

Decentralized Molecular Influenza Testing and Seamless Implementation Can be Achieved

Sanford Health’s solution to decentralize molecular Influenza (flu) testing across the entire health system was established from their need to provide a consistent, high-quality patient experience regardless of which facility the patient accessed. After deciding to move forward with the GeneXpert® technology, Sanford Health partnered with Cepheid for an efficient and seamless implementation across their entire system.

Introduction

Sanford Health is an integrated health system headquartered in the Dakotas. It is the largest rural, not-for-profit health care system in the nation, with 44 medical centers and 482 clinics in nine states and four countries. It serves 2.74 million people in more than 300 communities across 252,215 square miles.

As part of their initiative to provide uniform laboratory services throughout the Sanford Health system, the laboratory team at Sanford Health initiated the search for a standardized solution for influenza testing. They were looking for a technology that was rapid, accurate, easy-to-use, and had a broad test menu with the potential to bring molecular testing to all sites, whether small or large, urban or rural. Throughout the process, the team identified several challenges, including their vast geographical spread and conflicting viewpoints on how to deliver the highest standard of care. Buy-in of multiple stakeholders and technical professionals was needed to

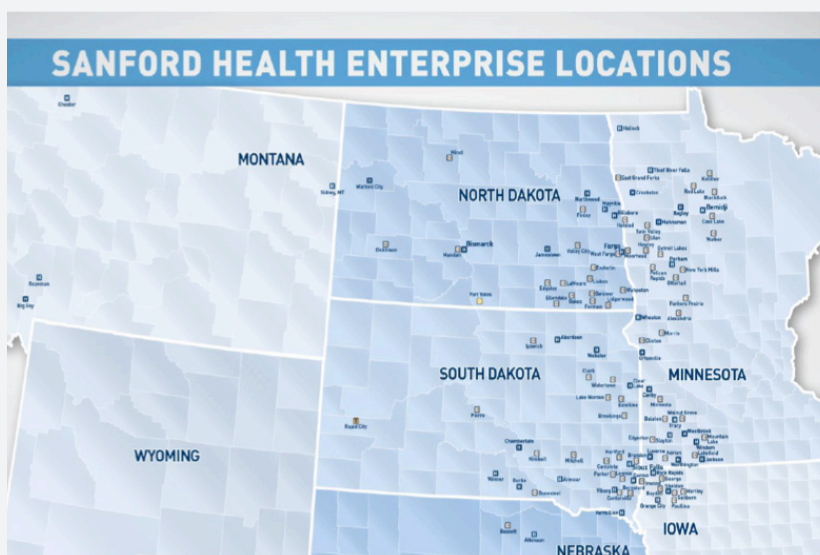
standardize the technology. In order to achieve success, a cultural shift in their flu testing was needed.

Decision-making process

Prior to the standardization initiative, Sanford Health offered five different flu test methods using multiple vendors. The Clinics/ Outpatient/Rural areas all utilized a rapid antigen detection test (RADT), while Hub laboratories had a polymerase chain reaction (PCR) test from two different vendors, RADT, and a direct fluorescent antibody test. This situation created operational challenges that included stocking five different flu kits, managing five different vendors, and offering a different standard of care in each facility. The technical challenges included management, maintenance, and service of the different flu tests and maintenance of several Individualized Quality Control Plan (IQCP) files. All these complexities created a need for a simple solution to overcome these challenges.

Sanford Health — Largest Rural Healthcare System in the U.S.

Serving 2.74 million people in 300 communities across 252,215 square miles in nine states and four countries

