

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0112423	<b>(X3) Date Survey Completed</b> 06/10/2021
<b>Name of Provider or Supplier</b> Tenafly Pediatrics	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<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 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 on 10/20/20 and 4/21/21. 3. The LD confirmed on 6/10/21 at 11:45 AM that the laboratory did not follow the OM.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Hardy Diagnostic Bacitracin Discs (HDBD) and interview with the Registered Nurse (RN), the laboratory failed to discard expired (HDBD) from 2/28/21 to the date of survey. The findings include: 1. On the date of</p>

the survey the laboratory used expired HDBD Lot # 404704 expired 2/28/21 2. Approximately 323 patients were tested with expired HDBD. 3. The RN confirmed on 6/10/21 at 12:00 pm that the laboratory used expired HDBD.

**D5471**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check each lot number and shipment of Bacitracin Discs for positive and negative reactivity from 8/13/20 to the date of the survey. The LD confirmed on 6/10/21 at 11:00 am that QC was not performed.