SANF PRD HEALTH

CUSTOMER SUCCESS STORY

Sanford Health Leverages Data Innovations'® Instrument Manager™ and EP Evaluator™ to Create Inspector-Ready Reports and Enhance Lab Productivity

Facts at a Glance

Sanford Medical Center Fargo

- 600-bed acute care facility
- Serving the Upper Midwest since 1908
- A top 100 provider for cardiac care
- Nationally ranked children's hospital
- · Level II trauma center

Sanford Broadway Clinic Laboratory

- Serves Sanford Medical Center Fargo and area labs
- Four million annual tests (three million in clinical chemistry)
- LIS: Epic Beaker Clinical Pathology
- Four Abbott ARCHITECT analyzers connected by Data Innovations® Instrument Manager™
- Instrument Manager integrates with DI's EP Evaluator™ quality assurance program

Introducing Sanford Health & Sanford Broadway Clinic Laboratory, Fargo

Sanford Health is one of the United States' largest health systems with 43 hospitals and 250 clinics. In fact, Sanford Health is the largest employer in the Dakotas with a team of about 27,000 people.

Sanford Broadway Clinic Laboratory is one of Sanford Health's four reference laboratories. It serves the system's Sanford Medical Center in Fargo, ND, (see sidebar for key medical center and lab facts) and clinical labs within the Fargo region. Other Sanford Health regions are Sioux Falls, SD; Bismarck, ND; and Bemidji, MN.

Each year about four million tests are performed at Sanford Broadway Clinic Laboratory, and about three million of them in clinical chemistry. About 90% of the tests are analyzed on the Abbott Diagnostics automated line. The lab, which employs 250 people, is equipped with two Abbott clinical chemistry analyzers and two Abbott immunoassay analyzers.

Connecting with Data Innovations® Over the Years

Data Innovations'® Instrument Manager™ connects the Sanford Broadway Clinic Laboratory's analyzers and automated system with their LIS system as the two instruments in the Bemidji, MN-based lab.

"We have been involved with Data Innovations (DI) for a long time. Basically what we wanted was a way to transmit data from instruments to the laboratory information system (LIS) and apply autoverification rules to results coming off instruments. In this way, we can identify samples for technologists to look at and point them in the right direction," said Timothy McManamon, PhD, Technical Director General Laboratory, Sanford Broadway Clinic.

Sanford Broadway Clinic Laboratory has come to know DI, the world's largest laboratory middleware company, through three different instrument suppliers secured by Sanford Health over the years. DI, established in 1989, created Instrument Manager™ to improve lab workflow and efficiency by enabling labs to interface automation, instrumentation, information systems and locations and is chosen by laboratories worldwide.

Sanford Health Laboratories' LIS is Epic Beaker Clinical Pathology. Sanford Broadway Clinic Laboratory bases its autoverification rules on delta checking (comparing current value to previous value within a specified timeframe) and panic values (indicating results needing urgent attention).

"We also have autoverification limits. We pull data from the LIS for the previous six months, and we try to keep autoverification rate in the 90% range. We also look at autoverification by unit and area of the hospital—such as outpatients—to see if we can tweak different areas in order to get better percentage of samples autoverifying," Dr. McManamon added.

Connectivity and verifying clinical lab test results are important functions enabled by DI solutions. Sanford Broadway Clinic Laboratory has taken DI middleware to an even higher level.

Leveraging Instrument Manager and EP Evaluator

By leveraging Instrument Manager with EP Evaluator, the lab instantly imports data directly from instruments to statistical modules with EP Evaluator and produces professional and printable reports summarizing results.

"EP Evaluator is awesome. The two main things we use it for are the six month analytical measuring range validation and the six month instrument-to-instrument comparison. Occasionally we use it for a normal range study," said Dr. McManamon.

"We pull information out of Instrument Manager to EP Evaluator—it is basically a few clicks, and all the data is there. I would say our six month instrument-to-instrument comparison report data entry time went from probably 10 hours (of

a phlebotomist's time) to three seconds. Now we have reports, based on parameters we set up, indicating a pass or fail and the reports look more professional to inspectors," he continued.

EP Evaluator is the leading quality assurance software for clinical labs seeking to measure and improve performance. Designed by a board certified clinical chemist, EP Evaluator provides lab leaders with clear and concise 'inspector-ready' reports helping to meet CLIA '88 (Clinical Laboratory Improvement Amendments) and CAP (College of American Pathologists) requirements — as well as those by The Joint Commission.

The reports, presenting data analysis based on the lab's specified parameters, are used by Sanford Broadway Clinic Laboratory to validate ranges and assess instrument operations. The lab holds certificates of compliance with CLIA and accreditation by CAP.

Sophisticated reporting and easy ability for data entry was not always the case. The lab's former reports were acceptable, but there was room for improvement. Before using EP Evaluator with Instrument Manager, the lab printed results on paper. Then, a phlebotomist entered data in a Microsoft Excel® spreadsheet, analyzed the data and presented results.

"When you are not familiar with what the numbers should be, there are always typos and errors. And we had to wait for results to come back from the vendor of the calibration material," Dr. McManamon recalled.

