

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0113132	<b>(X3) Date Survey Completed</b>  09/24/2018
<b>Name of Provider or Supplier</b>  Tenafly Pediatrics	<b>Street Address, City, State</b>  704 Palisade Avenue, Teaneck, 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 Testing Personnel (TP), the laboratory failed to perform CA correctly on six of six TP in 2017 and 2018. The findings include: 1. The CA was not assessed for test performance (procedure 3). 2. An arrow was drawn from Test Evaluation elements 2 to 13, procedures A,B,C and E were used to assess all but they were not all applicable. 3. The TP # 1 listed on CMS form 209 confirmed on 9/24/18 at 1:00 pm that CA was not performed correctly.</p>
<b>D5305</b>	<p><b>TEST REQUEST</b> CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure</p>

accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Test Requisitions (TR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that TR included relevant and necessary information for accurate and reliable testing and reporting from January 2018 to the date of survey. The findings include: 1. A review of ten TR revealed ten of ten did not have the specimen source and collection date recorded. 2. The laboratory did not document any efforts made to get the information. 3. The TP #1 listed on CMS form 209 confirmed on 9/24/18 at 2:20 pm that specimen source and collection date was not on the TR.

**D5411**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(a)

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of the QBC Hematology Control Manufacture Package Insert (MPI), observation of the control and interview with the Testing Personnel (TP), the laboratory failed to follow MPI instructions for stability of QBC Quality Control (QC) material at the time of the survey. The findings include: 1. The MPI stated that controls were stable for 4 days once opened. 2. There was no open or expiration date documented on QC in use. 3. The TP stated the controls were used for one week and then discarded. 4. Approximately 10 to 20 patients were run each day. 5. The TP #1 listed on CMS form 209 confirmed on 9/24/18 at 1:20 pm that the MPI was not followed.

**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 of the identification system used for Urine Cultures (UC) for positive and negative reactivity from 9/22/16 to the date of the survey. The findings include: 1. The laboratory used a split media plate with Sheep's Blood Agar and Eosin Methylene Blue (EMB) for UC identification. 2. The laboratory identified organisms at the specie level and did not

perform any QC or Biochemical reactions. 3. The laboratory reported on the Final Report: a. "Looks like E. coli" b. "Looks like E. coli - not confluent growth (prob just under 100,000)" 4. The LD confirmed on 9/24/18 at 2:35 pm that QC was not performed for positive and negative reactivity on UC media.

**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 Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check QC on each batch of Urine (UC) and Throat Culture (TC) media from 9/22/16 to the date of the survey. The findings include: 1. TC media was not checked for its ability to select or inhibit specific organisms. 2. UC media was not checked for: a. Ability to support growth b. Ability to select or inhibit specific organisms 2. The TP #1 listed on CMS form 209 confirmed on 9/24/18 at 2:10 pm that the laboratory did not perform the above QC.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

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.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Normal Reference Intervals (NRI) were indicated on the FR for tests performed in the laboratory from 9/22/16 to the date of survey. The findings include: 1. There was no NRI for Throat and Urine Culture results. 2. % Granulocytes and Lymphocytes/Monocytes did not have a NRI. 3. The TP #1 listed on CMS form 209 confirmed on 9/24/18 at 2:25 pm that the NRI were not on the FR.