Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2039306	12/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Oxford Primary Care	430 Snow Street, Oxford, AL	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the calibration verification (C/V) records for the Alfa Wasserman Ace Axcel Chemistry analyzer and an interview with the Laboratory Director, the surveyor determined the the laboratory failed to perform and document C /V's for two out of seventeen analytes during the first half of 2020. The findings include: 1. A review of the records for the Alfa Wasserman Ace Axcel Chemistry analyzer revealed all analytes were calibrated with one- or two-calibrator kits. CLIA

	regulations specify analytes calibrated with less than three calibrators must have a calibration verification (C/V) performed every six months. 2. A review of the Chemistry analyzer records revealed the laboratory performed a C/V on fifteen analytes on 5/11/2020, however there was no documentation of a C/V on Carbon Dioxide (CO2) or Total Bilirubin (TBil). 3. In an interview on 12/3/2020 at 1:45 PM, the Laboratory Director confirmed the above noted findings, stating CO2 and TBil were possibly missed because these tests required a different C/V kit. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of quality control records and an interview with the Laboratory Director, the laboratory failed to document Chemistry and Hematology quality control (QC) shifts and trends over time for a one year period since November 2019. The findings include: 1. During the initial tour, the surveyor reviewed the analyzers in use and the test menu for this laboratory. The Laboratory Director stated patient testing began the end of November 2019. 2. A review of the QC records for the Alfa Wasserman Ace Axcel Chemistry analyzer and the Sysmex XP-300 Hematology analyzer revealed only the daily QC instrument printouts were available. The laboratory had no records documenting the monitoring of QC shifts and trends over time. (Examples include printing Levi-Jennings charts or periodically submitting data to a QC company's Interlaboratory Quality Assurance Program [IQAP]). 3. During an interview on 12/3/2020 at 12:45 PM, the Laboratory Director confirmed the above noted findings. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the Chemistry records, and an interview with the Laboratory Director, the surveyor determined the the laboratory failed to perform and document

	complete validations of the manufacturer's performance specifications for three out of seventeen analytes on the Alfa Wasserman Ace Axcel Chemistry analyzer, before patient testing began. The findings include: 1. A review of the October 2019 validation records for the Alfa Wasserman Ace Axcel Chemistry analyzer revealed the Laboratory Director had failed to ensure validations for three analytes were completed before the instrument was used for patient testing in November 2019. The following records were missing: A) Calcium: no documentation of precision or reportable range studies B) Total Cholesterol: no documentation of precision studies [The laboratory could find no documentation these studies were performed.] C) Potassium (K): invalid precision and reportable range studies; documentation showed K values were imprecise with a "canceled" error, and the reportable range study was not linear. 2. During an interview on 12/3/2020 at 1:25 PM, the Laboratory Director confirmed the above noted findings. SURVEYOR ID #32558 Licensure and Certification Surveyor