Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0708685	03/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Our Children's Clinic, Pa	4024-A Old Tar Road, Winterville, NC	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of Centers for Medicare and Medicaid Services (CMS) 209, review of 2018, 2019 and 2020 American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with technical consultant (TC) 3/6/20, the laboratory failed to ensure PT samples were tested by all TP who routinely test patient specimens. Findings: Review of laboratory procedure "Quality Assurance Program" revealed "Proficiency Testing (PT)...A. Proficiency samples are to be treated like patient samples and tested during routine work." Review of CMS 209 Laboratory Personnel Report submitted at time of survey revealed 7 TP routinely perform testing at the facility. Review of 2018, 2019 and 2020 AAB PT records revealed the laboratory participated in 5 PT events since the last quarter of 2018 until time of survey 3/6/20. Of the 5 PT events only 2 of 7 TP tested PT samples. TP#5 tested samples in 4 of the 5 PT events and TP# 4 tested samples in 1 of the 5 PT events. TP#1, TP#2, TP#3, TP#6 and TP#7 failed to participate in the PT events. Interview with TC at approximately 11:30 confirmed PT samples were not tested by all TP who routinely test patient specimens.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on review of procedure manual, review of 2018, 2019 and 2020 laboratory competency records and interview with TC 3/6/20, the laboratory failed to establish and follow a procedure for the assessment of TC competency. Findings: Review of procedure manual revealed the LD had delegated the following to the TC: a. Write new procedures with the Lab Director signing off before implementing. b. Review procedures every two years and make any necessary changes. c. Review monthly QC for all waive and non-waived testing. d. Review Proficiency Testing results and provide corrective action report for any PT failures. e. Perform competency assessment on non-waived testing initial, 6 months and annually depending on testing personal status. f. Help with and review Calibraton every 6 months. Review of procedure manual revealed the no competency policy or procedure for the assessment of the responsibilities delegated to the TC. Review of 2018, 2019 and 2020 laboratory competency records revealed no documentation of a yearly competency assessment for the TC. Interview with TC at approximately 11:30 a.m. confirmed the laboratory did not have a policy for the assessment of TC competency and she did not have documentation of competency assessments for 2018, 2019 or 2020. She stated she was unaware that her competency needed to be assessed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2018 and 2019 AAB PT records and interview with TC 3/6/20, the laboratory failed to evaluate unacceptable (incorrect) PT results. Findings: Review of laboratory procedure "Quality Assurance" revealed "C. Proficiency results are reviewed by the director. PT failures are investigated, corrected, and remedial action is taken under the direction of the laboratory director." Review of 2018, 2019 and 2020 AAB PT records revealed the following unacceptable (incorrect) results were not evaluated, investigated, corrected or had any remedial action taken: . 1. AAB PT event Q3 Nonchemistry 2018 - Specimen #1 - incorrect results for Erythrocytes (RBC), Hemoglobin (HGB) and Hematocrit (HCT). 2. AAB PT event Q1 Nonchemistry 2019 - Specimen #4 - incorrect results for RBC, HGB and HCT. 3. AAB PT event Q2 Nonchemistry 2019 - Specimen #4 - incorrect results for Neut/Gran % - Module A. Interview with TC at approximately 11:30 p.m. confirmed the unacceptable (incorrect) results had not been evaluated. She stated she was under the assumption that as long as the score was 80% or better no evaluation or investigation was required and was unaware that all unacceptable or incorrect PT results required an evaluation.
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 review of laboratory procedure, 2018 and 2019 calibration records, and interview with TC 3/6/20, the laboratory failed to perform calibrations every 6 months on the Coulter AcT diff hematology analyzer. Findings: Review of laboratory procedure "CBC Procedure" revealed "Quality Control-Coulter AcT diff Operator's Guide, Section 5, pages 5-16....A. Calibration...1. Calibration needs to be performed when:...c. Every 6 months as required by CLIA." Review of 2018 and 2019 hematology calibration records revealed calibration was performed in June of 2018, calibration was due in December of 2018 but not performed until April of 2019, a period of approximately 9 months in which calibration was not performed. During exit interview with TC at approximately 1:00 p.m. the TC confirmed calibration was not performed every 6 months as required.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of 2018 and 2019 American Association of Bioanalysts (AAB) proficiency testing (PT) records, review of corrective action for 2019 AAB PT event Q3 Nonchemistry and interview with TC 3/6 /20, the laboratory director (LD) failed to establish and ensure a corrective action plan was followed for unacceptable (incorrect) and unsatisfactory PT results. Findings: Review of laboratory procedure manual revealed no documentation that a correction action plan had been established for unacceptable (incorrect) or unsatisfactory PT results. Review of 2018 and 2019 AAB PT records revealed the laboratory had unacceptable PT results on 4 consecutive PT events. a. 3 of the PT events had unacceptable (incorrect) results with no corrective action documented. See D5211. b. 2019 AAB PT event Q3 Nonchemistry PT results revealed the laboratory had scored

	unsatisfactory results on the analytes Erythrocyes and Hemoglobin. Corrective action was noted as "Start up passed and all 3 levels of QC were in range on 9-24-19 day PT samples were tested." Review of 2019 AAB PT event Q3 Nonchemistry corrective action; "Start up passed and all 3 levels of QC were in range on 9-24-19 day PT samples were tested.", revealed the corrective action was not completed in a timely manner, and did not include further evaluations as to why the PT event was unsuccessful. For example: a. The review of the PT event did not take place until 2/25 /20, approximately 5 months after the unsuccessful event. b. The review failed to note evaluation of the calibration status of the analyzer. c. The review failed to note evaluation of previous QC beyond the date in which PT was performed. d. The review failed to include a rerun of the PT samples. e. The review failed to include evaluation of the TP who performed the testing for the PT event to determine if instructions were followed correctly or whether the TP needed further training in test performance. During exit interview with TC at approximately 1:00 p.m. TC confirmed the laboratory did not have an established corrective action plan for unacceptable or unsatisfactory PT results.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of 2018, 2019 and 2020 AAB PT records, review of TP competency records and TC interview 3/6/20, the TC failed to ensure competency of all TP included assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. Findings: Review of 2018, 2019 and 2020 AAB PT records revealed only 2 0f 7 TP tested PT samples. See D2007. Review of TP competency records revealed no documentation that the 5 TP who did not participate in PT testing, TP#1, 2, 3, 6 and 7, were assessed of test performance through testing previously analyzed specimens or internal blind testing samples. During exit interview with TC at approximately 1:00 p. m. TC confirmed TP who had not tested PT samples were not assessed of test performance through testing previously analyzed specimens or internal blind testing samples.