

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0664370	(X3) Date Survey Completed 01/26/2022
Name of Provider or Supplier West Loop Laboratory	Street Address, City, State 300 North John Redditt Dr Suite #7, Lufkin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of accuracy assessment records, and confirmed in interview of laboratory personnel, the laboratory failed to have a policy that defined acceptance criteria for performing split sample accuracy assessments with a reference laboratory. The findings included: Note: There is no commercially available proficiency testing material. Therefore, the laboratory must verify the accuracy of tests that do not have compatible proficiency testing samples offered. 1. Review of the laboratory's policies found no policy available that defined acceptance criteria for evaluating accuracy performed when the laboratory performed split sample accuracy assessments. 2. Review of the laboratory's accuracy assessments from September 2021 through December 2021 found the laboratory performed an in-house CBC and would perform a split sample with a reference laboratory. However, the results were not evaluated against any acceptable criteria to determine if results were accurate. 3. An interview with the testing person on January 26, 2022 at 11:00 hours in the office confirmed the findings. Upon her review of the records, she agreed there was no established acceptance criteria for evaluating the data.</p>
D5485	<p>CONTROL PROCEDURES CFR(s): 493.1256(h)</p> <p>If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time.</p>

The performance of alternative control procedures must be documented.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, quality control records, patient records, and confirmed in interview of laboratory personnel, the laboratory failed to have a mechanism in place to (A) detect immediate errors and (B) monitor test system performance over time for 150 patients tested for CBC (complete blood count) from August 1, 2021 through January 5, 2022. The findings included: A. No mechanism in place to detect immediate errors 1. Review of laboratory policy titled, "Quality Assurance Reviews" stated, "The nurse shall make sure controls on the QBC are run daily and appropriately documented. She shall also document the patient results and if the results are awry, she should re-run the test and appropriately so document. The results should be immediately available to the physician..." 2. Review of quality control records found the laboratory did not have an alternate mechanism in place to detect immediate errors from August 1, 2022 through January 5, 2022. 3. Review of patient records from August 1, 2022 through January 5, 2022 found the laboratory tested 150 patients when it did not have an alternate mechanism in place to detect immediate errors (see patient alias list - QBC Autoread Results of Patients Run from August 1, 2021 through January 5, 2022). 4. An interview with the testing person on January 26, 2022 at 10:30 hours in the office confirmed the findings. She stated that she does periodic split samples with a reference laboratory and thought that covered the alternate mechanism. B. No mechanism in place to monitor the test system's performance over time 1. Review of laboratory policy titled, "Quality Assurance Reviews" stated, "Each month the nurse should review all aspects of quality control and quality assurance and she should document any problems encountered and how they were resolved on the quality assurance. 2. The laboratory did not perform at least two levels of quality control testing each day of patient testing. Therefore, there were no records that could be reviewed monthly. a. The laboratory did not have a mechanism in place to detect errors over time. 3. The laboratory was asked to provide documentation of having a mechanism in place to detect errors over time. No documentation was provided. 4. An interview with the testing person on January 26, 2022 at 10:00 hours in the office confirmed the findings.