Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0678391	01/17/2018
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
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 a review of 2017 Proficiency Testing (PT) attestation records and interview with testing personnel number one, the laboratory did not involve all nine testing personnel in rotating PT complete blood count (CBC) samples, in 2017. The findings include: 1) Review of the 2017 PT records revealed testing personnel number one performed all PT sample CBC testing for 2017 events one, two, and three. 2) Interview on January 17, 2018 at 11:00 a.m. with testing personnel number one confirmed the PT CBC samples were not rotated among the 9 testing personnel in 2017.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the 2016 and 2017 proficiency testing (PT) records and interview with testing personnel number one, the laboratory failed to test the PT samples the same number of times that it routinely test patient samples, during the two year period. The findings include: 1) Review of the 2016 and 2017 events one, two and three PT records revealed each PT sample was tested twice. 2) Interview on January

	17, 2018 at 11:40 a.m. with testing personnel number one confirmed each PT sample is tested twice and the average is reported to the PT agency. The patient CBC samples are routinely tested once.
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 observation of the laboratory, review of nine testing personnel training and competency assessment forms and interview with testing personnel number one, the laboratory failed to include all required competency assessment elements for the performance of the complete blood count (CBC) in 2016 and 2017. The findings include: 1. Observation of the laboratory on January 17, 2018 at 9:40 a.m. revealed the Beckman Coulter AcT diff instrument in use for patient CBC testing. 2. Review of the forms in use for nine testing personnel training and competency assessment documentation revealed that all six required competency assessment methods were not included in the competency assessment. The required elements include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results, quality control records, proficiency testing results and preventative maintenance records; direct observation of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and problem solving skills. 3. Interview with testing personnel number one on January 17, 2018 at 12: 15 p.m. confirmed that competency assessment methods used did not include all six required elements as specified in subpart M for the nine testing personnel in 2016 and 2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: _____ Based on review of the Quality Assurance (QA) Plan stating "The Laboratory Director will complete a monthly QA checklist", lack of monthly QA documentations and interview with the Laboratory Director, the Director failed to follow written policy for documenting monthly QA reviews for 2016 and 2017. The findings include: 1. Review of the QA Plan states "The Laboratory Director will complete a monthly QA checklist" (copy attached). 2. Lack of monthly QA documentations for 2016 and 2017. 3. Interview at approximately 3:00 p.m. January 17, 2018 with the Laboratory Director confirmed there was no monthly QA documentation for the two year period. _____

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: _____ Based on review of collection procedure January 17, 2018 which lacked labeling requirements for fingerstick CBC's (complete blood count's) and interview with Primary Laboratory Person, the laboratory failed to have a procedure in place for labeling CBC fingerstick specimens prior to testing. The findings include: 1. Review of collection procedure January 17, 2018 which lacked labeling requirements for fingerstick CBC's (complete blood count's). 2. Interview at approximately 11:00 a.m. January 17, 2018 with Primary Laboratory Person confirmed the laboratory failed to have a procedure in place for labeling CBC fingerstick specimens prior to testing. _____
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 at approximately 9: 40 a.m. January 17, 2018 of in use Quality Control Materials lacking open dates and open vial expiration dates for CBC testing, review of CBC control material's assay sheet stating 35 day open vial expiration date and interview with Primary Laboratory Person, the laboratory failed to document open date and 35 day open date expiration on in use CBC control materials. The findings include: 1. Observation at approximately 9:40 a.m. January 17, 2018 of in use Quality Control Materials lacking open dates and open vial expiration dates for CBC testing. 2. Review of CBC control material's assay sheet stating 35 day open vial expiration date. 3. Interview at

	approximately 10:00 a.m. January 17, 2018 with Primary Laboratory Person confirmed the laboratory failed to document open date and 35 day open date expiration date on in use CBC control materials observed 1/17/18. _____
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: _____ Based on documentation of expired Quality Control materials 11/26/16 used for CBC testing 11/28/16, 11/29/16 and 11/30 /16 and interview with Primary Laboratory Person, the laboratory failed to not use CBC controls past their expiration date of November 26, 2016. The findings include: 1. Documentation of expired Quality Control materials 11/26/16 used for CBC testing on 11/28/16, 11/29/16 and 11/30/16 (control sheets attached). 2. Interview at approximately 2:00 p.m. January 17, 2018 with Primary Laboratory Person confirmed the laboratory failed to not use expired CBC control materials on dates 11/28/16, 11/29 /16 and 11/30/16 past their expiration date of 11/26/16. _____
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: _____ Based on lack of Quality Control documentation for Uricult media, lack of Individualized Quality Control Plan (IQCP) and interview with Primary Laboratory Person, the laboratory failed to have an IQCP procedure in place for Uricult Media since January 1, 2016. The findings include: 1. Lack of quality control documentation for new lot numbers and new shipments for Uricult media. 2. Lack of an IQCP procedure for Uricult Media since January 1, 2016. 3. Interview at approximately 11:00 a.m. January 17, 2018 with Primary Laboratory Person confirmed the laboratory did not have an IQCP in place for Uricult media since January 1, 2016. _____
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 the 2016 event two proficiency testing (PT) records, the laboratory PT procedure and interview with the laboratory director, the laboratory failed to establish and follow a corrective action plan for unacceptable PT scores, in 2016. The findings include: 1) Review of the 2016 event two PT records revealed hematocrit sample numbers FH2-06, FH2-08 and FH2-10 were scored as unacceptable, resulting in a score of 40%, with no corrective action documented. 2) Review of the laboratory PT procedure revealed corrective action performance and documentation process was not included. 3) Interview on January 17, 2018 at 1:30 p. m. with the laboratory director confirmed the 2016 event two corrective action was not performed and documented.