

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0113132	(X3) Date Survey Completed 04/29/2021
Name of Provider or Supplier Tenafly Pediatrics	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all Testing Personnel (TP) who performed Hematology tests participated in the College of American Pathologists (CAP) PT events in the calendar years 2019 and 2020. The finding includes: 1. A review of all PT events revealed that only two out of six TP performed PT all events in 2019 and 2020. 2. The TP #1 listed on CMS form 209 confirmed on 4 /29/21 at 1:30 pm that PT events were not rotated between TP.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p>

	<p>This CONDITION is not met as evidenced by: Based on surveyor review of the COVID 19 Veritor Plus system, patient test results and interview with the Testing Personnel (TP), the laboratory failed to report COVID 19 test results to the State of New Jersey (NJ) from September 2020 to the date of the survey. The findings include: The laboratory did not report as follows: 1. The Laboratory did not report Negative COVID 19 results to the State of NJ. 2. The Laboratory performed approximately 40 COVID 19 tests per day. 3. The TP #1 listed on CMS form 209 confirmed at 2:30 pm on 4/29/2021 that the laboratory did not report all COVID test results.</p>
<p>D3037</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain all records from Throat Culture PT events performed with the College of American Pathologists (CAP) in the calendar year 2020. The finding includes: 1. The laboratory did not retain the PT results for D1-B 2020 Throat Culture event. 2. The TP #1 listed on CMS form 209 confirmed on 4/29/21 at 2:00 pm that PT record was not retained.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL 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 review of the COVID 19 Veritor System and interview with the Testing Personnel (TP), the laboratory failed to follow the Information for Use (IFU) when performing Covid tests from September 2020 to the date of the survey. The findings include: The laboratory did not follow the IFU as below: 1. The Laboratory did not report negative Covid 19 results to the State of New Jersey. 2. The Laboratory performs approximately 40 tests per day. 3. The TP # 1 as listed on CMS form 209 confirmed at 2:05 pm on 04/29/2021 that the laboratory did not follow the IFU.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to report Covid 19 testing accurately from September 2020 to the date of the survey. The findings state: 1. The laboratory performed non Food and Drug Administration (FDA) Emergency Use Authorization (EUA) cleared tests and there was no statement stating "This test has not been FDA cleared or approved; The test has been authorized by FDA under an Emergency Use Authorization (EUA). 2. The TP #1 listed on the CMS form 209 on 04/29/2021 at 2:00 pm that COVID 19 tests were not reported accurately.

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 Testing Personnel (TP), the Laboratory Director failed to have education documented for two out of six TP from 9/24/18 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 4/29/21 at 1:10 pm that all education records were not available.