

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0113132	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier Tenafly Pediatrics	Street Address, City, State 704 Palisade Avenue, Teaneck, NJ	
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
D3009	<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 NJCLL for calendar year 2023. A Surveyor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 4/30/24 that the laboratory did not have a NJCLL license for 2024.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Work Records (WR) and interview with the Laboratory Director (LD), the laboratory failed to follow procedure "Protocol for Horiba when controls fail" on 3/16/24 and 3/28/24. The findings include: 1. The procedure "Protocol for Horiba when the controls fail" states "1. Try running the controls 2X" if controls fail "2. Run another start-up" and "3. run controls again" 2. On 3/16/24 and 3/28/24 Control, lot #MX446 low was run five times consecutively</p>

on each date. 3. The LD confirmed on 4/30/224 at 11:00 am the laboratory did not follow the PM.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

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.

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 4/26/21 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 documented evidence that CV calculated for Calibration. 3. The LD confirmed on 4/30 /24 at 10:45 am that the laboratory did not follow the OM.