

Reaching new heights of accuracy and efficiency

Avera McKennan lab meets highest international standards

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A good laboratory is integral to the operations of a hospital, but an outstanding laboratory such as Avera McKennan's is one that assures a higher measure of quality, leading to more accurate diagnoses and better treatment.

"Avera McKennan's laboratory has always been a good lab," said Leo Serrano, laboratory director. In recent years, however, a journey toward process improvement has turned a good lab into an outstanding lab, proven by its achievements as the first hospital laboratory in the nation and world to earn ISO 15189SM accreditation through the College of American Pathologists, and its standing as a 5.4 Sigma lab. Six Sigma is a measure of quality based on variance, or error rate. The highest rating of 6 Sigma signifies 3.4 errors per million opportunities.

"Physicians base up to 70 percent of their treatment decisions on lab results," Serrano said. So although a better than average lab at 3.8 Sigma in 2004, the Avera McKennan lab embarked on the first LEAN project at the hospital to improve efficiency and quality. This project was so successful, it became the pilot which launched a hospital-wide Process Excellence initiative, leading to ongoing LEAN projects throughout the hospital.

In April 2004, five lab staff stepped away from their regular full-time duties to immerse themselves in a 16-week LEAN project. "Laboratories never have too many people working. It was a huge commitment to pull these people from the line for that length of time," said Cheryl Wildermuth, lab quality manager.

Long hours paid off. "Very early, we saw very positive results," Wildermuth added.

One of the first changes was moving to the LEAN principle of single piece flow rather than the batch approach. Formerly, phlebotomists went to the patient care units, collected blood, carried that tube of blood for an hour and dropped off the whole batch at the end of the rounds. The change involved collecting

the blood and immediately sending it to the lab via pneumatic tube. Lab staff in turn began processing tests on a single piece basis, rather than waiting for a whole batch. "We were able to equalize the flow of specimens throughout the day for fantastic results," Wildermuth said. Lab turnaround time was reduced by 44 percent, from about 62 minutes to 35.

At the same time, the lab staff were

ISO 15189 signifies level of 'world class'

In January 2009, the Avera McKennan Laboratory became the first hospital laboratory in the nation and world to achieve ISO 15189SM accreditation, through the College of American Pathologists.

The voluntary accreditation is based on the International Organization for Standardization (ISO) for laboratory technical competence and continual quality management. This program optimizes processes to improve patient care and strengthen quality standards while reducing errors and risks. It is achieved through a highly disciplined approach to implementing and sustaining change.



Q: What is ISO?

A: ISO is a worldwide federation of national standards bodies from more than 140 countries. ISO is a non-governmental organization established in 1947 to promote the development of standardization and related activities in the world with a view to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activity. ISO's work results in international agreements, which are published as International Standards.

Q: What is ISO 15189?

A: ISO 15189:2007 is an internationally recognized standard specifically designed for medical laboratories. Although it is not currently a requirement in the United States, it is a clear indication that a laboratory has achieved world class best practices in quality management systems and laboratory technical competence.

Q: What does this mean to patients and physicians?

A: Since it is recognized that 70 percent of the objective data found in a patient's medical record comes from the medical laboratory, knowing that the laboratory has been examined by an outside third party and found to meet the highest standards of quality and competence is of immeasurable importance. The ISO 15189 accreditation program assesses, certifies and accredits the world class performance level of medical laboratories.

Q: Why would a laboratory choose to undergo such a rigorous program to gain this voluntary accreditation?

A: This is the ultimate mark of excellence in the field and sets a laboratory apart from all of the other 100,000+ federally licensed laboratories in the United States.

Source: College of American Pathologists

planning for a relocation and redesign of the lab, expecting to increase the size of the floor plan by at least 30 to 50 percent. Mapping of traffic patterns showed the tremendous number of steps staff were taking, and presented opportunities for improvement with a new design. With the advent of a central core area where the majority of lab tests are processed, the new space was designed to be 1,000 square feet less than the original lab, but with much better process flow.

The original lab was very departmentalized, with a hematology department, chemistry department and so on, Serrano explained. "People did only specialized work. So while some staff members had idle down time, others were incredibly busy," he said.

