

Challenge

NeoDiagnostix offers FISH testing (fluorescence *in situ* hybridization) for chromosomal abnormalities to referring laboratories and physicians. The testing process is labor intensive and requires multiple steps. Once slides have been processed, microscope images are captured and analyzed. A final report is then prepared containing relevant images from the FISH analysis.

With an increasing test volume, laboratory operations had become difficult to manage and manual report preparation using a Word template was time consuming and arduous. The management team realized that they needed a way to uncover issues before they became problems.

Approach

This project highlights our 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 NeoDiagnostix's specific information requirements and to understand its needs for a portal accessible by partner laboratories and physicians. To improve efficiency, we considered the entire process from sales to invoicing. Workflow rules and access control requirements were then captured and reduced to specification objects managed by the 1Platform4 software.

The NeoDiagnostix team worked with early versions of the system, gaining experience and influencing the next iteration where specification objects were added and changed. This step ensured that the system evolved organically in a manner that fit their workflow. As an added benefit, they realized that workflow and other types of reports could be used to monitor and help direct the sales organization.

Auto-generated specimen reports were developed that are tailored for NeoDiagnostix's partner laboratories and the software was configured to provide real-time sales analytics. Implementation was complete in four months.

Results

- Specimen workflow tailored to needs of several partner laboratories
- Electronic approvals by the laboratory manager and medical director streamlines operations and obviates needs for on-site paper review
- Physicians and partner laboratories log onto a secure portal with authentication credentials to check progress and access their reports. Report preparation is automated and customized for partner laboratories. Auto-generated email alerts them to report availability
- Specimen Aging Chart, Physician Demand Report and Daily Specimens Received Report gives valuable information to the sales force

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 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.

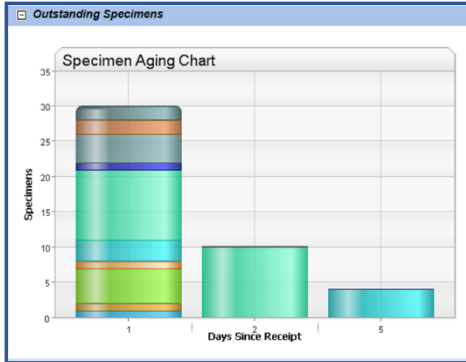
About BioIT Solutions

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 and inspect specimens
- Print barcoded labels and scan at point of use



- View “Dashboard” of specimen status including Specimen Aging Chart - facilitate operations management and help direct the sales team
- Daily Specimens Received Report and Physician Demand Report provide additional information for sales management

NeoDiagnostix Daily Specimens Received

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Printed: 7/17/2015 1:01:03AM
Shipping Days: 11
Total Shipping Days: 22

Account Manager 001						
Partner Lab	Specimen #	Week-to-Date	MTD Received	MTD Reported	Ave. Rcvd/Day	Ave. Rptd/Day
	1	1	1	0	0.09	0.00
	0	1	2	3	0.18	0.27
	1	2	6	4	0.55	0.36
	1	15	40	22	3.64	2.00
	9	33	76	56	6.91	5.09
	0	3	9	7	0.82	0.64
	0	3	9	10	0.82	0.91
Total:	12	58	143	102	13.01	9.27

Account Manager 002						
Partner Lab	Specimen #	Week-to-Date	MTD Received	MTD Reported	Ave. Rcvd/Day	Ave. Rptd/Day
	0	2	5	3	0.45	0.27
	20	70	213	179	19.36	16.27
	0	0	1	0	0.09	0.00
Total:	20	72	219	182	19.90	16.54

Account Manager 003						
Partner Lab	Specimen #	Week-to-Date	MTD Received	MTD Reported	Ave. Rcvd/Day	Ave. Rptd/Day
	0	5	20	15	1.82	1.36
	2	6	18	10	1.64	0.91
	9	29	77	54	7.00	4.91
	1	2	6	8	0.55	0.73
	1	5	13	10	1.18	0.91
	0	5	23	18	2.09	1.64
Total:	13	52	157	115	14.28	10.46

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- Track barcoded samples or submit samples for testing
- Create work lists of samples for processing and data collection
- Manage inventories of patient samples and materials created for laboratory processing
- Dynamically generated “user view” based on assigned access levels
- Clear visibility and control over processing activities

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- On-line review and approval by laboratory supervisor and medical director with electronic signatures
- Render branded reports including referring lab logo
- Partner portals to securely access test results and progress
- Create invoices for billing

NeoDiagnostix Cervical DNA Dtex® Test Report

Patient Name:	Jane Smith	Specimen Type:	ThinPrep
Date of Birth:	01-01-1960	Indications:	HPV POSITIVE, NILM
ID Number:	DTEX-2015-12345	Ordering Physician:	Gyn E. Cologist
Case Number:	CX35523	Physician Address:	101 River Road
Collection Date:	07-01-2015		Anywhere, USA 12345
Date Received:	07-17-2015		123-456-7890
Test Requested:	Cervical DNA Dtex®		

Number of Cells	Analyzed Cells	Abnormal Cells		Polyloid Cells
	3q	5p	3q5p	3q 5p Cen7
1007	0	0	7	7
Test Result	POSITIVE			
Reference Range				
Negative	< 5 abnormal cells			
Positive	≥ 5 abnormal cells			
Positive	≥ 12 polyloid cells			

Interpretation:
Cervical cells with abnormal copy number of chromosomal regions 3q26 and/or 5p15 were observed in this specimen. There were 5 or more aneuploid cells observed, therefore the result is positive. This result is consistent with cells exhibiting genomic instability caused by human papilloma virus (HPV). Cervical cells exhibiting genomic instability may indicate a higher risk of cervical dysplasia and progression to more severe cervical disease. Detailed results of the analysis are summarized in the table above, along with a representative image of a cell with an abnormal copy number of regions 3q26 and/or 5p15.

Materials and Methods:
Analysis of gene specific loci at chromosomal regions 3q26, 5p15 and CEN7 was performed using Fluorescent In-Situ Hybridization (FISH) with a probe set specific for the TERC gene on chromosome region 3q26 and the TERT locus at 5p15. In addition, a probe specific for chromosome 7 centromere was applied to assess DNA ploidy. Cervical cells were fixed to a slide and hybridized with these fluorescent probes. Analysis of the hybridization was performed to assess the presence of normal, abnormal and polyloid cells.