AHEAD OF THE CURVE: LabCorp enters brave new world of genetic-based testing
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By Robert Boyer, Times-News, Burlington, N.C.
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Feb. 17--In June 2000, scientists from the U.S. and Great Britain announced that they had cracked the humane genome, or code of human life.

The researchers said they had mapped 97 percent of the genome and accurately sequenced 85 percent of the DNA code.

The Human Genome Project completed the mapping in 2003.

The breakthrough was hailed as one of the greatest in human history, one that, according to a story from BBC News, "will revolutionize medicine over the coming decades, giving us new tests and drugs for previously untreatable diseases." That prophecy has come to pass, and fast, says Brad Smith, Lab-Corp's executive vice president for corporate affairs. LabCorp, based in Burlington, is the second largest clinical testing laboratory in the U.S.

Traditional tests for things like blood counts, physicals, cholesterol level, thyroid and Pap smears make up about 65 percent of its business. Later this year, LabCorp will move into its new headquarters in downtown Burlington.

A sculpture depicting a DNA strand will adorn the courtyard.

The artwork could well symbolize how genetic testing is fundamentally changing Alamance County's largest employer.

To borrow the title of Aldous Huxley's famous book, the mapping of humanity's complete genetic code is propelling LabCorp "into a brave new world" of testing in the 21st century.

LABCORP BEGAN its turn toward genetic testing about a dozen years ago. Since 2002, such esoteric (specialized) and genomic testing has grown from 27 percent of the company's business to 34 percent. Within three to five years, Smith and other LabCorp officials say that figure could grow to 40 percent.

The advances in clinical testing that sprang from unlocking the instructions for human life are revolutionizing medicine and LabCorp's role in it, Smith said.

"It really is a dramatic change in our business. The role of our company has undergone a revolutionary change." The revolution, Smith and other LabCorp officials say, is still in its infancy.

One of the most promising areas of growth and advances, Smith said, is "companion diagnostics," or testing matched to new therapies or drugs.

The tests use genetic markers to, among other things, help pharmaceutical companies determine specific patients that will benefit from a drug or those who will have an adverse reaction to it.

Other tests help doctors determine the proper dose for patients by determining the speed at which each person metabolizes a dose.

Dosing tests, which are based on a patient's genetic makeup, are especially helpful, Smith said, when it comes to prescribing psychiatric drugs and blood-thinners that prevent clots and strokes.

A test LabCorp developed for Genentech Inc., the California maker of Herceptin, a drug to treat a certain type of cancer, has been a boon to everyone involved, Smith said.

The drug is effective only for those with a certain gene. The test looks for that gene in patients.

Until the test was developed, the Herceptin was in short supply. Being able to pinpoint the patients who need the drug solved the supply problem, Smith said.

A genetic test to aid in prescribing bucindolol, a heart failure drug in development by **ARCA Discovery Inc.**, of Denver, identifies and eliminates study patients who have adverse reactions to the drug.

"When you look at the study, this becomes a very effective drug for the pool of patients who aren't going to have the adverse reactions," Smith said.

With some drugs, genetic testing for adverse reaction could save a drug from being yanked from the market, Smith said.

What these and other genetic tests offer, in essence, is "boutique medicine," where doctors can tweak dosages and offer specialized treatment to each patient.

"It's like customized medicine, personalized medicine based upon each person's individual genetics. We're basically there," Smith said. "The more targeted the therapy is, the more likely it's going to be effective." In addition to the aforementioned benefits, such tests save patients and insurance companies money because neither have to pay for unneeded or ineffective drugs, Smith said.

The tests also benefit LabCorp's bottom line in a big way, by putting the lab foursquare into what Smith called the "continuum of care." On the front end of that continuum, LabCorp works with a pharmaceutical company to create a test for a drug in development. On the back end, the doctors order the test from LabCorp.

"If we help develop the test, we're going to be in a leading position to be the test laboratory of choice for physicians who prescribe the new drugs for their patients," Smith said. "We're involved in the whole continuum of patient care. Whereas historically, tests may have only been used to only diagnose disease, now it's an integral part of the treatment of the patient." THE TURN TO more genetic based testing is leading to major changes throughout LabCorp.

The company recently acquired Tandem Labs of Utah to strengthen its companion diagnostics testing.

To meet the growing market, Smith said LabCorp will need to hire more specialized scientists and researchers to keep up. It will also continue to need a local pool of trained, skilled workers.

LabCorp has seen the future and prepared for it with an extensive testing and distribution network, Smith said.

The company has esoteric, forensic and identity testing centers in Burlington. Other labs include a molecular diagnostic in the Research Triangle Park; a virology (study of viruses and the diseases they cause) specialized testing lab is in Minneapolis. A hematology (study of blood-related diseases) testing lab is outside of Denver; another blood-testing lab is in Los Angeles.

The company, Smith said, can also deal effectively with the regulatory complexities involved in genetic testing and has strong relationships with insurers.

With its labs and 1,600 patient service centers and more than 2,600 drivers, Smith is confident LabCorp's national distribution infrastructure gives the company a competitive advantage.

LabCorp is at the forefront of testing advances and "at least equal to if not the largest in the country" compared to the largest clinical laboratory when it comes to genomic and specialized testing, Smith said. Challenges in this brave new world include the age-old problems of improving efficiency and "making sure that you get appropriately paid" for the new tests, Smith said. Keeping up with the everchanging regulatory and insurance requirements to insure payment and stay in compliance with the law are other challenges.

SMITH PREDICTED THAT in the next 5 to 10 years, genomic and esoteric tests will become much more prevalent, with new tests for cancers and for "diseases that don't exist today." The tests will have a "dramatic impact" on early detection and treatment of diseases like cervical cancer and early screening for ovarian cancer. LabCorp is working with Yale University to develop an earlyscreening tests for ovarian cancer.

LabCorp is also working on developing an earlier test for lung and colon cancers, and more tests to match different types of cancer treatments for patients to increase effectiveness.

Through the years, Burlington and Alamance County has provided LabCorp "with an excellent employee population," Smith said. "We think it's a great place to be headquartered and do business from.

In the coming years, LabCorp will continue, Smith added, to count on the Alamance-Burlington School System, Alamance Community College and area universities to provide well-educated workers.

The training program partnerships LabCorp has with ACC are especially valuable because, Smith said, they increase the company's chances of attracting and keeping local workers.

LabCorp also welcomes the influx of new business and industry and new skilled workers into the county. Companies like Honda Aero, which is building a jet-making operation near the Burlington Alamance

Regional Airport, will help LabCorp grow and get more good employees by drawing new people to the area, Smith said.

Smith and his LabCorp colleagues think the best of this new frontier is yet to come.

"The future is unlimited," he said. We're just at the beginning." To comment on this and other Times-News stories, go to TheTimesNews.com and scroll to the bottom of the story