

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0112423	(X3) Date Survey Completed 09/27/2023
Name of Provider or Supplier Tenafly Pediatrics	Street Address, City, State 570 Piermont Road, Closter, 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 9/26/23 that the laboratory did not have a NJCLL license for 2023.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Laboratory Director (LD), the laboratory failed to maintain the patient raw data print-outs from the Horiba Micros 60 used for hematology testing. The findings include 1. The LD stated "after the raw data print-outs have been manually entered into the Electronic Medical Records (EMR) they are shredded". 2. The raw data print-outs containing</p>

	<p>results and data alarm flags were not maintained. 3. The LD confirmed on 9/27/23 at 10:00 am that raw data print-outs containing results and data alarm flags were not maintained</p>
<p>D5401</p>	<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), and interview with the Laboratory Director (LD), the laboratory failed to have a procedure for Quality control verification (QVC) for Hematology testing from 6/10/21 to the date of survey. The TP confirmed on 9/26/23 at 10:00 am that the laboratory failed to have the above mentioned procedure.</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to have all procedures needed for Hematology tests run on the Horiba Micros 60 analyzer from 6/10/21 to the date of the survey. The findings include: 1. The laboratory failed to have a procedures for: a. Description of the course of action to take if a test system becomes inoperable. 2. The LD confirmed on 9/27/23 at 11:50 am that the laboratory did not have the above procedure.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</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.

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 10/20/20 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 CV calculated for Calibration performed in the calendar years 2021, 2022 and 2023. 3. The LD confirmed on 9/27/23 at 11:45 AM that the laboratory did not follow the OM. Note: This is a repeat deficiency.

D5779

CORRECTIVE ACTIONS

CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual PM, Patient Work records (PWR) and interview with the Laboratory Director (LD) the laboratory failed to follow the Corrective Action (CA) policy for morphology flags from 6/10/21 to the date of survey. The finding includes: 1. The PM stated "All morphology flags should be manually verified for the presence of pathological elements". 2. Ten out Ten PWR had Morphology flags for blood cell population. 3. The LD confirmed on 9/27/23 at 11:00 am that the laboratory failed to follow the laboratory's CA policy.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to establish a procedure for verifying manually entered results into the Electronic Medical Record from 6/10/21 to the date of survey. The finding includes. 1. The laboratory did not retain Patient Work Records used verify manual entered test results. 2. The LD confirmed on 6/27/23 at 11:15 am that the laboratory did not have the procedure mentioned above.