

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1002756	(X3) Date Survey Completed 01/13/2021
Name of Provider or Supplier Oxford Pediatric Group Plc	Street Address, City, State 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of Beckman Coulter AcT Diff Coulter ES Cell QC (quality control) records from 1/2/19 through 1/13/21, control assay sheets and interviews with testing personnel (TP) #1, #3 and #6 at 12:00 pm on day of survey (1/13/21), the laboratory failed to follow the manufacturer's instructions for the expiration date on the hematology QC material from 11/23/2020 through 1/13/21. Findings include: 1. The Beckman Coulter AcT Diff control 4C ES Cell manufacturer's instructions state vials of hematology controls (low, normal, high) may not be used past the printed expiration date on the vial. 2. Beckman Coulter 4C ES Cell Controls which were observed in the refrigerator on the day of survey had a printed expiration date of 11/23/2020 and were still in use on 1/13/2021. The controls in use were: Low Control lot number 06830- expiration date 11/23/2020 Normal lot number 07830 - expiration date 11/23/2020 High lot number 08830 - expiration date 11/23/2020 3. Lot numbers 06830, 07830 and 08830 (Beckman Coulter 4C ES Cell Controls) were in use on the day of survey 1/13/21. 4. Interview with TP #1, #3 and #6 confirmed the controls mentioned above were in use the day of survey and had been used since the expiration date of 11/23/2020. CBC's (Complete Blood Counts) had been performed and reported on approximately 248 patients during the time period from 11/23/2020 through 1/13/2021.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p>

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 the lack of education and training documentation available the day of survey (1/13/21) and interview with TP #1 and office manager, the laboratory director had not ensured that testing personnel (TP) listed on the CMS (Centers for Medicare and Medicaid Services) 209 personnel form as TP # 7 and #8 had the appropriate education and training to perform moderate complexity testing prior to testing patients. Findings Include: 1. There was no documented education or training available to review for TP #7 or #8 on the day of survey. 2. TP #7 and #8 began testing samples in October 2020 based on review of QC (Quality Control) and PT (Proficiency Testing) records. 3. Interview with the office manager prior to the survey on 1/13/21 and with TP #1 on 1/14/21 via telephone, confirmed initial training for the TP #7 and #8 was not documented as performed before they began performing moderate complexity laboratory testing. 4. There was no documentation available to indicate that the laboratory director had ensured testing personnel had the proper education or training before allowing TP #7 and #8 to begin performing moderate complexity laboratory testing on patient samples.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of moderate complexity laboratory testing records from 7/2/18 through 1/13/21 and interview with the technical consultant at 1:00 pm on 1/13/21, the Technical Consultant had not documented review of laboratory records such as Quality Control (QC), Proficiency Testing (PT), worksheets. Findings Include: 1. Review of the laboratory records from 7/2/18 through 1/13/21 revealed the following records had not been documented as reviewed by the technical consultant since 6/7/18: a. AcT Diff hematology quality control (QC) records from 1/2/19 through 1/13/21. b. AcT Diff hematology calibration records from 4/7/19 through 12/14/2020. c. Temperature records (room, refrigerator, freezer) from 7/2/18 through 1/13/21 d. Proficiency records (3rd event of 2018, 2nd and 3rd events of 2019 and all 3 events of 2020) 2. Interview with the technical consultant at 1:00 pm on the day of the survey (1/13/21) confirmed he had not documented review of the records..

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 lack of documentation of annual evaluations/competency records on the day of survey, 1/13/21, review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with TP and clinic office manager, the Technical Consultant failed to evaluate annually and document the performance of TP responsible for performing moderate complexity laboratory testing. An annual evaluation/competency must be performed each year of employment by the technical consultant. Findings include: 1. There were no Competency/Evaluation records available for review for TP #1, #2, #3, #4, #5, and #6 on 1/13/21. 2. Interview with the TP #1 and clinic manager confirmed the annual evaluation/competencies for TP #1 through #6 had not been documented as performed by the technical consultant since the last survey on 6/7/2018.