

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1021318	(X3) Date Survey Completed 03/13/2024
Name of Provider or Supplier Tenafly Pediatrics-Clifton Facility	Street Address, City, State 1135 Broad Street, Clifton, 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 a NJCLL for calendar year 2024 or any prior years. The Laboratory manager confirmed on 3/13 /24 at 12:30 pm that the laboratory did not maintain a NJCLL for 2024 or any prior years.</p>
D5411	<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 1/22/20 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</p>

documented evidence that CV calculated for Calibration. 3. The LD confirmed on 3/13/24 at 12:45 pm that the laboratory did not follow the OM.

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 surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD), the LD failed to ensure that PS procedures performed for Complete Blood Count (CBC) tests performed on the Horiba analyzer were adequate from 1/23/20 to the date of survey. The findings include: 1. There was no evidence that Accuracy was performed. 2. The LD confirmed on 3/13/24 at 12:15 pm that PS records were not adequate.