

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1021321	<b>(X3) Date Survey Completed</b> 01/22/2020
<b>Name of Provider or Supplier</b> Tenafly Pediatrics-Paramus Facility	<b>Street Address, City, State</b> 26 Park Place, Paramus, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Laboratory Director (LD), the laboratory failed to perform the CA correctly for seven out of seven Testing Personnel (TP) from 3/23/18 to the date of the survey. The findings include: 1. The laboratory did not document assessment of test performance on seven TP. 2. Seven of seven TP did not have a CA performed in the calendar year 2018. 3. One of seven TP did not have a CA performed in the calendar year 2019. 4. The LD confirmed on 1/22/20 at 10:30 am that the CA was not performed correctly.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 observation of the incubator and Throat Culture (TC) plates, review of the Procedure Manual (PM), and interview with the Laboratory Director (LD), the laboratory failed to follow the PM for streaking TC specimens from 3/23/18</p>

to the date of the survey. The finding includes: 1. The PM stated to use one plate for each patient but observation of the incubator revealed the laboratory streaked two patients per plate. 2 The LD confirmed on 1/22/20 at 10:20 am that the laboratory did not follow the PM.

**D5477**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(4)(g)

(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.

This STANDARD is not met as evidenced by:  
Based on the surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check each new lot number and shipment of Throat Culture media for sterility from 3/23/18 to the date of the survey. The LD confirmed on 1/22/20 at 10:50 am the laboratory did not perform the above QC.

**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 surveyor review of Personnel Files (PF) and interview with the Laboratory Director (LD), the LD failed to have education documented for five out of seven Testing Personnel from 3/23/18 to the date of the survey. The LD confirmed on 1/22 /20 at 10:00 am that all education records were not available.