



Great Basin Receives FDA 510(k) Clearance for Shiga Toxin Direct Test

*Company continues to expand menu, adding the only stand-alone molecular test for Shiga toxin-producing *E. coli* (STEC) detection cleared by FDA*

Salt Lake City, March 23, 2016 - Great Basin Scientific, Inc. (NASDAQ: GBSN), a molecular diagnostics company, announced today that the U.S. Food & Drug Administration (FDA) has granted 510(k) clearance for its Shiga Toxin Direct Test. The Company received notification of clearance from the FDA on March 22, 2016. The Company continues to execute against its menu expansion objectives, now providing the only FDA-cleared stand-alone molecular test to detect Shiga toxin-producing *E. coli* (STEC) and the serotype O157 directly from a patient specimen. The Shiga Toxin Direct Test can be run on the Great Basin Analyzer, which also performs Great Basin's commercially available low-plex tests for *Clostridium difficile* (*C. diff*) and Group B *Streptococcus* (GBS), as well as the Company's multi-plex Staph ID/R Blood Culture Panel, which is pending 510(k) clearance from the FDA.

The Centers for Disease Control (CDC) reports STEC are a leading cause of bacterial enteric infections in the United States and has issued patient testing guidelines to ensure as complete as possible detection and characterization of STEC and STEC O157 infections to help avoid serious complications for patients and improve clinical outcomes. Providing patients with appropriate treatment early in the course of STEC infections is especially critical as improper antibiotic therapy in patients with STEC infections may be associated with more severe disease, including renal damage or even death. The conventional methods of testing for STEC, however, demonstrate low sensitivity (54.7 percent) compared to PCR¹ and take significant time and effort, requiring 36-120 hours to receive a result.

Great Basin's Shiga Toxin Direct Test enables a streamlined workflow for laboratory technicians, offering sample-to-result testing with less than one minute of hands-on

time, and without a specimen enrichment step. Quickly detecting *stx1* and *stx2* genes provides information clinicians need to make appropriate and timely therapeutic decisions to improve patient outcomes and the potential for lower overall cost of care. Great Basin's Shiga Toxin Direct Test also identifies the serotype O157, a strain of *E. coli* linked to development of hemolytic uremic syndrome (HUS), a life-threatening condition.

"We are pleased to receive 501(k) clearance for our Shiga Toxin Direct Test, and are excited about the opportunity to drive new site placements with this unique test," said Ryan Ashton, co-founder and Chief Executive Officer of Great Basin Scientific. "By offering the only direct-from-patient specimen test, and identifying the O157 strain and quickly detecting *stx1* and *stx2* genes, we are providing clinicians a powerful tool to provide a better outcome for their patients. The clearance of this test is particularly timely given the growing number of multistate outbreaks for Shiga toxin-producing *Escherichia coli* O157 (STEC O157) infections."

¹ [J Clin Microbiol.](#) 2015 Jul;53(7):2148-53. doi: 10.1128/JCM.00115-15. Epub 2015 Apr 29.

[Real-Time PCR Assay for Detection and Differentiation of Shiga Toxin-Producing *Escherichia coli* from Clinical Samples.](#)

About Great Basin Scientific

Great Basin Scientific is a molecular diagnostics company that commercializes breakthrough chip-based technologies. The Company is dedicated to the development of simple, yet powerful, sample-to-result technology and products that provide fast, multiple-pathogen diagnoses of infectious diseases. The Company's vision is to make molecular diagnostic testing so simple and cost-effective that every patient will be tested for every serious infection, reducing misdiagnoses and significantly limiting the spread of infectious disease. More information can be found on the company's website at www.gbscience.com.

Forward-Looking Statements

This press release includes forward-looking statements regarding the Company's continuing business efforts related to its products, including but not limited to, assistance of health providers to define a clear treatment path sooner for improved patient outcomes, shorter hospital stays and dollars saved in hospitalization costs per

patient, the development of simple, yet powerful, sample-to-result technology and products that provide fast, multiple-pathogen diagnoses of infectious diseases, the Company's ability to drive new site placements with the new test and related statements. Forward-looking statements involve risk and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risk and uncertainties include, but are not limited to: (i) our limited operating history and history of losses; (ii) our ability to develop and commercialize new products and the timing of commercialization; (iii) our ability to obtain capital when needed; and (iv) other risks set forth in the Company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Annual Report on Form 10-K for the year ended December 31, 2015. These forward-looking statements speak only as of the date hereof and Great Basin Scientific specifically disclaims any obligation to update these forward-looking statements, except as required by law.

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