Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0678391	08/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Terrace Pediatric Group, Llc	342 21st Ave N, Nashville, TN	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of room temperature and humidity records available for review and interview with the lead testing person, the laboratory failed to document the room temperature and humidity in 2018 and 2019. The findings include: 1. There were no room temperature and humidity records available for review from January 1, 2018 through August 22, 2019. 2. Interview with the lead testing person on August 22, 2019 at 2:00 p.m. confirmed the laboratory did not monitor the room temperature and the humidity January 1, 2018 through August 22, 2019.
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 a review of calibration records from December 28 2017 to August 22, 2019 and an interview with the lead testing person, the laboratory failed to calibrate the hematology analyzer at least once every six months during the two year period. Findings include: 1. Review of calibration records for 2017 through 2019 disclosed a nine to ten month period between calibrations, from 12-28-17 to 9-7-18 to 7-3-19. 2. An interview with the lead testing person at 2:00 p.m. on August 22, 2019 confirmed calibrations were not done at least at a six month interval during the two year period.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of Complete Blood Count (CBC) Quality Control (QC) records and interview with the Technical Consultant (TC) the TC failed to ensure CBC QC are in acceptable range before reporting patient CBC results in 2018 and 2019. The findings include: 1. Review of CBC QC records revealed out of range CBC QC in 2018 for the following: 2018 1) Low QC Platelets (PLT) 10/11, 10/15, 10/20, 10/22-11/5. 2) Normal QC White Blood Cells (WBC), Red Blood Cells (RBC), Hematocrit (HCT), Hemoglobin (HGB), Mean Corpuscular Hemoglobin Concentration (MCHC), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), and PLTs 9/22, 10/27. 3) Normal RBC QC 10/19, 11/2. 4) Normal PlT QC 10/23, 10/31, 11/01, 11 /03. 5) High QC for RBC- 9/11, 9/14, 9/18, 9/22, 9/24, 9/29, 10,1, 10,5, 10/8, 10/9, 10 /11, 10/12, 10/16, 10/19/ 10/20, 10/27, PLT 10/22, 10/19-11-03, 11/16, 11/20. 2019 6) High QC HGB 1/9 1/11, 1/19, 1/24, 1/28, 2/8, 2/13, 2/14, 2/27, 6/18. 7) High QC PLT 7/19, 7/23. 2. Interview with the TC on August 22, 2019 at 2:00 p.m. confirmed the TC failed to ensure CBC QC are in acceptable range before reporting patient CBC results in 2018 and 2019.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform

	test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of employee personnel records for 2018 and interview with the lead testing person, the laboratory's technical consultant failed to document the six required criteria for assessing personnel competency for TP 1, 2, and 3 out of 11. The findings include: 1) Review of employee personnel records for 2018 did not reveal documentation of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills. 2) An interview with the lead testing person on August 22, 2019 at 2:00 p.m. confirmed TP 1, 2 and 3 of 11 TP evaluated during 2018 were not evaluated using the six criteria for competency required by Centers for Medicare and Medicaid (CMS).