

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0112423	<b>(X3) Date Survey Completed</b>  04/02/2019
<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>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Throat Culture and Urine Culture media for sterility from 1/1/19 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 4/2/19 at 10:30 am the laboratory did not perform the above QC.</p>
<b>D5807</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Report (FR), Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to identify the source of the Reference Intervals (RI) used for Hematology tests from 1/1/19 to the</p>

date of the survey. The findings include: 1. The RI found on the FR and the Result Report (RR) from the ABX Micros 60 did not agree with the established RI in the PM. 2. RI differed as below: a. White Blood Cells (WBC) FR: 5 - 14 RR: 3.5 - 10 PM: 4.5-13 b. Hemoglobin (Hgb) FR: 11 - 11 - 14 RR: 11 - 16.5 PM: 11 - 15 c. Hematocrit (HCT) FR: 35 - 45 RR: 35 - 50 PM: 35 - 45 d. Platelets (PLT) FR: 140 - 400 RR: 150 - 450 PM: 150 - 450 e. Lymphocytes % FR: 25.5 - 45 RR: 17 - 48 PM: 25 - 45 f. Granulocytes % FR: 34 - 64 RR: 43 - 76 PM: 30 - 60 g. Monocytes % FR: 1 - 5 RR: 4 - 6 PM: 1 - 15 3. The LD confirmed on 4/2/19 at 12:00 pm that the source of the RI on the FR was unknown.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on the surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have training documented on the AB Micros 60 for four out of five TP from 1/1/19 to the date of the survey. The TP #4 listed on the CMS from 209 confirmed on 4/2/19 at 11:20 am that all TP did not have training documented.