The LEAN team identified 80 percent of the testing volume, and designed a work cell that performed all these tests. "By doing so, we were able to maximize productivity," Serrano said. The old lab work set-up involved one person per instrument. In the new work cell, one person was trained to handle eight instruments. In the old lab, everything in was processed in batches. "It was hurry up and wait." The improved work flow takes place in well-paced six-minute cycles, Serrano said.

Consistent results

While the improvement in turnaround time was significant, what's even more important is that this has stayed consistent for going on five years. Although test volume has grown by more than 30 percent, turnaround time has remained at 35 minutes or less. Error rates continue to average only about 70 errors per million opportunities or lower – thousands fewer than before the 2004 LEAN project.

In 2006, Johnson and Johnson conducted an evaluation of 62 labs worldwide that had implemented LEAN principles, and Avera McKennan's ranked Number 1.

While maintaining and improving upon accuracy and efficiency, the lab also focuses on quality by staying on the cutting edge with the newest developments. Examples include:

- The latest generation hematology and blood chemistry analyzers
- Molecular diagnostics to isolate DNA from organisms in identifying infectious disease

Outstanding lab work supports lifesaving care

As home to the only bone marrow transplant program in the state and wider region, Avera McKennan must have a laboratory to back up this lifesaving program for people with certain types of cancer, such as leukemia, lymphoma or multiple myeloma.

"The laboratory is critical in maintaining the integrity of a transplant program," said Dr. Vinod Parameswaran, hematologist with Avera Hematology and Transplant and medical director of Avera McKennan's stem cell processing lab. "We are doing world class work here."

For example, lead stem cell technologist Leslie Cooper, working with Dr. Parameswaran, lab director Leo Serrano and pathologist Dr. Henry Travers, developed use of a cryoprotectant to successfully store stem cells.

A cryoprotectant is a combination of chemicals which help stem cells survive at freezing temperatures for storage. This team developed a new combination of chemicals never used before.

As a recent graduate from the University of Texas Medical Branch at Galveston Blood Bank Specialist Program, Cooper was eligible to submit a technical paper on the project, titled "Cryopreservation of Peripheral Blood Progenitor Cells by Uncontrolled Rate Freezing at 95 degrees Centigrade Using Cryoprotectant Containing a Final Concentration of 5% Dimethyl Sulfoxide." She was awarded the 2009 AABB-Fenwal Scholarship, Specialty in Blood Banking Scholarship Award, sponsored by Fenwal, Inc. She was one of two awardees named by Fenwal nationwide.

The research will be nationally published in a leading peer journal, and will benefit stem cell programs across the nation and world.

- The CYP 450 lab analyzer to seek out DNA mutations in liver enzymes to determine whether a patient metabolizes drugs quickly or slowly, for individualized dosing of certain medications
- A six-color laser based flow cytometer to count and sort cells, used extensively in the diagnosis of different types of malignancies such as leukemia and lymphoma

While the lab analyzes specimens of blood and other body fluids, a separate histology and anatomic pathology department analyzes biopsies, tumors, body tissues and organs, and performs autopsies. Serrano says one of the lab's greatest achievements is to establish its own virology department. "Our microbiology is very sophisticated. We identify thousands of organisms, and can determine what medications those organisms are sensitive to," Serrano said. This department also offers rapid virus identification using a direct fluorescent assay. "Our goal is to be able to identify many viruses within 24 hours."

Striving for continual improvement, in 2007 the lab decided to pursue ISO 15189:2007 through the College of American Pathologists (CAP), a new international standard designed just for laboratories which recognizes both quality

system management and technical competence of medical laboratories.

Accurate results, better treatment

"A test result is only as good as the quality that is put into it," Serrano said.

"A patient's life is at the end of every test result." Efficiency and accuracy are only part of an overarching quality management system.

The lab already is in compliance with federal regulations through CLIA, the Clinical Laboratory Improvement Act. This law requires that laboratories be registered by the federal government depending on their level of complexity. ISO 15189 is a voluntary certification program, so rigorous that not many labs even pursue it. "ISO certification documents and verifies that we are the top performing hospital laboratory," Serrano said.

