

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0719777	(X3) Date Survey Completed 06/03/2026
Name of Provider or Supplier Tots N Teens Pediatrics, Pc	Street Address, City, State 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
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Policies and Procedures and an interview with the Laboratory Director (LD) and Testing Personnel 1 (TP1), the LD failed to establish and maintain a Quality Assurance Program (QAP) to assure the quality of laboratory services provided. The surveyor noted no documentation of the procedure from the date of the last survey, 04-24-2024 to the date of the current survey, 06-03-2026. The findings include: 1. A review of Policies and Procedures revealed no evidence of a QAP established and maintained for the laboratory patient testing services from 2024-2026. 2. LD and TP1 confirmed the above findings during the exit conference on 06-03-2026 at 1:40 PM.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on reviews of personnel records listed on the CMS 209 Form (Laboratory Personnel Report) and an interview with Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to specify in writing which of the LD's duties and responsibilities were assigned to a designee. The surveyor noted there was no documentation for the delegation of responsibilities from the date of the last survey, 04-24-2024 to the date of the current survey, 06-03-2026. The findings include: 1. A review of personnel records revealed the LD had no documentation authorizing a qualified designee to perform TP competency assessments in all phases of the laboratory testing process. 2. LD and TP1 confirmed the above findings during the exit conference on 06-03-2026 at 1:40 PM.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:
Based on review of the laboratory Policy and Procedure (P&P) manual and interviews with the Laboratory Director (LD) and Testing Personnel 1 (TP1), the Technical Consultant (TC) failed to ensure an written policy defining and guiding TP what process to follow when Quality Control (QC) values were outside established limits after several runs. The surveyor noted no documentation of the procedure from the date of the last survey, 04-24-2024 to the date of the current survey, 06-03-2026. The findings include: 1. A review of the P&P manual revealed no written policy and procedure for TP to follow when one or all the QC levels have parameters with QC values outside manufacturer's acceptable ranges. 2. An interview with the TP1 at 11:50 AM revealed she was only verbally informed by the manufacturer to accept QC when two of the three levels are within acceptable limits. 3. LD and TP1 confirmed the above findings during the exit conference on 06-03-2026 at 1:40 PM.