

DIAGNOSTICS

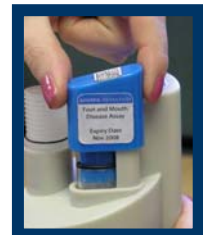


Bio-Seeq-Clinical is a molecular testing system that utilizes LATE-PCR and is being developed by Smiths Detection Diagnostics to deliver accurate, sensitive and rapid in vitro diagnostic test results in the laboratory or at the point of care (POC). The system merges LATE-PCR, a novel PCR method that has significant performance advantages over traditional PCR (greater multiplexing, lower limits of detection), with a sample processing device that performs automated sample preparation and advanced PCR instrumentation in a single integrated system. The highly automated platform design leverages Smiths Detection's core competence in developing rugged, portable, easy to use platforms for testing in military, emergency response, security and veterinary applications. In addition to the automated sample processing, on-board software continuously monitors instrument performance and the integrity of the test results. Data management software enables bi-directional communication with the Laboratory Information System ensuring that the Clinical Laboratory has full visibility and control of the instrument and the complete testing process.



A key component, the Sample Preparation Unit (SPU) minimizes pre-analytical preparation time and potential sample handling errors. The device is completely sealed to isolate and contain any infectious material, or amplified product. Room temperature stable reagents required for both the nucleic acid extraction and the PCR reaction are pre-loaded in the SPU, along with appropriate controls for both sample preparation and PCR amplification. The SPU has been uniquely designed to process a wide range of sample types, which enables the customer to purchase a single product for a variety of samples including, swabs, urine, tissue and faeces.

The flexibility of the system is further enhanced by the menu of assays, each of which is pre-packaged in a Reagent Pack, which, when inserted into the SPU, transforms the generic SPU into an organism-specific test. An integrated barcode defines the testing protocol and facilitates automated implementation of process steps specific to the sample type and organism(s). Temperature stable reagents and a solid design allow the components to be stored without refrigeration, resulting in greater convenience and simpler logistics.



The integration of sample preparation and PCR reaction technologies completely automates the entire testing process, providing true 'sample in, answer out' functionality. After the appropriate Reagent Pack is attached, the operator simply places the patient sample into the Sample Prep Unit, scans the barcode and inserts the single-use consumable into the Bio-Seeq instrument. The Bio-Seeq automatically performs the sample preparation and PCR analysis with no further operator intervention. Sample to result involves less than 1 minute of operator hands on time.

Bio-Seeq-Clinical System is designed to support the growing challenges of the clinical laboratory by providing a diagnostic platform that requires minimal operator intervention and produces patient results in less than 90 minutes.

The first assay, MRSA is scheduled to begin clinical trials in the UK in February 2009. Upon completion of the UK Trials, we expect to submit the product for FDA approval.