

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0113242	<b>(X3) Date Survey Completed</b>  06/10/2021
<b>Name of Provider or Supplier</b>  Tenafly Pediatrics	<b>Street Address, City, State</b>  32 Franklin Street, Tenafly, 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 6/19/20 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 6/19/20 and 12/2/20. 3. The LD confirmed on 6/10/21 at 3:00 pm that the laboratory did not follow the OM.</p>