

Challenge

OTraces, a global US-based company, develops highly accurate and sensitive ELISA multi-biomarker cancer screening tests with a predictive power greater than 95% using a unique algorithm which dramatically reduces biological background signals. These tests are performed on a company-developed system which includes a software-controlled instrument, reagents and data analysis algorithm.

With clinical studies at the Gertsen Institute in Moscow and a potentially significant market in Russia, OTraces recognized the need for an IT system that remotely interfaces with their instruments and robotics, includes sample accessioning tracking and reporting, enables quality control, and integrates with the OTraces highly complex data analysis algorithm.

Approach

This project highlights BioIT's unique methodology: we rapidly deploy our highly configurable 1Platform4® software and then tune functionality.

We kicked off the project with a session to learn about OTraces' specific requirements and to understand its unique needs vis-à-vis remote location of laboratory operations, data processing using its novel algorithm, and quality control of sample processing and data management. The BioIT team considered the entire process from sample accessioning and processing at a remote location to data analysis and auditing by the US-based team and finally direct report generation at the remote location. Workflow rules and access control requirements were then captured and reduced to specification objects managed by the 1Platform4 software.

The OTraces team along with their clinical partners worked with early versions of the system, influencing the next iteration where specification objects were added and changed. Thus, the system evolved organically in a manner that fit their workflow. As an added benefit, sample data and results were archived for future research into ways to improve the tests or to develop new tests. Implementation was complete in four months.

Results

- Remote data capture from Moscow cancer center
- Algorithm-directed calculation of protein concentration
- Quality control to ensure high integrity data
- Automated report preparation
- Ability to scale rapidly to new laboratories and countries
- Customized, secure diagnostics management website portal

Customer Experience

BioIT has provided OTraces with software development, IT support and key advice on laboratory operations for over three years. We at OTraces consider BioIT to be more than just a vendor, but a partner. They have helped us develop key software for diagnosing cancer through a simple blood test.” Keith Lingenfelter, CEO

1Platform4™ Suite

The 1Platform4 Suite integrates multiple scientific and business processes into a single web-based application.

The suite consists of a software foundation on which various highly configurable modules are assembled and tailored to each client's specifications and needs. 1Platform4 also includes integration tools for connecting to external systems and laboratory instruments.

- User-defined workflow modules transform complicated tasks into routine activities.
- Complex processes are managed without custom software, adapting to each client's scientific and business practices.
- Easily and rapidly deployed solution based on widely supported technologies (SQL Server, Microsoft ASP.NET, web browser access).
- System hosting by BioIT Solutions ensures data integrity and security without customer-supplied IT infrastructure. We verify systems security with routine vulnerability assessments; SOPs ensure operational consistency.

About BioIT Solutions

BioIT Solutions offers a range of services from enterprise systems built on our 1Platform4 Suite for advanced computational, workflow, and data management systems for biological research, drug development and diagnostics to ... IT strategy, architecture and management consulting.

Company founders have worked in the biotechnology sector for over 20 years in a variety of information-technology capacities, including senior positions as CIO, and directors of Bioinformatics, Quality Systems and Clinical Systems. The breadth of our experience makes us an ideal partner for early-stage companies, as well as those with legacy systems in need of modernization.

1 Manage samples and studies at multiple locations

- Facilitate Serum Sample Collection
- Manage Assay Test Kits

Assay Entry/Update

Test Method: Breast Cancer
Test Run Name: Gertsen Institute 80-120
Diagnostic Kit Number:
Test Run Status: Plates Saved to Database
Status Date: 15-Nov-12

Modification History

Plate Code	Target	Target Name	Plate Status	Status Date	Plate Info
P00095-1	IL-6	Interleukin 6	Plate Data Saved	15-Nov-12	Plate Detail Report
P00095-2	PSA	Prostate Specific Antigen	Plate Data Saved	15-Nov-12	Plate Detail Report
P00095-3	IL-8	Interleukin 8	Plate Data Saved	15-Nov-12	Plate Detail Report
P00095-4	VEGF	Vascular Endothelial Growth Factor	Plate Data Saved	15-Nov-12	Plate Detail Report
P00095-5	TNFa	Tumor Necrosis Factor alpha	Plate Data Saved	15-Nov-12	Plate Detail Report

5 Assay Plates Displayed

2 Manage instruments and sample runs; perform real-time quality assurance

- Run multi-marker test in 40 cohort groups
- Report virtual microplate images per biomarker
- Repeat any biomarker run deemed weak
- Group acquired data with quality report

Plate Code: P00065-1
Target Protein: Interleukin 6
Plate Read By: Prognoz Prognoz 16-Dec-2010 07:32:22

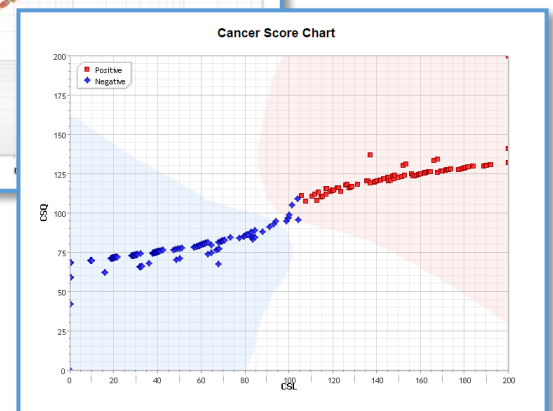
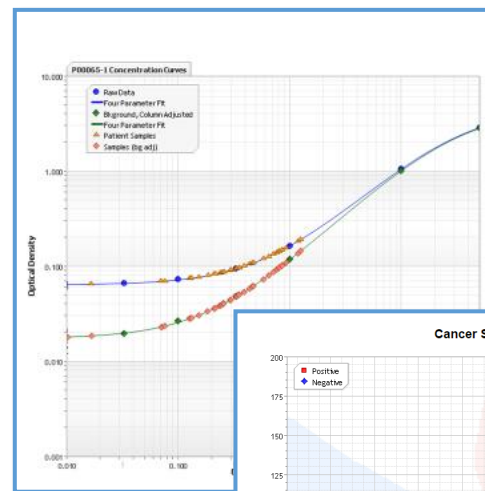
	1	2	3	4	5	6	7	8	9	10	11	12
A	0.092	0.101	0.085	0.080	0.095	0.094	2.958	2.797	0.122	0.118	0.141	0.156
B	0.058	0.071	0.095	0.098	0.071	0.068	1.063	1.057	0.071	0.068	0.127	0.152
C	0.089	0.083	0.083	0.088	0.079	0.075	0.165	0.164	0.080	0.080	0.184	0.201
D	0.112	0.103	0.089	0.121	0.149	0.148	0.094	0.095	0.101	0.100	0.145	0.168
E	0.110	0.107	0.093	0.100	0.145	0.141	0.074	0.072	0.127	0.127	0.079	0.091
F	0.068	0.062	0.075	0.091	0.074	0.075	0.067	0.065	0.087	0.087	0.134	0.153
G	0.084	0.090	0.068	0.072	0.090	0.091	0.063	0.058	0.086	0.096	0.088	0.102
H	0.070	0.079	0.072	0.078	0.095	0.094	0.069	0.066	0.131	0.137	0.173	0.195

3 Perform data analysis and modelling

- Run group data through calibration curves
- Report adjusted sets to OTCAD for modeling
- Receive verified model (version control)

Run screening algorithm per group per model

- Generate group cancer score chart
- Generate individual screening report
- Obtain physician approval



4 Prepare report; archive results & reports

- Publish study report
- Archive individual cohort results
- Archive group run reports
- Archive study outcomes