Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0678391	12/12/2023
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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to test proficiency testing samples the same as patient samples for seven of seven events reviewed for 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Hematology Auto Differentials (FH1) proficiency testing records revealed the laboratory tested PT samples in duplicate and submitted the average of the results for the following PT events: - 2021 FH1-C samples FH1-11 through FH1-15 - 2022 FH1-A samples FH1-1 through FH1-5 - 2022 FH1-B samples FH1-6 through FH1-10 - 2022 FH1-C samples FH1-11 through FH1-15 - 2023 FH1-A samples FH1-1 through FH1-5 - 2023 FH1-B samples FH1-6 through FH1-10 - 2023 FH1-C samples FH1-11 through FH1-15 2. An interview with the lead testing person on 12/12/23 at 1:30 p.m. confirmed the laboratory does not routinely test patient samples in duplicate and, therefore, did not test PT samples in the same manner as it tests patient samples when it performed duplicate testing of the PT and reported the average result for seven of seven PT events reviewed in 2021, 2022, and 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of quality control (QC) package inserts, and staff interviews, the laboratory failed to label three of three QC vials with an open date and updated expiration date on the date of the survey. The findings include: 1. Observation of the laboratory on 12/12/23 at 08:45 a.m. revealed an Abbot Cell-Dyn Emerald (SN: 030820-008393) in use for patient CBC testing utilizing three levels of Cell-Dyn 18 Plus QC material (Lot: 3289). The vials were not labeled with either an open date or corrected expiration date. 2. Review of the Cell-Dyne 18 Plus Control assay sheet revealed the control material has an "8 Consecutive-Day Open-Tube Stability". 3. Interview with the lead testing person on 12/12/23 at 1:30 p.m. confirmed that quality control material observed in the laboratory was not labeled with an open date and updated expiration date.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of the laboratory's quality control (QC) logs, and staff interview, the laboratory failed to ensure QC for complete blood count (CBC) patient testing was rotated among all testing personnel (TP) in 2021, 2022 and 2023. The findings include: 1. Observation of the laboratory on 12/12/23 at 08:45 a.m. revealed an Abbot Cell-Dyn Emerald (SN: 030820-008393) in use for patient CBC testing utilizing three levels of Cell-Dyn 18 Plus QC material (Lot: 3289). 3. Review of the Form CMS-209 revealed nine testing persons who perform CBC patient testing. 2. Review of the laboratory's 2021, 2022, and 20223 quality control logs revealed no records of CBC QC being performed by TP1, TP2, and TP7. 4. Interview with the lead testing person on 12/12/23 at 1:30 p.m. confirmed that quality control was performed by designated testing personnel and was not rotated among all personnel who perform patient CBC testing in 2021, 2022 and 2023.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvement Amendments (CLIA) certificate of compliance, CLIA Application for Certification (form CMS-116), Laboratory Personnel Report CLIA (form CMS-209), and staff interview, the laboratory director failed to ensure compliance with regulation 493.51(a)(4) by not notifying the department of Health and Human Services (HHS) state agency within 30 days of when the laboratory director personnel changed on 07/01/22. The findings include: 1. Review of the CLIA certificate of Compliance revealed the laboratory director was not the same as the laboratory director listed on the forms CMS-116 and CMS-209 completed for the survey conducted on 12/12/23. 2. Interview on 12/12/23 at 1:30 p.m. with the Laboratory Director and lead testing person confirmed the laboratory failed to notify the HHS state agency within 30 days of when the laboratory director changed on 07/01/22.
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 the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), review of testing personnel (TP) competency assessment records, and staff interview, the technical consultant failed to ensure assessment of blind testing or external proficiency testing was included as part of the competency assessment for three of nine testing personnel in 2021, 2022, and 2023. The finding include: 1. Review of the Form CMS-209 revealed nine testing personnel for moderately complex testing. 2. Review of the competency assessment records revealed neither blind testing nor external proficiency testing was included as part of the annual competency assessments of TP1, TP2, and TP7 in 2021, 2022, and 2023. 3. Interview with the Lab Director and lead testing person on 12/12/23 at 1:30 p. m. confirmed neither internal blind testing nor external proficiency testing was included as part of the competency assessment for TP1, TP2 and TP7 in 2021, 2022, and 2023.