

Challenge

OncoPlex Diagnostics provides clinical proteomics and genomics testing services to support personalized treatment. The company laboratory is CAP accredited and CLIA certified.

The management team recognized the need for an advanced data management system to streamline daily operations, ensure data integrity and security to meet regulatory requirements, and enhance customer satisfaction. Major challenges included integration of existing systems into a single user interface, extramural interaction with third party providers and physicians, replacement of spreadsheets and paper records, and desired improvements to patient report preparation.

Approach

BioIT's approach to this project exemplifies our unique methodology. We start with a rapid deployment of our highly configurable 1Platform4™ software and then tune functionality to streamline our client's information management processes.

The project began with the BioIT team learning the specific requirements of OncoPlex Diagnostics and its customers and providers. In this initial phase, OncoPlex's data needs, workflow rules and access control requirements were captured in specification objects managed by the 1Platform4 software.

Members of the OncoPlex team worked with early versions of the system, gaining experience and influencing the next iteration where specification objects and rules were added and changed. This step ensured that the system evolved organically in a manner that fits the way they work.

Finally, specimen reports were developed that detail test results and highlight relevant information about the proteomic profile. The initial implementation process was complete in four months.

Results

- Patient sample accessioning and barcode labeling
- Automation replaced manual spreadsheets and paper recordkeeping
- Integration of laboratory mass spectrometer data
- Direct integration of a spectrophotometric plate reader
- Patient report preparation with on-line review and electronic signature approvals; patient reports provide unique results for physician interpretation and development of a personalized approach to treatment
- Seamless integration of CRM and upfront order entry systems
- Direct interface to third party billing provider

Customer Experience

"The BioIT portal is so flexible, it's allowed us to pivot quickly and offer new tests that show commercial promise." Thomas Guiel, Chief Operating Officer

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.

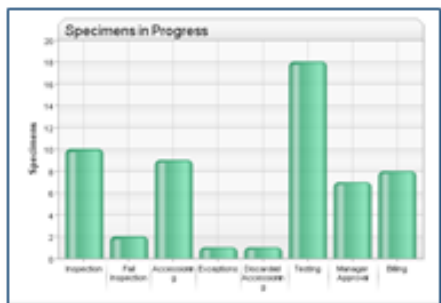
About BioIT Solutions

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.

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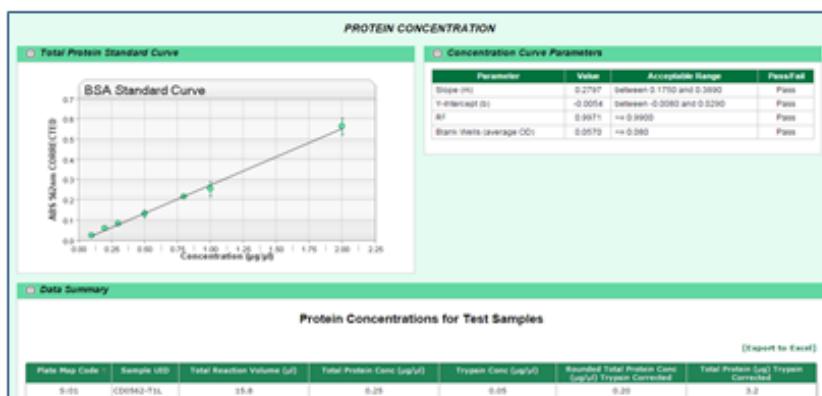
- Accession samples and inspect
- Print barcoded labels and scan at point of use
- View “Dashboard” of specimen status



Requestion #	Specimen UID	Status
500		Inspection
506		Inspection
507		Accessioning
509		Inspection
517		Inspection
518		Accessioning
519		Accessioning
523		Inspection
527		Inspection
539		Inspection

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- Track barcoded samples in the freezer or submit to testing
- Create work lists of samples for instrument set up and data collection
- Process raw data using automated quality control checks and analysis methods
- Capture images – either manually or through instrument integration
- Manage inventories of patient samples and materials created during laboratory processing
- Each user view is dynamically generated based on assigned access levels
- Clear visibility and control over data and activities



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- On-line review and approval by laboratory supervisor and medical director with electronic signatures
- Render branded patient reports like the one at right
- Transmit completed test information to billing vendor via web services
- Search and retrieval tools provide easy access to the database of test results

OncoPlexDx Clinical Marker Profile Report

Patient Report

Patient Name: _____ Requestion #: 758
 Gender: _____ Specimen Received: 24-Mar-2015
 Date of Birth: _____ Date Reported: 02-Apr-2015
 Medical Record #: _____ Referring Physician: _____
 Incoming Specimen ID: AS15-1447-A5 Physician Institution: _____
 OPDx UID: CE0313 Pathology Institution: _____

OncoPlex Dx, a CAP-accredited, CLIA-certified diagnostics laboratory uses SRM-Mass Spectrometry and genomic profiling to provide characterization of patient tumors linking proteomics and genomics in the same tumor cells.

Specimen Image	Diagnosis Code (ICD-9)	Specimen Source
	162.9, Malignant Neoplasm of bronchus or lung, unspecified	Left Femur

Pathology Comment
The specimen was adequate for evaluation and tumor cells were collected using a pathologist-directed laser microdissection system.

Result Highlights
19 Clinical Protein Markers were evaluated by Mass Spectrometry and 3 have potential for therapeutic implications.
50 Clinical Genetic Markers were evaluated by Next Generation Sequencing and SMARCB1, TP53, harbor mutation(s) which may have potential therapeutic implications.

Proteomic Results & Clinical Implications (Method: Targeted Mass Spectrometry)

Agent(s)	Clinical Marker	Patient Result (amol/ug)	Interpretation	Implication
cab-Paclitaxel	SPARC Protein	430	Expressed	Potential Benefit
irinotecan, Topotecan	TOP2B Protein	1259	Expressed	Potential Benefit
MSLN-Targeted Clinical Trial	MSLN Protein	481	Expressed	Potential for Clinical Trial
Cetuximab, Panitumumab	EGFR Protein	1790	Expressed	Uncertain Benefit
Trametinib, Dabrafenib	KRAS Protein	460	Expressed	Uncertain Benefit
Genitacinone	RRM1 Protein	206	Expressed	Uncertain Benefit
Crizotinib, Ceritinib	ALK Protein	ND	Not Detected	Uncertain Benefit