

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1021318	<b>(X3) Date Survey Completed</b>  03/23/2018
<b>Name of Provider or Supplier</b>  Tenafly Pediatrics-Clifton Facility	<b>Street Address, City, State</b>  1135 Broad Street, Clifton, 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 lack of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check QC on each batch of Urine Culture Media (UCM) from 11/13/15 to the date of the survey. The findings include: 1. The laboratory did not check UCM for: a. Ability to support growth. b. Ability to select or inhibit specific organisms c. Sterility of media. d. visual check 2. The LD confirmed on 3/23/18 at 10:30 am that the laboratory did not perform the above-mentioned QC checks.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>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</p>

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 General Supervisor (GS), the Laboratory Director failed to have education records for five out of seven Testing Personnel from 11/13/15 to the date of the survey. The GS #1 listed on CMS form 209 confirmed on 2/23/18 at 9:40 am that there were no education records for five out of seven TP.