Laboratory QUALITY You Can Count On

MultiCare Health System's laboratories, collectively known as LABORATORIES Northwest, have achieved Six Sigma Verification and received recognition November 30, 2017 by Sten Westgard of Westgard QC following final on-site verification. This award acknowledges exceptional quality and highly correlated results run on eleven instruments across six laboratory sites (Auburn Medical Center, Allenmore Hospital, Good Samaritan Hospital, Tacoma General Hospital/Mary Bridge Children's Hospital, Covington Medical Center, and Gig Harbor Clinic). Our providers and patients can be assured that not only are results accurate, they are the same clinically at any of our sites. MHS/LabsNW is the first laboratory system in the world (multi-instrument and multi-site) to qualify for Six Sigma Verification.

The Westgard Sigma Verification Program allows laboratories to prove their performance at the highest caliber of world class standards. Verification indicates the laboratory has the right methods, the right staff, the right training, the right Quality Control (QC) implementation and most importantly, is reporting the right test results. While accreditation programs (such as Joint Commission and College of American Pathologists) mandate a documented and implemented policy for QC, the Sigma VP program requires on-going quantitative evidence of instrument performance at a 4-Sigma level or higher. Describing errors (or defects) at sigma levels is a measure used in other industries, including airlines and manufacturing. Testing at a 6-Sigma level indicates no more than 3.4 defects per 1 million testing events. Performance at this level provides confidence in the test result without the time/expense of repeats or redraws. In fact, because of our quality performance, we release critical results immediately without repeat (unlike most health systems), saving at least 20 minutes.

Sigma Verification is more than a simple one-time achievement; we now have an obligation to progressive future performance. Continued Verification requires lab leader and technologist knowledge and performance through examinations, annual renewal of all assays by verification data (minimum 3 months of data), demonstrated process improvement, and new tests must be added annually to the list of verified methods.

Achievement of Six Sigma Verification highlights the laboratories' ongoing commitment to quality while reducing costs, optimizing efficiency, and improving service and satisfaction. It is a tangible way the laboratory partners with the rest of the health system and with our patients - ensuring high quality, reliable, timely, and accurate test results.

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What is Quality Assurance?

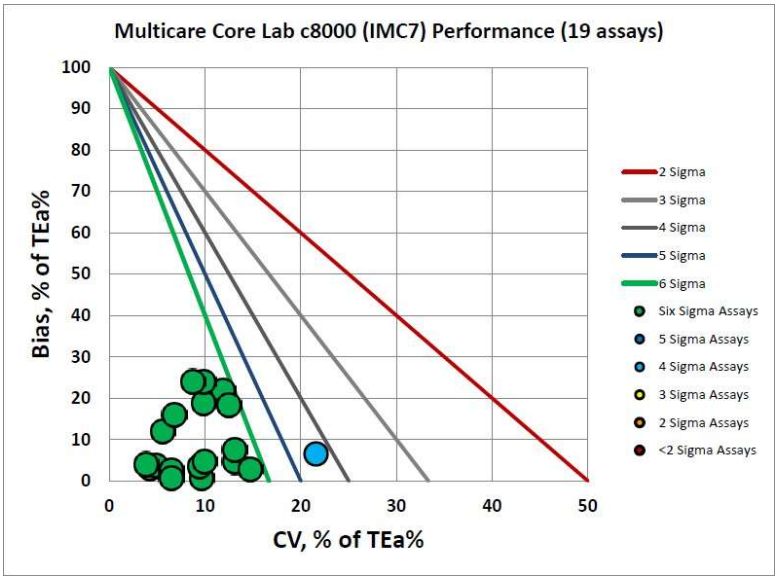
Quality Assurance indicates a comprehensive program of actions and processes to facilitate the identification and correction of errors, promote process improvement, enable safe environments, confirm staff competency, and most importantly, ensure the high quality of the results generated by the laboratory. Implementation of a quality assurance program is an accreditation and regulatory mandate; our goal is to not just meet the requirements, but to far exceed them and leverage our program to demonstrate world class performance.

What is Quality Control (QC)?