So, EP Evaluator has made it possible for the lab to select statistical modules (meeting CAP and CLIA requirements) that also address features the lab needs to assess. EP Evaluator offers up more than 30 statistical choices within these key lab performance areas:

- Accuracy and Linearity
- Method Comparison
- Precision
- Reference Interval
- Sensitivity
- Lab Management
- Coagulation
- Other

Sanford Broadway Clinic Laboratory leaders tap the reportable range module, a part of Accuracy and Linearity; and multiple instrument comparison, a popular module within Method Comparison (see ee.datainnovations.com for complete module listing, regulatory requirements addressed and software versions). EP Evaluator offers options including: selection of instrument, specification of parameters (for example, allowable error limits), input of test data, data analysis and import and export of data.

Results in Productivity, Quality Assessment, Test Range Enhancement

The lab has experienced many benefits from the relationship with Data Innovations and the leverage of Instrument Manager and EP Evaluator including productivity improvement, quality assessment and readiness for inspections and test range enhancement.

"EP Evaluator is awesome. We pull information out of Instrument Manager to EP Evaluator - it is basically now a few clicks, and all the data is there."

For example, the six month Analytical Measuring Range Validation report used to take 10 hours of a phlebotomist's time. Now, due to Instrument Manager's connectivity working in harmony with EP Evaluator's robust features, it takes minutes for electronic retrieval of data from lab instruments to report printing.

A page from the multiple instrument comparison report offers up a concise quality assessment: It presents a clear graph showing error index by instrument. An accompanying table shows a multiple instrument comparison with pass or fail results (and those exceeding allowable error appear in red). Space is available for a lab representative's signature and date. Meanwhile, a phlebotomist remains focused on patient care responsibilities.

"I would say our six month instrument-toinstrument comparison report data entry time went from probably 10 hours (of a phlebotomist's time) to three seconds. And now we have reports, based on parameters we set up, indicating a pass or fail. They look more professional to inspectors and offer an objective analysis of data."

"Now, I go in [to the program], click and click and all the data comes into EP Evaluator. I look at it, make adjustments to whatever parameters, print it and have it ready in a notebook," Dr. McManamon said.

They are the go-to documents during lab inspections, when CLIA and CAP officials, for example, assess standards for quality assurance such as those relating to patient test management.

"It is much cleaner to hand a report from EP Evaluator to an inspector. The report shows criteria to evaluate data, and clearly shows that it passed.—versus giving them a spreadsheet that has data on it, a graph or two out of (Microsoft) Excel® and initials and signature from the director," said Dr. McManamon.

Sanford Broadway Clinic Laboratory also turned to EP Evaluator for data in a recent normal range test study. At issue was the parathyroid hormone (PTH) blood test. It's a popular test choice among www.datainnovations.com

doctors, as PTH controls calcium, phosphorous and vitamin D levels in patients' blood. The Fargo-area physicians wondered whether the lab's PTH normal range was correct.

Enter EP Evaluator. The lab used the software to compare its results to other labs in its network.

"We had reports with a full range of Vitamin D levels. We did histograms of different patient populations, and we presented the data in a (Microsoft) PowerPoint® presentation to the doctors, stating: This is how we compare to other labs and this is our proposed new normal range," Dr. McManamon recalled.

"EP Evaluator gave us statistical data to answer their questions and validate what they were seeing clinically: we needed a new normal range. It was dramatic,

because the PTH test involves so much," he continued.

In summarizing the value the lab has garnered by integrating Instrument Manager with EP Evaluator, Dr. McManamon said, "It provides a consistent review of all results. And our technologists do not have to look at all kinds of normal results or results they do not need to look it. Instrument Manager™ focuses their attention, and they do not get 'screen fatigue' from looking at result after result."

"By using EP Evaluator, we have experienced a huge improvement in productivity. Every six months, we use parameters we set up to evaluate the data and present it in clear, concise reports. Inspectors look at them and it looks much more professional. It's an objective analysis of the data."

About Data Innovations

Founded in 1989, Data Innovations® (DI) is the world's largest and most successful clinical and blood laboratory middleware company. With a focus solely on laboratory data management, DI offers the most complete middleware system in the market to manage laboratory operations—including pre-analytical, analytical and post-analytical sample processing and on-clinical tasks such as equipment maintenance and specimen archiving.

Locations

North America

120 Kimball Avenue Suite 100 South Burlington, Vermont 05403

2914 S. Cleveland Avenue Fort Myers, Florida 33901

Sales Tel: 802-264-3470 Technical support Tel: 802-658-1955

Europe

34 av. Jacques Brel 1200 Brussels, Belgium Sales Tel: +32 2 332 24 13 +32 2 770 62 22

Technical support Tel: +32 2 332 24 13

S.D.L.M Tour Egée 9, 11 Allée de l'Arche La Défense 92671 Courbevoie Cedex +33 1 76 63 74 20 +32 2 770 62 22

P.G.P. (UK) Ltd. 2nd Floor, 3 Brindley Place Birmingham B1 2JB +44 1543 410 996

Latin America

Rua Cotoxó, 303 Cj 71 Perdizes Tower II São Paulo, Brasil 05021-000 Sales Tel: 55-11-38013283 Technical support Tel: 55-11-38013283

Asia

Room 3709, 37/F., 118 Connaught Road West Hong Kong Sales Tel: 852-2398-3182 Technical support Tel: 852-2398-3182

