Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1002756	09/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Oxford Pediatric Group Pllc	101 Farm View Drive, Oxford, MS	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review Beckman Coulter DxH 500 QC (quality control) records from installation on 3/23/21 through 9/13/22 and confirmation with testing personnel (TP) #2 at 3:00 p.m., the laboratory failed to retain the quality control (QC) assay sheets for each lot used. QC assay sheets include acceptable ranges, storage requirements, lot numbers and standard deviations and should be kept for a minimum of 2 years. Findings include: 1. Review of the DxH 500 records indicated QC lot 3522139 was in use on the day of the survey. According to the QC records there were 8 lot numbers of QC used but the assay sheets were not retained with the change of a new lot number. 2. Review of the DxH 500 records from 3/23/21 until 9/13/22 revealed the following hematology QC lots had been used: a. DxH 500 QC lot # 352112211, 362112212, 372112213- low, normal, high expiration date- 5/5/21 b. DxH 500 QC lot # 352112511, 262112512, 372112513- low, normal. high expiration date- 8/5/21 c. DxH 500 QC lot # 352112611, 362112612, 372112613- low, normal, high expiration date- 9/5/21 d. DxH 500 QC lot # 352112811, 362112812, 372112813- low, normal, high expiration date-11/5/21 e. DxH 500 QC lot # 352112911, 362112912, 372112913- low, normal, high expiration date-12/5/21 f. DxH 500 QC lot # 352113011, 362113012, 372113013- low, normal, high expiration date- 1/5/22 g. DxH 500 QC lot # 352113111, 362113112, 372113113- low, normal, high expiration date- 2/5/22 h. DxH 500 QC lot # 352213311, 362213312, 372213313- low, normal, high expiration date- 4/5/22 3. Interview with TP#2 at 3:00 p.m. on 9/13/22 confirmed the lab did not retain QC assay sheets with each lot number of QC material for the Beckman Coulter DxH 500 hematology analyzer.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of Beckman Coulter DxH 500 hematology analyzer maintenance records from installation on 3/23/21 through 9/13/22 and interview with the Testing Personnel (TP) #2 as listed on the CMS 209 at 2:00 p.m. on 9/13/22, the laboratory failed to document as performed the monthly maintenance on the DxH 500 analyzer as required by the manufacturer. Findings include: 1. Review of the DxH 500 records from 3/23/21 through 9/13/22 revealed the following monthly maintenance had not been documented as performed since installation on 3/23/21. Monthly or every 1,000 cycles: Perform Bleach Cycle Monthly: Clean the WBC Bath Filter B. TP#2 at 3:00 p. m. on 9/13/22 confirmed monthly maintenance was not documented as performed for the DxH 500 hematology analyzer.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) records available on 9/13/22, the CMS (Centers for Medicare and Medicaid Services) 209 form and interview with the technical consultant/laboratory director (TC/LD), TP#2 and office manager, the laboratory director had not ensured that all testing personnel as listed on the CMS 209 personnel form had received the appropriate documented training prior to performing CBC (complete blood count) testing on the DxH 500 hematology analyzer. Findings Include: 1. Based on review of laboratory personnel records and lack of training documentation available the day of survey, TP#7 and TP#8 had no initial training for moderate complexity CBC testing prior to performing testing on patients. TP #7 - hire date - 4/5/21 TP #8 - hire date - 10/21 2. An interview with the TC/LD and TP #2 at 4: 30 p.m. on 9/13/22 confirmed that no initial training for CBC testing had been documented for TP #7 and TP #8 prior to testing patients. THIS IS A REPEAT DEFICIENCY
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of testing personnel records from 1/13/21 through 9/13/22, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with the office manager and TP #2, the technical consultant (TC) failed to evaluate and document the performance of TP #7 and TP #8 at least semiannually during the first year of employment. Findings include: 1. Review of the laboratory personnel records indicated that there were no 6 month evaluations available for TP#7 and TP #8. TP#7 hire date 4/5/21 - 6 month evaluation due in October 2021. TP#8 hire date 10/21- 6 month evaluation due in April 2022. 2. Interview with the office manager and TP #2 confirmed in an interview at 4:30 p.m. on 9/13/22 that no 6 month evaluation/competency was performed on TP #7 or TP#8 during the first year of performing moderate complexity testing.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel (TP) records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with the clinic office manager and TP#2, the technical consultant failed to evaluate annually and document the performance of testing personnel #2 through #7 who are responsible for performing moderate CBC (complete blood count) testing. Findings include: 1. Based on laboratory personnel records available for review on the day of survey, there were no annual evaluations/competencies performed by the technical consultant on TP #2 through TP #7 since the last survey on 1/13/21. 2. Interview with the office manager and TP #2 confirmed no annual evaluation/competencies for TP #2 through TP #7 had been performed by the technical consultant for the years 2021 and 2022. THIS IS A REPEAT DEFICIENCY