

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1021321	<b>(X3) Date Survey Completed</b> 03/13/2024
<b>Name of Provider or Supplier</b> Tenafly Pediatrics-Paramus Facility	<b>Street Address, City, State</b> 26 Park Place, Paramus, NJ	
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>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL for calendar year 2024 or any prior years. The Laboratory manager confirmed on 3/13 /24 at 11:30 am that the laboratory did not maintain a NJCLL for 2024 or any prior years.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Operators Manual (OM), Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to follow the OM for "Preparation for Calibration" from 6/30/23 to the date of survey. The findings include: 1. The OM states to "perform a repeatability/precision study by running one normal patient sample tens times" , "Calculate the Coefficient of Variation (CV) for each of the 5 parameters to ensure repeatability is acceptable ". 2. There was no CV</p>

calculated for Calibration performed pm 6/30/23 and 1/29/24. 3. The LD confirmed on 3/13/24 at 10:45 AM that the laboratory did not follow the OM.

**D5807**

TEST REPORT  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on the surveyor review of the Final Reports (FR), and interview with the Laboratory Director (LD), the laboratory failed to have accurate Reference Interval (RI) for Endocrinology tests from 1/22/20 to the date of survey. The findings include:

1. A review of eight FR revealed as follows:
  - a. Five out of eight FR's had an RI of 12-18 g for Hemoglobin (Hgb).
  - b. One out of eight FR's had an RI of 4.0-6.2% for Red Blood Cell (RBC).
  - c. One out of eight FR's had no RI for all Complete Blood Count (CBC) analytes.
2. The LD confirmed on 3/13/24 at 10:00 am that laboratory failed to have accurate RI.