA National Forensic Laboratory Information System reported a greater-than-300 percent increase of fentanyl encounters.[3] The assay also addresses a public need in Canada, where opioid poisoning hospitalization rates have increased 27 percent over the past five years.[4]

The Thermo Scientific DRI Tricyclics Serum Tox Assay can help clinicians detect the use of tricyclic antidepressants in potential overdose victims. A TCA overdose can result in loss of consciousness, coma, convulsions, hypotension, pulmonary complications or sudden death.[5] Used properly, TCAs can be prescribed for depression, bipolar disorder, chronic pain and insomnia.

The additional assays are the result of another successful collaboration in Ortho's MicroTip Partnership Assays (MPA) program with strategic vendors to deliver an expanded testing menu on MicroTip-capable VITROS Systems in key disease states to hospital labs and hospital networks. MPAs enhance a lab's value by allowing them to offer esoteric testing to clinicians in step with today's evolving needs for serving diverse patient populations.

> ***"Collaborations in our MicroTip Partnership Assay program help expand our reach in delivering innovative, important new assays to our customers to help them drive value in their lab," said Piper Antimarino, Ortho's head of clinical labs product portfolio. "This collaboration with Thermo Fisher Scientific on the DRI Fentanyl Assay will help authorities address a major societal problem, and the DRI Tricyclics Serum Tox Assay helps advance the safe use of a therapeutic drug, which is consistent with Ortho's commitment to reliability and safety."***

The DRI Fentanyl Assay is available in the United States for Criminal Justice and Forensic Use Only. This product is not intended for clinical diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae or patient management. The DRI Tricyclic Serum Tox Assay is 510(k) cleared in the United States.

About Ortho Clinical Diagnostics

Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the global clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks, and labs in more than 125 countries and territories, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. Ortho brings sophisticated testing technologies, automation, and information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. For the immunohematology community, Ortho's blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward.

1. For Criminal Justice and Forensic Use Only (US)

2. DEA Intelligence Brief. DEA-DCT-DIB-003-18. May 2018.

3. Jannetto, P. et. al. The Fentanyl Epidemic and Evolution of Fentanyl Analogs in the United States and the European Union. Clinical Chemistry 65:2, 242-253. 2019.

4. https://www.cihi.ca/en/opioids-in-canada/2018/opioid-related-harms-in-canada

5. TCA_Woolf_TCA - Evidence Based Consensus Guideline _Clin Tox_2008

Thermo Scientific and DRI are trademarks of Thermo Fisher Scientific and its subsidiaries.

PR-05445

Press contact:
For media inquiries please contact

Ortho Media Relations
Ortho Clinical Diagnostics
media@orthoclinicaldiagnostics.com
(+1) 908 704 8256