Quality Control refers to use of stable laboratory products tested along with patient samples to ensure accuracy, precision, reproducibility, and standardization of the analyses. The QC program of a laboratory defines the quality of the testing; a robust QC program ensures instruments are *not* random number generators. Laboratory horror stories exist in our industry where QC is assayed repeatedly until the "correct" number is generated. Should patient tests then be assayed at the same repetition cycle to produce the correct results? No! Our quality control program utilizes complex statistical analysis of QC material and instrument performance to tailor individualized processes to ensure reliable test results at the first time of testing.

Why don't all assays perform at Six-Sigma level?

Physiologic and chemical properties of the tested analytes vary greatly. Certainly, six-sigma performance is our aspirational goal for all assays, but in many cases the current technology simply does perform at this level. So, what is a laboratory to do? Our strategy is to understand and evaluate the sigma performance level of *each assay*, ensuring the quality of ALL our testing methods despite technologic limitations. Quality performance and sigma levels are key criteria used to select new instrumentation and methodologies.



Why did our laboratory system pursue this recognition?

QC/QA has long been a passion and an evolving journey in the laboratory. John Baker, Manager of Core Laboratory Science and Technology, has developed, implemented, tweaked, revamped, and revised our QA/QC program over many years, always seeking higher quality and extending the same policies and expectations for all testing locations. His knowledge and performance is highly regarded in the clinical laboratory industry and MHS/LNW was invited to participate in this new, revolutionary means of evaluating quality. Not only were we able to use these new tools to validate many of our assays, it has provided additional framework for our future work. Another realized benefit is that this designation mandated a level of staff expertise through education and examination as Quality Managers. 18 leaders and technologists across the laboratory system are qualified at this level. This provides an even higher level of competence, ownership, and engagement that will be foundational as we continue to extend the program out to more of our team members.

Additionally, our participation in this program was sought in part because of our unique approach to integration and standardization of clinical laboratory medicine across our health system. MHS/LNW is the FIRST laboratory *system* to qualify for this designation internationally. There are approximately 32 stand-alone facilities who've achieved the Verification to date; with our 6 we represent 25%! It should be noted that all MHS/LNW departments and locations utilize innovative and advanced tools to ensure and maintain quality.

Why don't all clinical laboratories adopt these tools?

The development of the Six Sigma Verification Program and use of sigma analysis as a set of tools is relatively new in our industry, but it will likely create long-range ripples building to a tide of change. MHS/LNW is fortunate that our existing instrumentation and QC program qualified us at the levels for Verification. Many instruments in the market place are not capable of meeting these quality metrics. In addition, incorporation of this new tool into a QC program requires vigorous statistical analysis and monitoring protocols as well as advanced training and technical performance. It's not easy! But we are committed to it to reap the extraordinary benefits to patient care.

Does this mean there will no longer be laboratory errors?

Unfortunately, the answer to this is not yet. The production of laboratory test results is complex and involves numerous variables prior to testing, including patient preparation, sample collection, sample viability, appropriate sample handling, timing, and correct identification and labeling. These are all areas that are much more difficult to control and are all areas monitored for improvements in our quality assurance program. Impacts of these variables are evaluated as much as possible prior to release of the patient results. Managing these pre-analytic variables is of critical priority in the laboratory, and underscores our efforts in communication, training and education, competency of staff, and a clear understanding of these concerns in the interpretation of test results.

Why should I choose a MultiCare/LABORATORIES Northwest Laboratory?

A lab test is *not* a lab test is *not* a lab test. With our expertise and commitment to quality, our patients and providers can be reassured that the laboratory results informing treatments, diagnoses, and health monitoring are accurate. **The Six-Sigma Verification program demonstrates that our laboratory exceeds beyond the top 1% of laboratories internationally.** *We have the right methods, the right staff, the right training, the right Quality Control (QC) implementation and most importantly, we report the right test results.*

Special Recognition to: John Baker, Dan Lee, Craig Vilk, Ebon'e Jones, Kyle Congo, Carrie Taylor, Evan McGovern, Brenda Lawing, Megan Williams, Lorie Linley, Evan Davis, Brian King, Tim Uy, Lois Sams, Carol Lynch, Rita Tsang, Gay Johnson, and Luana Ugalde.

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