

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0719777	<b>(X3) Date Survey Completed</b>  09/28/2022
<b>Name of Provider or Supplier</b>  Tots N Teens Pediatrics, Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to ensure the previous Laboratory Director signed the attestation statements for three of eleven events in 2021. The findings include: 1. A review of the API PT records revealed the no signature by the previous Laboratory Director (or designee) on attestation statements for the following surveys: a) 2021 Hematology 1st Event. b) 2021 Hematology 2nd Event. c) 2021 Hematology 3rd Event. 2. During an interview on September 28, 2022, at 12:33 PM, Testing Personnel #1 confirmed the above findings.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Medonic M Series Complete Blood Count (CBC) Hematology analyzer maintenance records and an interview with Testing Personnel #1, the laboratory failed to document performance of monthly maintenance as defined</p>

by the manufacturer's requirements. This was noted for six of 20 months reviewed in 2021 and 2022. The findings include: 1. A review of the Medonic M Series CBC Hematology analyzer revealed the following monthly maintenance was not documented: a) 2021: March, April, June, and July. b) 2022: July and August. 2. During an interview on September 28, 2022, at 12:26 PM, Testing Personnel #1 confirmed the above findings.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
Based on a review of the validation records for the Medonic M Series Hematology analyzer, and an interview with Testing Personnel #1, the previous Laboratory Director failed to document review and approval of the installation procedures as verification of the manufacturer's performance specifications before patient testing began. This was noted on one of one new instruments performing moderate-complexity testing. The findings include: 1. A review of the validation records for the Medonic M Series Hematology analyzer revealed no documentation (signature and date) by the previous Laboratory Director to indicate review and approval of the procedures verifying the manufacturer's performance specifications. Patient CBC (Complete Blood Count) testing began July 29, 2021. 2. A review of the Medonic M Series Method Validation Evaluation revealed, "...#4. The Lab Director must sign and date to indicate all documents have been reviewed and accepted. ...". 3. During an interview on September 28, 2022, at 10:29 AM, Testing Personnel #1 confirmed the above findings.

**D6045**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:  
Based on a review of personnel records and an interview with Testing Personnel #1, the Technical Consultant failed to ensure periodic training was provided for one of three testing personnel in 2022. The findings include: 1. A review of the personnel records revealed Testing Personnel #3 resigned in 2014 and was rehired in August 23, 2021. The records only included annual competencies performed August 23, 2021 and August 26, 2022. There was no documentation of training upon rehire. 2. During an

interview on September 28, 2022, at 10:26 AM, Testing Personnel #1 was unaware the laboratory should have retrained Testing Personnel #3, since it was seven years between her resignation and rehire.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on a review of personnel records and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate and document the semi-annual competency for one of three testing personnel in 2022. The findings include: 1. A review of the personnel records revealed Testing Personnel #3 resigned in 2014 and was rehired in August 23, 2021. The records only included annual competencies performed August 23, 2021 and August 26, 2022. There was no documentation of a semi-annual competency evaluation. 2. During an interview on September 28, 2022, at 10:26 AM, Testing Personnel #1 was unaware the laboratory should have retrained Testing Personnel #3, and performed a semi-annual competency, since it was seven years between her resignation and rehire.