Microbial monitoring from the frontlines to space: Department of Defense Small Business Innovation Research technology aboard the International Space Station

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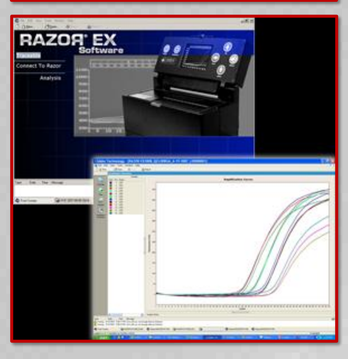
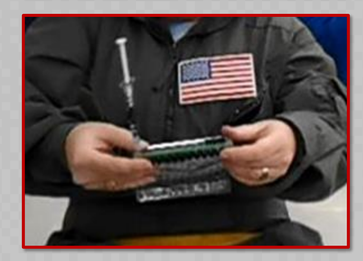


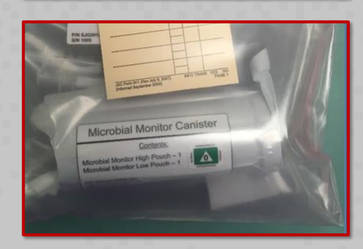
The RAZOR® EX, a quantitative Polymerase Chain Reaction (qPCR) instrument, is a portable, ruggedized unit that was designed for the Department of Defense (DoD) with its reagent chemistries traceable to a Small Business Innovation Research (SBIR) contract beginning in 2002. The PCR instrument's primary function post 9/11 was to enable frontline soldiers and first responders to detect biological threat agents and bioterrorism activities in remote locations to include field environments. With its success for DoD, the instrument has also been employed by other governmental agencies including Department of Homeland Security (DHS). The RAZOR® EX underwent stringent testing by the vendor, as well as through the DoD, and was certified in 2005. In addition, the RAZOR® EX passed DHS security sponsored Stakeholder Panel on Agent Detection Assays (SPADA) rigorous evaluation in 2011.

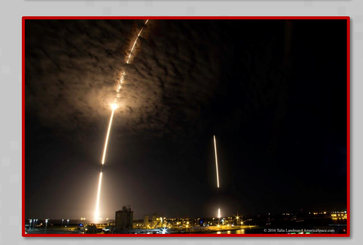
The identification and quantitation of microbial pathogens is necessary both on the ground as well as during spaceflight to maintain the health of astronauts and to prevent biofouling of equipment. Currently, culture-based monitoring technology has been adequate for short-term spaceflight missions but may not be robust enough to meet the requirements for long-duration missions. During a NASA-sponsored workshop in 2011, it was determined that the more traditional culture-based method should be replaced or supplemented with more robust technologies. NASA scientists began investigating innovative molecular technologies for future space exploration and as a result, PCR was recommended. Shortly after, NASA sponsored market research in 2012 to identify and review current, commercial, cutting edge PCR technologies for potential applicability to spaceflight operations. Scientists identified and extensively evaluated three candidate technologies with the potential to function in microgravity. After a thorough voice-of-the-customer trade study and extensive functional and safety evaluations, the RAZOR® EX PCR instrument (BioFire Defense, Salt Lake City, UT) was selected as the most promising current technology for spaceflight monitoring applications.

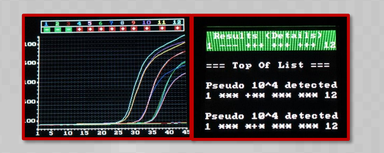
In 2015, the RAZOR® EX hardware was chosen as one of the commercial-off-the-shelf instruments incorporated into the Water Monitoring Suite of technologies for rapid development and flight demonstration. The RAZOR® EX launched on SpaceX-9 in July 2016 and flight testing initiated with validation and hardware functionality, and established consistency with ground controls.

A series of DoD-funded precursor SBIR projects and collaborations with military government agencies successfully led to the RAZOR® EX development and produced a beneficial product to address technology requirements of multiple customers. The on-board experiments have shown the existing instrumentation can be used in many environmental scenarios, both land-based as well as space-based. NASA's in-flight testing of the technology validated its functionality and sensitivity in microgravity. The instrument's small footprint, portability, and direct 'sample-to-answer' results provide autonomy to crewmembers. RAZOR® EX also provides a potential viable system to address microbial monitoring requirements necessary for future, long-duration spaceflight missions.









1999: Idaho Technology SBIR for JBAIDS field PCR

2002: Idaho Technology SBIR for freeze-dried real-time PCR reagents

2004: RAZOR® EX system developed

2008: RAZOR® EX system upgraded with color screen

2011: RAZOR® EX biosurveillance system SPADA validation by DHS

2012: Idaho Technologies becomes BioFire Diagnostics, Inc.

2012: NASA Microbial Monitor Project

2014: BioFire Defense created from bioMérieux acquisition

2014: RAZOR® EX identified as candidate for spaceflight

Feb 2015: Selected for flight hardware demonstration

July 2016: RAZOR ® EX Launched to ISS

Sept 2016: Began on-orbit testing

July 2017: Flight test complete