For patients, the bottom line benefit is accurate answers that result in better treatment. "We don't touch the patients with our hands, we touch them with our data and our findings," Serrano said. "Every number is a patient, every patient is a person, and our goal is to do the right thing for every patient, every time."



Avera McKennan Laboratory: By the numbers

- 125,000:** Average tests per month
- 1,000+:** Different tests conducted by the laboratory
- 35 minutes:** Average turnaround time from specimen collection to result verification
- 5.4:** Sigma rating on 6 point scale based on errors per million tests
- 99.9993%:** Avera McKennan laboratory's accuracy rating (70 errors per million tests)

24 hours in the lab

The Avera McKennan laboratory is staffed 24/7/365.

Midnight-4 a.m.: Night shift processes any tests that were specially ordered during then night hours, and conduct daily maintenance on testing equipment

4:30-8 a.m.: Specimens arrive from patient care units. Turnaround time of 35 minutes is the target so physicians can review them on their morning rounds. Turnaround time is measured on the hour to consistently meet this goal.

8 a.m.-7 p.m.: Inpatient load drops off as the outpatient load picks up. Couriers drop specimens off throughout the day from clinics or the Avera Behavioral Health Center, to keep work load steady throughout the day.

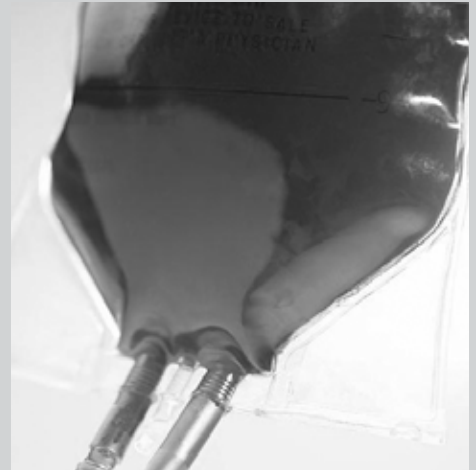
7 p.m.-Midnight: Couriers bring large numbers specimens from locations up to 200 miles away, which are processed as they are received. The goal is to have results entered on computer by midnight so physicians and patients in regional locations also receive timely results. Results are transmitted electronically to hospital floors or physician offices.



Pheresis is the latest technology in blood donation

Each year, 4.5 million people benefit from blood – a lifesaving gift that only willing donors can provide.

Avera McKennan's laboratory partners with the Community Blood Bank to collect blood products, and serves as the only collection facility in Sioux Falls to offer pheresis, an exciting technology that benefits both donors and patients. Traditional whole blood donation is always an option as well.



Pheresis, also known as apheresis, is a special type of blood donation in which the donor's blood travels through a machine which removes one component – in this case platelets – and then returns to the donor.

Avera McKennan's cutting-edge cancer care, including bone marrow transplant, places heavy demands on the local blood supply. Blood is also used in heart surgeries, to care for accident victims, and in many other ways. Platelets are cells produced in the bone marrow that are needed to prevent bleeding. Donation of these cells is important, as certain patients need transfusions of only platelets to survive, especially cardiac, cancer and organ transplant patients.

Platelets are in high demand, because they have a shorter shelf life of five days, and seriously ill patients may need multiple transfusions. When whole blood is donated, it is separated into three components: red blood cells, plasma and platelets. A single pheresis donor can give a concentrated dose of platelets which otherwise would require six to eight whole blood donors to provide.

Platelet donors benefit because the process does not take a whole unit of blood, and the body can quickly manufacture platelets to replace those donated. In fact, pheresis donors can give platelets more often – every two or three days up to 24 times per year – and help more people with their donations. Whole blood donors in comparison can donate every 56 days, or about every other month, for about six times per year.

Patients benefit because their risk of reaction is reduced, as they are exposed to only one donor rather than six to eight. Blood given at the campus blood bank in Avera Doctors Plaza 2 is used at Avera McKennan, the Avera Heart Hospital of South Dakota, or at a hospital within the Avera network in South Dakota, Minnesota or Iowa. Each month, Avera McKennan and its associated facilities use an average of 2,000 units of blood components.

For information about giving whole blood, or platelets through pheresis, the Avera Community Blood Bank can be reached at 322-7111.