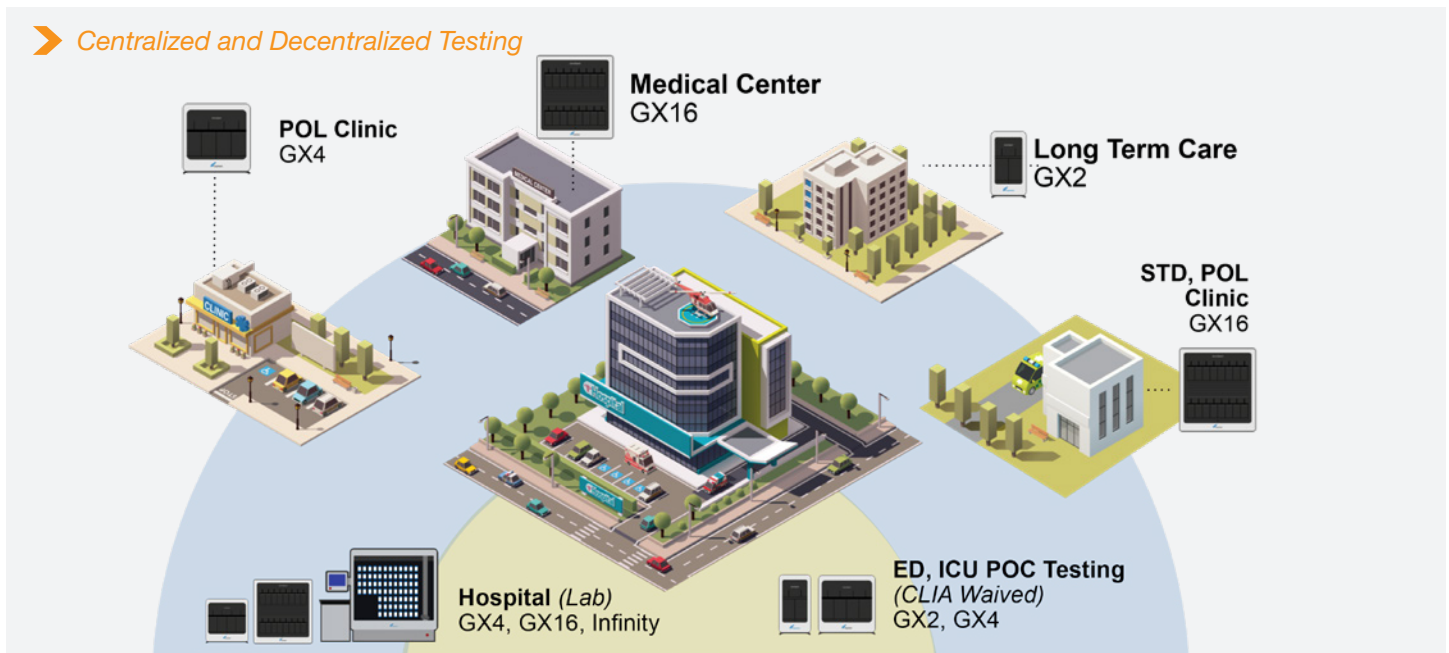


-  44 medical centers
-  \$4.6 billion in annual revenue
-  482 clinics
-  188,574 Sanford Health Plan Members
-  1,382 physicians, 973 advance practice providers and 6,503 registered nurses delivering care in more than 80 specialty areas
-  29,622 employees

Each year, Sanford provides:

- 5.3 million outpatient and clinic visits
- 84,466 admissions
- 136,436 surgeries and procedures
- 9,537 births
- 210,129 emergency department visits

➤ Centralized and Decentralized Testing



Cepheid's GeneXpert® Systems are scalable and therefore could offer testing on the same platform using the same technology anywhere in their health system. This meant that they could manage the same lot of reagents and centralize their supply chain.

Sanford Health was also looking for a technology that offered breadth of tests on the same platform, eliminating the need to add other technologies and more complexities to their process. Cepheid was able to meet this need. Because the test cartridge configuration is identical for all analytes, Sanford could expand molecular testing using a single platform.

Finally, Sanford Health's molecular technical director, Jody Thompson, MD, MLS (ASCP), led a comprehensive comparative evaluation between three molecular systems. The rejection of the two competitive systems was based on differences in test performance, workflow, test menu, scalability and financial considerations.

Cepheid's single-use cartridge base technology is simple to use and accurate. It automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time PCR. The single-use disposable GeneXpert cartridges hold the PCR reagents and host the PCR process. The sample processing time is typically less than one minute, and most tests results are available within one hour.

