BD Viper XTR
Molecular Diagnostic Automation Platform

Key Goals and Accomplishments

Automated Extraction Process Directly from Specimens
New Extraction Chemistry
High Performance – Sensitivity and Specificity
Compatible with New Specimen Types (Vaginal Swabs, Cytology)
World Class Reliability and Confidence in Results
Next Generation Platform for Future Assays

Approach and Tools

Overall Project Planning & Management
Critical Parameter Analysis
System Specification Development & Documentation (Database)
Module Specifications & Requirements Traceability Analysis & Documentation
Risk Management & Failure Modes & Effects Analysis
Statistical Experiment Design (DOE) & Structured Problem Solving
User & Clinical Validations
Technical Writing (Protocols, Reports, Submission)

Results and Recognition

Demonstrated on-time project delivery and credibility.

Continued long-term relationship with world's largest medical test lab

>99% agreement wit h expected results

Increased Throughput with Less Hands-On Time