

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0316522	(X3) Date Survey Completed 10/13/2022
Name of Provider or Supplier Children's Clinic Of Oxford Pa	Street Address, City, State 2888 S Lamar Blvd, 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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for the Abbott Cell-Dyn Emerald hematology analyzer from 5/2/2022 through 8/19/2022, manufacturer's acceptable ranges for Abbott Cell-Dyn 18 Plus hematology controls, Lot #2094, and the Lab Accession Log, results of at least two of three levels of control failed to meet the manufacturer's criteria for acceptability for four days during this time frame, when a total of 26 patient complete blood count (CBC) tests were performed and reported. Findings include: Review of QC records for the Abbott Cell-Dyn Emerald hematology analyzer from 5/2/22 through 8/19/22, manufacturer's acceptable ranges for Abbott Cell-Dyn 18 Plus hematology controls, Lot #2094, and the Lab Accession Log revealed on the following days the normal and high controls, of three levels of hematology control, were outside the manufacturer's acceptable ranges for red blood cell count (RBC) when the patient CBC tests listed below were performed and reported: 6/7/2022 - Patients #33563, #47479, #47316, #47312, #43151, #42547, #42246, #43609, #32223. 6/16/2022 - Patients #24291, #40868, #48301, #40609. 6/17/2022 - Patients #46757, #47393, #48400, #39469, #44408, #23703, #23783. 6/21/2022 - Patients #29059, #47501, #29285, #28314, #44338, #17434.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <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</p>

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 the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, personnel records since the last survey on 3/25/2021, and the Lab Accession Log from 2/7/2022 through 10/13/2022, the laboratory director failed to ensure Testing Personnel #3, listed on the CMS 209 personnel form, received the appropriate training for performing complete blood count (CBC) testing on the Abbott Cell-Dyn Emerald hematology analyzer, prior to testing 63 patient CBC specimens between 2/7/2022 and 10/13/2022. Findings include: Review of personnel records since the last survey on 3/25/2021 revealed no documentation of training for Testing Personnel #3, listed on the CMS 209 personnel form. Review of the Lab Accession Log from 2/7/2022 through 10/13/2022 revealed Testing Personnel #3 had performed CBC testing on 63 patient specimens since 2/7/2022.

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 the CMS 209 personnel form, personnel records since the last survey on 3/25/2021, and the Lab Accession Log from 2/7/2022 through 10/13/2022, the technical consultant failed to evaluate and document the performance of Testing Personnel #3, listed on the CMS 209 personnel form, at least semiannually during the first year this individual tested patient CBC specimens. Findings include: Review of the Lab Accession Log from 2/7/2022 through 10/13/2022 revealed Testing Personnel #3 began performing CBC testing on patient specimens on 2/7/2022. Review of personnel records since the last survey on 3/25/2021 revealed the technical consultant failed to evaluate and document the performance of Testing Personnel #3 at least semiannually since 2/7/2022.