



## Micronics PanNAT STEC Test and System Receive FDA Clearance

June 4, 2018 – Redmond, WA – Micronics, Inc. has announced today that its test for the detection of Shiga toxin-producing *E. coli* (STEC) has received clearance from the U.S. Food and Drug Administration. The Micronics PanNAT STEC Test is performed in a disposable microfluidics-enabled cartridge and is a qualitative, *in vitro* nucleic acid amplification-based test that simultaneously detects and differentiates the *stx1* and *stx2* Shiga toxins and *E.coli* O157. The cartridge contains all of the reagents required for the test, including a novel approach for integrated positive and negative quality controls. Sample, reagents, and waste are captured in the cartridge for ease of disposal.

Also cleared by the FDA is the Company's PanNAT System, a compact, fully automated molecular diagnostic device that processes the individual test cartridges. The benchtop-sized instrument is easily portable and designed for use across a diverse range of centralized laboratories. In the event of short-term power loss, the instrument is battery powered. Additionally, the design of the user friendly interface simplifies the test process.

Users simply insert a patient sample tube into the PanNAT STEC Test cartridge, and then insert it into the instrument to initiate the test. The instrument provides a sample-in to result-out answer in approximately one hour, with no sample preparation required.

The PanNAT STEC Test is Micronics' first molecular diagnostic test to receive FDA clearance required for U.S. sales and distribution. CE Marking of the system and test also are planned for Europe.

"The ease of use of the PanNAT System and STEC Test provide a needed solution for rapid testing," said Karen Hedine, Micronics' President. "Micronics believes that the PanNAT System is poised to take advantage of the expanding use of low to medium multiplex assays for timely diagnosis across a diverse group of customers, while also being responsive to the reimbursement environment."

Micronics, Inc. is a wholly-owned subsidiary of Sony Corporation of America. The company is based in Redmond, Washington and holds an early and broad patent estate in microfluidics.

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