➤ Comparison of Rapid Molecular* Platforms

	Cepheid	Roche	Alere
Technology	X	X	
Operations	X	X	
Financial	X		X
Scalable	X		
Menu	X		
Features	X		

* Rapid molecular=turnaround time ≤ 30 minutes

Other key drivers were Cepheid's capability to interface easily with Sanford Health's Laboratory Information System and the availability of Cepheid's C360 connectivity solution to facilitate the collection of data from GeneXpert Instruments. Having software that helps to monitor data in real time was a huge benefit to management from a system monitoring perspective.

▾ Implementation

After the decision was made to move forward with the GeneXpert technology, the next challenge was implementing 70 GeneXpert Systems at 70 sites. This was an enormous undertaking, best described by Dr. Thompson, "We had zero experience with system-wide implementation and did not have a dedicated project manager, but Cepheid stepped in."

Cepheid's Field Application Specialists (FAS), its implementation team, took the lead as project managers and partnered with Sanford Health's team to organize an aggressive implementation plan. The objective was to complete system installations and training at all 70 sites within 10 weeks and to prepare each site to be ready for patient testing within 90 days.

To start the implementation planning process, the FAS team opened the lines of communication between Cepheid sales, Cepheid internal support, Sanford Health's lab leadership and all 70 Sanford sites. Their shared tasks included creating implementation schedules, coordinating purchase orders and shipment of GeneXpert Systems and reagents, planning implementation calls, customizing and presenting webinar trainings to Sanford Health's requirement, and installing and providing training on the GeneXpert System and the Xpert® Flu/RSV assay.

The FAS team seamlessly exceeded their goal by more than a month of having the Xpert® Xpress Flu/RSV assay implemented and live at all 70 sites by October 31st, in preparation for the upcoming influenza season. Key factors to their success included robust planning, open communication, and commitment from both the Sanford Health and Cepheid teams. By the end of the implementation process, 172 operators were trained and ready to provide molecular testing to Sanford Health patients for the next flu season.

Conclusion

Cepheid and Sanford Health's mission statements both stress improving patient outcomes and are dedicated to health and healing. Lisa Deja, Territory Sales Executive for Cepheid, stated that "our missions are too similar for us not to partner." This commenced a two-year journey of collaboration and partnership that involved several field people and in-house executives, including a VIP visit to Cepheid's headquarters in Sunnyvale, California. This resulted in a unique partnership in which Cepheid played a true consultative role, providing guidance in Sanford Health's final decision to move forward with decentralizing molecular testing.

Decentralizing flu testing can be achieved by using the right technology and vendor partnership. Dr. Thompson said,

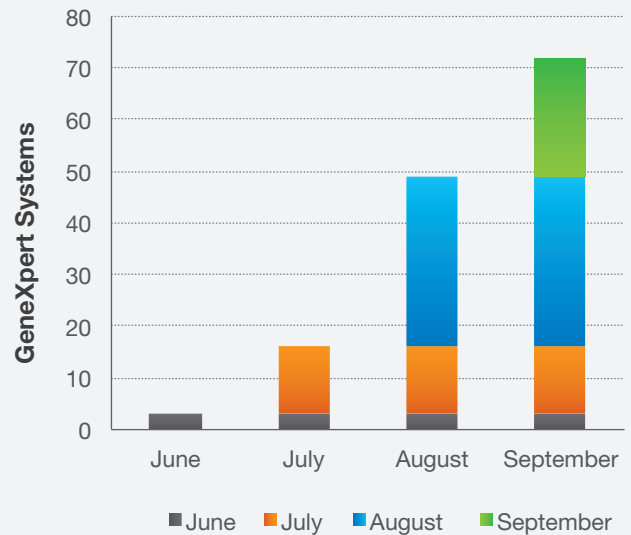


It took persistence, partnership, communication, and collaboration with Cepheid"

to successfully meet their objectives.

Implementation: GeneXpert Systems Installed

June	3
July	13
August	33
September	23
Total	70



For *in vitro* diagnostic use.

Sanford Health internal study data provided.

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