

For Immediate Release

Media Contacts:

Sandra Nielsen, Great Basin Corporation
sn Nielsen@gbscience.com
801.990.1055

Bao Nguyen, Edelman
bao-viet.nguyen@edelman.com
415.596.0587

**GREAT BASIN CORPORATION SUBMITS 510(K) APPLICATION TO FDA
FOR C. DIFFICILE MOLECULAR DIAGNOSTIC TEST**
Cost effective, sample-to-result test would provide detection of deadly infection

SALT LAKE CITY (November 14, 2011) – Great Basin Corporation, a privately held life sciences company developing sample-to-result molecular diagnostic solutions, today announced it has submitted a 510(k) application to the U.S. Food and Drug Administration (FDA) for its first molecular diagnostic test for *Clostridium difficile* (*C. diff*).

C. diff is one of the most common and deadly hospital-acquired infections (HAIs), impacting approximately 700,000 people in the U.S. annually, according to the Centers of Disease Control and Prevention. The company also plans to submit an application to European Union regulatory authorities before the end of 2011 to obtain CE Marking for the *C. diff* test.

“We are very pleased with the exceptional trial results as it exceeded our sensitivity and specificity performance targets. We believe the accuracy and workflow of the test will make it especially competitive in the marketplace,” said Ryan Ashton, CEO and president, Great Basin Corporation. “Once we secure approvals in the U.S. and Europe, we plan to launch our low-cost, sample-to-result assay and instrument without delay.”

Great Basin’s highly sensitive, easy-to-use, integrated cartridge system allows for more accurate and information-rich detection of infectious diseases, allowing providers to diagnose and define a clear treatment path sooner for improved patient outcomes, shorter hospital stays and significant cost savings. The company’s goal is to deliver assays that can be performed in a CLIA-rated waived or moderately complex laboratory at a lower cost than other molecular diagnostic solutions.

“The results of this clinical trial are informing our work as we prepare additional assays—focusing on the most virulent HAIs, including fungal pathogens and methicillin-resistant *Staphylococcus aureus* (MRSA)—for clinical trial in the first half of 2012,” continues Ashton.

Great Basin’s technology entails an integrated disposable cartridge containing all necessary reagents and an inexpensive bench-top analyzer that executes the assay, interprets the results and provides

electronic output to the clinician. The platform has several key advantages over other molecular solutions:

- Results in under one hour, depending on the target of interest
- True sample-to-result with no more than two to three hands-on steps
- On-demand testing; no batching of tests that delay results
- Multiplexes up to 64 distinct targets in a single assay

About *C. diff*

C. diff causes severe and sometimes deadly diarrhea, and is one of the most difficult to treat infections, with the BI strains of *C. diff* being especially virulent. Patients are often prone to disease recurrence leading to additional hospitalization. At the same time, a false positive test or misdiagnosis for *C. diff* can also lead to unnecessary and ineffective treatments.

The number of *C. diff* outbreaks has risen markedly since 2003, according to the Association for Professionals in Infection Control and Epidemiology. Accurate and rapid diagnosis of *Clostridium difficile* infection (or CDI) is essential to aid in therapy selection and improve patient outcome, prevent disease spread and lessen negative impacts on healthcare systems:

- CDI accounts for increased length of stay of 5.6 days
- Incremental cost of CDI infection is estimated at \$7,179
- CDI affects 13 per 1,000 admitted patients in US, and 11 per 1,000 patients in Europe

About Great Basin Corporation

Great Basin Corporation is a privately held life sciences company that commercializes breakthrough chip-based technologies for the molecular, rapid diagnostic testing market. 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. By providing more diagnostic data per sample, healthcare providers are able to treat patients with the right medication sooner, improving outcomes and reducing costs. 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.