Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0719777	11/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Tots N Teens Pediatrics, Pc	3729 Mary Taylor Road, Birmingham, AL	

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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel #2, the surveyor determined the laboratory failed to submit results for 2019 3rd Event Hematology before the cutoff date. This was noted on one out of seventeen 2018-2020 API survey events reviewed. The findings include: 1. A review of the instrument printouts with the 2019 3rd Event Hematology survey revealed the laboratory tested the proficiency testing samples on 11/21/2019. However, the laboratory failed to submit the PT results to API by the cutoff date on 12/02/2019, and scored 0% for this survey. 2. During an interview conducted on 11/03/2020 at 12:30 PM, Testing Personnel #2 confirmed the above noted findings, stating she realized on 12/03/2019 that she had forgotten to submit the results. .
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 a review of the Bacteriology records, and an interview with Testing Personnel #2, the surveyor determined the laboratory failed to perform quality controls (QC) on the Taxo A discs every 30 days as per the IQCP (Individualized Quality Control Plan), and failed to document the actually QC results. The laboratory failed to perform Taxo A disc QC 29 months of the 34-month period (January 2018-Octoberb 2020) reviewed. The findings include:1. A review of the IQCP for the Taxo A discs revealed QC should be performed every 30 days using Strep pyogenes as the positive QC, and Strep agalactiae as the negative QC. The IQCP was reviewed annually, and signed most recently by the Laboratory Director on 1/28/2020 with the comment, "no changes needed". 2. A review of the Taxo A disc QC revealed testing personnel only performed QC on 2/14/2018, 6/14/2018, 3/19/2019, 6/12/2019, 8/30 /2019, 11/1/2019, and 2/2/2020. The surveyor further noted, the laboratory failed to document the lot numbers of the QC organisms, and the actual QC results. On all the above date (except 6/14/2018), testing personnel only documented "Controls passed", "QC passed", or "Controls" with a check mark, with no documentation of the organisms used, or the QC results. 3. In an interview on 11/3/2020 at 2:40 PM, Testing Personnel #2 reviewed the above noted findings, and confirmed the laboratory was not performing Taxo A disc QC every 30 days as per IQCP.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records and an interview with Testing Personnel #2, the Laboratory Director failed to ensure that results were submitted before the cutoff date, 12/02/2019. This affected one of seventeen API surveys (2018 - 2020) reviewed by the surveyor. The findings include: 1. A review of the instrument printouts for the 2019 3rd Hematology survey revealed the laboratory tested the proficiency testing samples on 11/21/2019. However, the Laboratory Director failed to ensure the PT results were submitted before the deadline, and scored 0% for this event. 2. During an interview conducted on 11/03/2020 at 12:30 PM, Testing Personnel #2 confirmed the above findings. 3. Also see D2123.