Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2039306	08/31/2022
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of American Academy of Family Physicians (AAFP) Proficiency Testing records and an interview with the Laboratory Director, the laboratory failed to maintain a copy of instrument printouts for proficiency testing samples. This was noted on two out of five Hematology Proficiency Testing Events from 2021 to 2022. The findings include: 1. A review of AAFP Proficiency Testing records revealed the 2021 Hematology Event A and 2021 Hematology Event C instrument printouts were not retained. 2. During an interview on 08/31/2022 at 11:30 AM, the Laboratory Director confirmed the above findings.
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 review of the Sysmex XP-300 analyzer quality control records and an interview with the Laboratory Director, the laboratory failed to document a method monitoring Hematology quality control (QC) shifts and trends over time from the date of the last survey (12/03/2022) to the date of the current survey (08/21/2022). This was noted for four out of six months reviewed. The findings include: 1. A review of the Sysmex XP-300 analyzer quality control records revealed Levy Jennings charts were not retained for all three levels of Hematology QC in order to monitor shifts and trends in January 2021, April 2021, July 2021, and July 2022. 2. During an interview on 08/31/2022 at 2:20 PM, the Laboratory Director confirmed the above noted findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Sysmex XP-300 analyzer quality control (QC) records, Alfa Wassermann Ace Axcel analyzer quality control records, patient result logs, and an interview with the Laboratory Director, the laboratory failed to ensure at least two levels of quality control were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted two days out of 6 months reviewed from Jan 2021 to Jul 2022. The findings include: 1. A review of the QC records for the Sysmex XP-300 analyzer revealed no controls were run on 01/11/2021. The patient result log revealed two patient Complete Blood Count (CBC) tests were performed. 2. A review of the QC records for the Alfa Wassermann Ace Axcel analyzer revealed no controls were run on 04/29/2021. The patient result log revealed five patient Complete Metabolic Panel (CMP) tests were performed. 3. During an interview on 08/31/2022 at 3:00 PM, the Laboratory Director confirmed the above findings.